

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/05/97ISR Number: 3011271-0Report Type:Periodic Company Report #8-97223-003J
 Age:57 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Increased | Consumer | Ativan | PS | | ORAL |
| 7 MG DAILY | | Drug Interaction | | | | | |
| ORAL TAB | | | | Ritalin | SS | | |
| 15 MG DAILY | | | | Norvasc | C | | |
| | | | | Ventolin | C | | |
| | | | | Xanax | C | | |
| | | | | Zocor | C | | |

Date:11/17/97ISR Number: 3005889-9Report Type:Direct Company Report #
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Aggression | | Ritalin | PS | | |
| 10MIG SINCE | | Agitation | | | | | |
| Other | | Amnesia | | | | | |
| 1991 | | Confusional State | | | | | |
| | | Decreased Appetite | | | | | |
| | | Developmental Delay | | | | | |
| | | Disinhibition | | | | | |
| | | Disturbance In Attention | | | | | |
| | | Failure To Thrive | | | | | |
| | | Narcolepsy | | | | | |
| | | Personality Change | | | | | |

Date:11/19/97ISR Number: 3001611-0Report Type:Expedited (15-DaCompany Report #MPI-97418
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|--------------------------------|----------------|--------------|-----------------|----|------|
| Hospitalization - 55 MG | Aggression | Health | Methylphenidate | PS | ORAL |
| Initial or Prolonged 0.1 MG | Agitation | Professional | Clonidine Hcl | SS | ORAL |
| | Convulsion | | Bupropion | SS | ORAL |
| 150 MG | Disorientation | | | | |

Date:11/19/97ISR Number: 3001886-8Report Type:Expedited (15-DaCompany Report #MPI-97418
Age:9 YR Gender:Male I/FU:F

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|----------|------------|---------------|-----------------|------|--------------|-------|
| Hospitalization - 55MG PO | | Aggression | Health | Methylphenidate | PS | | ORAL |
| Initial or Prolonged 0.1MG PO | | Agitation | Professional | Clonidine Hcl | SS | | ORAL |
| | | | | Bupropion | SS | | ORAL |
| 150MG PO | | | | | | | |

Date:12/11/97ISR Number: 3006497-6Report Type:Expedited (15-DaCompany Report #MCD 09/11/97
Age:9 YR Gender:Male I/FU:F

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------------------------|------------------------|----------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged .1 MG | | Aggression Agitation | Health Professional | Clonidine Hydrochloride | PS | | ORAL |
| 55 MG | | | | Methylphenidate | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/11/97ISR Number: 3007720-4Report Type:Direct
Age:12 YR Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Methylphenidate | PS | | |
| 25 MG PER DAY | | Drug Withdrawal Syndrome | | Depakote | C | | |
| | | Inappropriate Affect | | Tenex | C | | |
| | | Lacrimation Increased | | | | | |
| | | Lethargy | | | | | |
| | | Salivary Hypersecretion | | | | | |
| | | Stereotypy | | | | | |

Date:12/24/97ISR Number: 3012851-9Report Type:Expedited (15-DaCompany Report #97J-10394
Age:25 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Convulsion | Foreign | Ritalin | PS | | ORAL |
| 10MG, DAILY, | | Depressed Level Of | Health | | | | |
| Hospitalization - | | Consciousness | Professional | Melleril | C | | |
| ORAL | | Leukocytosis | | Akineton | C | | |
| Initial or Prolonged | | Pyrexia | | Eurodin | C | | |
| | | White Blood Cell Count | | Nelbon | C | | |
| | | Increased | | | | | |

Date:01/02/98ISR Number: 3107767-3Report Type:Periodic
Age:40 YR Gender:Female I/FU:I

Company Report #FLUV002970385

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | Health | Luvox | PS | | ORAL |
| 75MG, PER | | Dyspnoea | Professional | | | | |
| ORAL | | Hyperhidrosis | | Ritalin | SS | | ORAL |
| 60MG, PER | | | | | | | |
| ORAL | | | | Clarityn | C | | |

Synthroid
Zocor

C
C

Date:01/02/98ISR Number: 3112227-XReport Type:Periodic Company Report #97USA10862
Age:19 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|--|---------------|---------|------|--------------|-------|
| Dose Duration | | | | | | |
| Hospitalization - DAILY; ORAL | Abnormal Behaviour | Health | Ritalin | PS | | ORAL |
| Initial or Prolonged | Belligerence Dissociation Hallucination Medication Error Psychotic Disorder Speech Disorder | Professional | | | | |

Date:01/02/98ISR Number: 3112228-1Report Type:Periodic Company Report #97USA11284
Age:10 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------------|---|---------------|---------|------|--------------|-------|
| Dose Duration | | | | | | |
| Hospitalization - 12.5 MG, BID | Arthralgia | Health | Ritalin | PS | | ORAL |
| Initial or Prolonged | Autoimmune Disorder Dermatitis Rash Maculo-Papular Urticaria | Professional | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/06/98ISR Number: 4517471-2Report Type:Direct Company Report #USP 080952
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | Medication Error | | Ritalin | PS | Ciba(Brand) | |
| TABLET | | | | Ritalin | SS | Ciba C Brand | |
| TAB | | | | | | | |

Date:01/08/98ISR Number: 3017194-5Report Type:Expedited (15-DaCompany Report #97D-10668
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------|---------------|---------|------|--------------|-------|
| Dose | | Agranulocytosis | Foreign | Ritalin | PS | | ORAL |
| Other | | Bronchitis | Health | | | | |
| 10 MG DAILY | | Ear Infection | Professional | | | | |
| ORAL | | Viral Infection | | | | | |

Date:01/14/98ISR Number: 3015202-9Report Type:Direct Company Report #
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-----|---------------|-----------------|------|--------------|-------|
| Dose | | Tic | | Methylphenidate | PS | | ORAL |
| Other | | | | | | | |
| 1 PO BID | | | | | | | |

Date:01/28/98ISR Number: 3087036-0Report Type:Direct Company Report #
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | Drug Ineffective | | Methylphenidate | PS | | ORAL |
| 20MG SR PO | | | | | | | |
| BID | | | | | | | |

Date:01/29/98ISR Number: 3089734-1Report Type:Periodic Company Report #8-97297-087K
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | Consumer | Redux | PS | | ORAL |
| ORAL | 2 YR | Palpitations | | Ritalin | SS | | |

Date:01/29/98ISR Number: 3112079-8Report Type:Periodic Company Report #8-97197-001L
Age: Gender:Unknown I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------|---|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Nervousness | Health | Redux | PS | | ORAL |
| ORAL | | Sedation | Professional Company Representative | Ritalin | SS | | |

Date:01/29/98ISR Number: 3112226-8Report Type:Periodic Company Report #97USA10832
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------------|------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Convulsion | Consumer | Ritalin | PS | | ORAL |
| DAILY, ORAL | 2 YR | | | | | | |
| Initial or Prolonged | | | | Marijuana | SS | | |
| RESPIRATORY | | | | | | | |
| (INHALATION) | INHALATION | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/02/98ISR Number: 3021792-2Report Type:Expedited (15-DaCompany Report #9720178
 Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------------|---------------|---------|------|--------------|-------|
| Hospitalization - | 12.50 MG | Aggression | Consumer | Zoloft | PS | | ORAL |
| Initial or Prolonged | TOTAL: | Drug Interaction | Health | | | | |
| DAILY:ORAL | | Insomnia | Professional | | | | |
| 30.00 MG | | | | Ritalin | SS | | ORAL |
| TOTAL:TID | | | | | | | |
| :ORAL | | | | | | | |

Date:02/04/98ISR Number: 3023923-7Report Type:Expedited (15-DaCompany Report #98CDN10042
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------------|----------------|---------------|---------|------|--------------|-------|
| Other | DAILY ORAL | Systemic Lupus | Foreign | Ritalin | PS | | ORAL |
| | | Erythematosis | Health | | | | |
| | | | Professional | | | | |
| | | | Other | | | | |

Date:02/05/98ISR Number: 3024031-1Report Type:Expedited (15-DaCompany Report #98USA10139
 Age:45 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|-----------------------|---------------|------------|------|--------------|-------|
| Other | 50MG,DAILY,OR | Chest Pain | Health | Ritalin | PS | | ORAL |
| AL | | Myocardial Infarction | Professional | | | | |
| | | | | Wellbutrin | C | | |

Date:02/05/98ISR Number: 3024423-0Report Type:Direct Company Report #
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Rash Generalised | | Ritalin | PS | | ORAL |
| 1T TAB BID PO | | | | | | | |
| 10MG/1T TAB | | | | | | | |
| QD PO 5MG | | | | | | | |
| (GENERIC) | | | | | | | |

Date:02/09/98ISR Number: 3026190-3Report Type:Expedited (15-DaCompany Report #98J-10049
Age:64 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dry Mouth | Foreign | Ritalin | PS | | ORAL |
| DAILY | | | | | | | |
| | | Eating Disorder | Health | Halcion | C | | |
| | | Oesophageal Stenosis | Professional | Meilax | C | | |
| | | Thirst | | Rhythmy | C | | |
| | | | | Sediel | C | | |

Date:02/12/98ISR Number: 3087877-XReport Type:Direct Company Report #
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis | | Ritalin | PS | | |
| 4 YR | | | | | | | |
| | | Therapeutic Response | | | | | |
| | | Decreased | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/20/98ISR Number: 3032689-6Report Type:Expedited (15-DaCompany Report #98USA10222
Age:29 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------------|---------------|----------|------|--------------|-------|
| Death | | Pulmonary Hypertension | Health | Ritalin | PS | | |
| 20MG, TID, | | | Professional | | | | |
| ORAL | 5 | MON | | Pondimin | SS | | |
| 60MG, DAILY, | | | | | | | |
| ORAL | 7 | MON | | | | | |

Date:02/20/98ISR Number: 3032697-5Report Type:Expedited (15-DaCompany Report #98F--10079
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|---------------|----------|------|--------------|-------|
| Other | | Aggression | Foreign | Ritaline | PS | | ORAL |
| 25 MG, DAILY, | | | Health | | | | |
| ORAL | | Homosexuality | Professional | | | | |
| | | | Other | | | | |

Date:02/27/98ISR Number: 3037659-XReport Type:Expedited (15-DaCompany Report #98USA10270
Age:21 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------|---------------|---------|------|--------------|-------|
| Other | | Visual Acuity Reduced | Health | Ritalin | PS | | ORAL |
| 20 MG, TID, | | | Professional | | | | |
| ORAL | | | | | | | |

Date:02/27/98ISR Number: 3043674-2Report Type:Direct Company Report #
Age:25 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | | |
|------------------------------------|--|--|---------|--|----|--|
| Hospitalization - 10MG/DAY | Epilepsy | | Ritalin | | PS | |
| Initial or Prolonged Disability | Mental Impairment Nervous System Disorder | | | | | |

Date:03/02/98ISR Number: 3132722-7Report Type:Periodic Company Report #9712159
 Age: Gender:Male I/FU:I

| Outcome Dose Other 50.00 MG | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|-------------|------------------------|---------------|------------|------|--------------|-------|
| | | Abdominal Pain | Consumer | Zoloft | PS | | ORAL |
| TOTAL: DAILY: | | Accommodation Disorder | | | | | |
| ORAL | | Constipation | | | | | |
| ORAL | | Dizziness | | Ritalin | SS | | ORAL |
| ORAL | | Drug Ineffective | | Xanax | SS | | ORAL |
| INTRAVENOUS | INTRAVENOUS | Dyspepsia | | Solumedrol | SS | | |
| | | Libido Decreased | | | | | |
| | | Nervousness | | | | | |

Date:03/02/98ISR Number: 3132826-9Report Type:Periodic Company Report #9706889
 Age:52 YR Gender:Male I/FU:I

| Outcome Dose Other 200.00 MG | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------------|----------|-----------------------|---------------|---------|------|--------------|-------|
| | | Coordination Abnormal | Consumer | Zoloft | PS | | ORAL |
| TOTAL: DAILY: | | Paraesthesia | Health | | | | |
| ORAL | | Thinking Abnormal | Professional | | | | |
| 200.00 MG | | | | Ritalin | SS | | ORAL |
| TOTAL: DAILY: | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/98ISR Number: 3132962-7Report Type:Periodic Company Report #9700569
 Age:59 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|-------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alopecia | Consumer | Zoloft | PS | | ORAL |
| 150.00 MG | | Depersonalisation | | | | | |
| TOTAL: BID: ORA | | Dizziness | | | | | |
| L | | Hyperhidrosis | | Ritalin | SS | | ORAL |
| ORAL | | Tinnitus | | Premarin | SS | | ORAL |
| ORAL | | | | Zocor | C | | |
| | | | | Synthroid | C | | |
| | | | | Melatonin | C | | |

Date:03/02/98ISR Number: 3140842-6Report Type:Periodic Company Report #9622246
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|-----------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | Consumer | Zoloft | PS | | ORAL |
| 25.00 MG | | Mania | Health | | | | |
| TOTAL: DAILY: O | | | Professional | | | | |
| RAL | | | | Ritalin | SS | | ORAL |
| ORAL | | | | Seldane | C | | |

Date:03/02/98ISR Number: 3144219-9Report Type:Periodic Company Report #9702398
 Age:14 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis | Consumer | Zoloft | PS | | ORAL |
| 75.00 MG | | Neurosis | Health | | | | |
| TOTAL: DAILY: O | | | | | | | |

| | | | | | |
|---------------|-------------------|--------------|------------|----|------|
| RAL | Oedema Peripheral | Professional | | | |
| 20.00 MG | Pruritus | | Ritalin | SS | ORAL |
| TOTAL:DAILY:O | Suicidal Ideation | | | | |
| RAL | Urticaria | | Prednisone | C | |

Date:03/02/98ISR Number: 3148580-0Report Type:Periodic Company Report #9617586
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dizziness | Consumer | Zoloft Tablets | PS | | ORAL |
| 50.00 MG | | Nausea | Health | | | | |
| TOTAL DAILY | | | Professional | | | | |
| ORAL | | | | Ritalin | SS | | ORAL |
| ORAL | | | | Ambien | C | | |

Date:03/02/98ISR Number: 3149433-4Report Type:Periodic Company Report #9708479
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Dreams | Consumer | Zoloft | PS | | ORAL |
| 100.00 MG | | Arthropathy | | | | | |
| TOTAL: DAILY: | | Condition Aggravated | | | | | |
| ORAL | | Emotional Disorder | | Klonopin | SS | | ORAL |
| 4.50 MG | | Nervousness | | | | | |
| TOTAL: TID: | | Rotator Cuff Syndrome | | | | | |
| ORAL | | | | Ritalin | SS | | ORAL |
| ORAL | | | | Tegretol | C | | |
| | | | | Zantac | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/06/98ISR Number: 3127759-8Report Type:Periodic Company Report #8-97072-003B
 Age:28 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Interaction | Health | Effexor | PS | | ORAL |
| 37.5 MG DAILY | | Drug Tolerance Increased | Professional | | | | |
| ORAL | | Headache | | Dexedrine | SS | | |
| | | Skin Discolouration | | Methamphetamine | SS | | |
| | | | | Ritalin | SS | | |
| 40 MG | | | | | | | |

Date:03/06/98ISR Number: 3146617-6Report Type:Periodic Company Report #8-96358-003B
 Age: Gender: I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------|---------------|--------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Stupor | Health | Effexor | PS | | ORAL |
| ORAL | | | Professional | Ritalin | SS | | ORAL |
| ORAL | | | | Ritalin Oral | C | | |

Date:03/12/98ISR Number: 3140499-4Report Type:Periodic Company Report #JAUSA-27007
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Abdominal Pain | Consumer | Risperdal | PS | Janssen | ORAL |
| 12 MG DAILY | | Back Pain | | | | | |
| Initial or Prolonged | | Extrapyramidal Disorder | | Ritalin | SS | | |
| ORAL | | | | | | | |

Date:03/16/98ISR Number: 3056072-2Report Type:Expedited (15-DaCompany Report #8-97199-009S
 Age:39 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|---|--|------------------------|----------|----|------|
| Death 60 MG DAILY Life-Threatening ORAL | Ascites Coma | Health Professional | Pondimin | PS | ORAL |
| Hospitalization - 20 MG THREE Initial or Prolonged TIMES DAILY ORAL | Oedema Peripheral Pneumonia Pulmonary Hypertension | Other | Ritalin | SS | ORAL |

| | |
|--------------------|---|
| Kcl | C |
| Klonopin | C |
| Lasix | C |
| Lithium | C |
| Methyltestosterone | C |
| Synthroid | C |
| Triazolam | C |
| Ritalin | C |

Date:03/19/98ISR Number: 3057890-7Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------|------------------------------|----------|--------------|-------|
| | | Aggression | | Methylphenidate Clonidine | PS SS | | |

Date:03/20/98ISR Number: 3059845-5Report Type:Expedited (15-DaCompany Report #9805481
Age:15 YR Gender:Male I/FU:I

| | |
|----------------------|-----------------------|
| Outcome | PT |
| Hospitalization - | Coordination Abnormal |
| Initial or Prolonged | Diarrhoea |

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| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|----|----------------|-----------------|------|--------------|-------|
| Gait Disturbance | | | | | | | |
| Headache | | | | | | | |
| Otitis Media | | | Report Source | Product | Role | Manufacturer | Route |
| Pharyngolaryngeal Pain | | | Foreign | Zoloft | PS | | ORAL |
| Photophobia | | | Health | | | | |
| Pyrexia | | | Professional | | | | |
| | | | Company | Methylphenidate | SS | | ORAL |
| | | | Representative | | | | |

Dose: 100.00 MG
 Duration: TOTAL:DAILY:0
 RAL
 Dose: 50.00 MG
 Duration: TOTAL:TID:ORA
 L

Date:03/25/98ISR Number: 3062047-XReport Type:Expedited (15-DaCompany Report #9804260
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----|---------------|-----------------|------|--------------|-------|
| Acidosis | | | Literature | Zoloft | PS | | ORAL |
| Blood Ph Decreased | | | Health | | | | |
| Decreased Appetite | | | Professional | | | | |
| Grand Mal Convulsion | | | | Methylphenidate | SS | | ORAL |

Outcome: Other
 Dose: 50.00 MG
 Duration: TOTAL:DAILY:0
 RAL; TAB
 Dose: 80.00 MG
 Duration: TOTAL:ORAL

Date:03/31/98ISR Number: 3066461-8Report Type:Expedited (15-DaCompany Report #98USA10422
 Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|---------------|---------|------|--------------|-------|
| Dystonia | | | Consumer | Ritalin | PS | | ORAL |
| Oculogyration | | | Health | | | | |
| Tic | | | Professional | | | | |

Outcome: Hospitalization -
 Dose: 20 MG DAILY
 Duration: Initial or Prolonged
 Route: ORAL

Date:03/31/98ISR Number: 3066465-5Report Type:Expedited (15-DaCompany Report #98D--10222
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Thrombocythaemia | Foreign | Ritalin | PS | | ORAL |
| 15 MG ORAL | | | Health | | | | |
| BID | | | Professional | | | | |

Date:04/06/98ISR Number: 3062930-5Report Type:Expedited (15-DaCompany Report #98 USA 10475
Age:34 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-----------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Attention | Health | Ritalin | PS | | ORAL |
| 120 MG, | | | | | | | |
| Initial or Prolonged | | Deficit/Hyperactivity | Professional | | | | |
| DAILY, ORAL | | Disorder | | Zoloft | C | | |
| | | Condition Aggravated | | | | | |
| | | Drug Ineffective | | | | | |

Date:04/09/98ISR Number: 3064067-8Report Type:Direct Company Report #
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| | | No Adverse Drug Effect | | Methylphenidate | PS | Schein | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/10/98ISR Number: 3062912-3Report Type:Direct
Age: Gender: I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | Aggression | | Methylphenidate | PS | | |
| | | Drug Ineffective | | Clonidine | SS | | |
| | | | | Nortriptyline | SS | | |

Date:04/15/98ISR Number: 3065705-6Report Type:Expedited (15-DaCompany Report #98D-10222
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | Thrombocythaemia | Foreign | Ritalin | PS | | ORAL |
| Other | | | Health | | | | |
| 15 MG, BID, | | | Professional | | | | |
| ORAL | 40 DAY | | Other | | | | |

Date:04/27/98ISR Number: 3071064-5Report Type:Expedited (15-DaCompany Report #98USA10611
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|-------------|---------------------------|---------------|---------|------|--------------|-------|
| Dose | | Arrhythmia | Health | Ritalin | PS | | |
| Congenital Anomaly | | Complications Of Maternal | Professional | | | | |
| TRANSPLACENTAL | 5 MG, ONCE, | Exposure To Therapeutic | | | | | |
| Other | | Drugs | | | | | |
| TRANSPLACENTA | | | | | | | |
| L | | | | | | | |

Date:05/05/98ISR Number: 3073598-6Report Type:Expedited (15-DaCompany Report #98USA10632
Age:50 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|-------------------------|---------------|---------|------|--------------|-------|
| Dose | | Blood Pressure Abnormal | Health | Ritalin | PS | | ORAL |
| Hospitalization - | | | | | | | |
| 10 MG, BID | | | | | | | |

| | | | | |
|----------------------|------------------------|--------------|---------------------|---|
| Initial or Prolonged | Bradycardia | Professional | Droperidol Solution | C |
| | Chest Pain | | Heparin Solution | C |
| | Dyspnoea Exertional | | Colace | C |
| | Eosinophil Count | | Serax | C |
| | Increased | | Phenylephrine | C |
| | Hypotension | | Aspirin | C |
| | Myocardial Infarction | | Nitroglycerine | C |
| | Nausea | | Maalox | C |
| | Pyrexia | | Milk Of Magnesia | C |
| | White Blood Cell Count | | Tylenol | C |
| | Increased | | | |

Date:05/05/98ISR Number: 3073716-XReport Type:Expedited (15-DaCompany Report #8-97199-009S
Age:39 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-------------|------------------------|---------------|--------------------|------|--------------|-------|
| Death | 60 MG DAILY | Ascites | Consumer | Pondimin | PS | | ORAL |
| Life-Threatening | ORAL | Condition Aggravated | | | | | |
| Hospitalization - | 20 MG THREE | Dyspnoea Exertional | | Ritalin | SS | | ORAL |
| Initial or Prolonged | TIMES DAILY | Oedema Peripheral | | | | | |
| Other | ORAL | Pneumonia | | | | | |
| ORAL | | Pulmonary Hypertension | | Phentermine | SS | | ORAL |
| | | | | Kcl | C | | |
| | | | | Klonopin | C | | |
| | | | | Lasix | C | | |
| | | | | Lithium | C | | |
| | | | | Methyltestosterone | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Synthroid C
 Triazolam C
 Ritalin C
 Phentermine C

Date:05/15/98ISR Number: 3079178-0Report Type:Expedited (15-DaCompany Report #98D--10317
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|----------|-------------------|------------------------|---------|------|--------------|-------|
| Hospitalization - DAILY, ORAL | | Pain In Extremity | Foreign | Ritalin | PS | | ORAL |
| Initial or Prolonged | | Swelling | Health Professional | | | | |

Date:05/20/98ISR Number: 3081539-0Report Type:Expedited (15-DaCompany Report #98CDN 10042
 Age:16 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Other | | Alopecia Fatigue Pain In Extremity | Foreign Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, BID, ORAL | 2 MON | Subcutaneous Haematoma | Other | | | | |
| | | Subcutaneous Nodule Systemic Lupus Erythematosis | | Ventolin | C | | |

Date:05/22/98ISR Number: 3083542-3Report Type:Expedited (15-DaCompany Report #98USA10731
 Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------|---------------|---------|------|--------------|-------|
| Other DAILY, ORAL | | Menorrhagia | Other | Ritalin | PS | | ORAL |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatinine | Health | Ritalin | PS | | ORAL |
| 20 MG, BID, | | Increased | Professional | | | | |
| ORAL | | Nephritis Interstitial | | Sertraline | C | | |
| | | | | Loratadine | C | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Condition Aggravated | Health | Carbamazepine | PS | | |
| 700 MG (100 | | Convulsion | Professional | | | | |
| Initial or Prolonged | | Otitis Media | | | | | |
| MG, 7 TIMES | | | | | | | |
| DAILY) | | | | Neurontin | | | |
| | | | | (Gabapentin) | SS | | ORAL |
| 400 MG (100 | | | | | | | |
| MG, QID) | | | | Ritalin | | | |
| | | | | (Methylphenidate | | | |
| | | | | Hydrochloride) | SS | | ORAL |
| 5 DAY | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/26/98ISR Number: 3167667-XReport Type:Periodic Company Report #001-0916-970004
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------|---------------|---|------|--------------|-------|
| Hospitalization - 700 MG (100 Initial or Prolonged MG, 7 TIMES DAILY) | | Convulsion | Health | Carbamazepine | PS | | |
| | | Otitis Media | Professional | | | | |
| | | | | Neurontin (Gabapentin) | SS | | ORAL |
| 400 MG (100 MG QID) | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |
| 5 DAY | | | | | | | |

Date:05/28/98ISR Number: 3084833-2Report Type:Expedited (15-DaCompany Report #98D--10334
 Age:46 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|---|-----------------------|---------|------|--------------|-------|
| Other 60 MG, DAILY, ORAL | | Headache | Foreign | Ritalin | PS | | ORAL |
| | | Monoparesis | Health | | | | |
| | | Nuclear Magnetic Resonance Imaging Abnormal | Professional Other | | | | |

Date:05/29/98ISR Number: 3085978-3Report Type:Direct Company Report #
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|------------|---------------|---------|------|--------------|-------|
| Other 10 MG TID | | Dyskinesia | | Ritalin | PS | | |

Date:06/01/98ISR Number: 3088623-6Report Type:Expedited (15-DaCompany Report #98USA10749

Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Renal Failure | Other | Ritalin | PS | | |
| DAILY, | | Renal Tubular Necrosis | | | | | |
| INTRANASAL | | | | | | | |

Date:06/09/98ISR Number: 3091168-0Report Type:Expedited (15-DaCompany Report #98GB-10522

Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-----------------|---------------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Depression | Foreign | Ritalin | PS | | ORAL |
| 5MG BID ORAL | | Suicide Attempt | Health Professional | | | | |

Date:06/10/98ISR Number: 3091704-4Report Type:Expedited (15-DaCompany Report #98HQ 10208

Age:57 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Condition Aggravated | Foreign | Ritalin | PS | | |
| INTRAVENOUS | DAILY | | | | | | |
| Initial or Prolonged | | Cough | Literature | | | | |
| INTRAVENOUS | | Pulmonary Granuloma | Health Professional | | | | |
| | | Pyrexia | | | | | |
| | | Silicon Granuloma | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/11/98ISR Number: 3096322-XReport Type:Periodic Company Report #97-11-0589
 Age:51 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|----------------------------------|------|--------------|-------|
| Dose Other | | Dizziness Drug Interaction | Consumer | Claritin (Loratadine) Tablets | PS | | ORAL |
| 10 MG ORAL | 1 | Flushing | | | | | |
| DOSE | | Headache | | Ritalin | SS | | ORAL |
| PO | | Hypertension Nausea Nervousness Tremor | | | | | |

Date:06/16/98ISR Number: 3094143-5Report Type:Direct Company Report #
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|---|---------------|-----------|------|--------------|-------|
| Dose Required | | Abnormal Behaviour | | Ritalin | PS | | |
| 2-3 TIMES | | Cough | | | | | |
| Intervention to DAILY | | Depressed Level Of | | Clonidine | SS | | |
| Prevent Permanent 1-2 DAILY | | Consciousness Dermatitis Emotional Disorder Growth Retardation Insomnia Mood Swings Muscle Twitching Nervousness Sedation | | | | | |
| Impairment/Damage | | | | | | | |

Date:06/16/98ISR Number: 3094976-5Report Type:Expedited (15-DaCompany Report #98HQ-10219
 Age:30 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | |
|--|---|---|---------|----|
| Hospitalization - 100 MG, DAILY Initial or Prolonged | Abdominal Pain Drug Withdrawal Syndrome Suicidal Ideation | Foreign Literature Health Professional | Ritalin | PS |
|--|---|---|---------|----|

Date:06/19/98ISR Number: 3096692-2Report Type:Expedited (15-DaCompany Report #98HQ-10221
Age:10 YR Gender:Female I/FU:I

| Outcome Dose Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|---|------------------------|------------|------|--------------|-------|
| Hospitalization - DAILY Initial or Prolonged | Depressed Mood | Literature | Ritalin | PS | | |
| | Drug Ineffective Emotional Distress Mood Altered Suicidal Ideation | Health Professional | Sertraline | C | | |

Date:06/19/98ISR Number: 3096702-2Report Type:Expedited (15-DaCompany Report #98HQ-10221
Age:10 YR Gender:Female I/FU:I

| Outcome Dose Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---|------------------------|------------|------|--------------|-------|
| Hospitalization - 3 DAY Initial or Prolonged | Bipolar Disorder | Literature | Ritalin | PS | | |
| | Depressed Mood Emotional Distress Suicidal Ideation | Health Professional | Sertraline | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/19/98ISR Number: 3096703-4Report Type:Expedited (15-DaCompany Report #98HQ-10217
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|------------------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Arrhythmia | Literature | Ritalin | PS | | |
| DAILY | | Grand Mal Convulsion Syncope Tic Transient Ischaemic Attack | Health Professional | Clonidine | SS | | |

Date:06/19/98ISR Number: 3096712-5Report Type:Expedited (15-DaCompany Report #98HQ-10217
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|------------------------|----------------------|----------|--------------|-------|
| Dose | | | | | | | |
| Death | | Grand Mal Convulsion Syncope Tic | Health Professional | Ritalin Clonidine | PS SS | | |

Date:06/19/98ISR Number: 3096914-8Report Type:Expedited (15-DaCompany Report #98HQ-10209
Age:57 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|---|---|---|---------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - INTRAVENOUS | DAILY, Initial or Prolonged INTRAVENOUS | Condition Aggravated Cough Dyspnoea Pulmonary Granuloma Pyrexia | Foreign Literature Health Professional | Ritalin | PS | | |

Date:06/19/98ISR Number: 3096917-3Report Type:Expedited (15-DaCompany Report #98HQ-10220
Age:39 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | |
|----------------------|---------------------|--------------|---------|----|
| Hospitalization - | Drug Abuser | Literature | Ritalin | PS |
| INTRAVENOUS | DAILY, | | | |
| Initial or Prolonged | Neovascularisation | Health | | |
| INTRAVENOUS | | | | |
| Other | Retinal Exudates | Professional | Talwin | SS |
| INTRAVENOUS | INTRAVENOUS | | | |
| | Retinal Haemorrhage | | Heroin | C |
| | Retinopathy | | | |
| | Vision Blurred | | | |

Date:06/19/98ISR Number: 3096918-5Report Type:Expedited (15-DaCompany Report #J980990
Age:57 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------------------|---------------|---------|------|--------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - | Chest X-Ray Abnormal | Literature | Ritalin | PS | | |
| INTRAVENOUS | INTRAVENOUS | | | | | |
| Initial or Prolonged | Condition Aggravated | Health | | | | |
| | Cough | Professional | | | | |
| | Dyspnoea | | | | | |
| | Pulmonary Granuloma | | | | | |
| | Pyrexia | | | | | |

Date:06/24/98ISR Number: 3098700-1Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

| | |
|---------|------------|
| Outcome | PT |
| Other | Aggression |
| | Amnesia |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|---------------|----------|--|---------------|---------------------|------|--------------|-------|
| Dose | Duration | Disturbance In Social Behaviour Drug Effect Decreased | Report Source | Product | Role | Manufacturer | Route |
| 1@ 730A PO 1@ | | | | Methylphenidate Hcl | PS | Danbury | ORAL |
| 12NOON | 2 MON | | | | | | |

Date:06/24/98ISR Number: 3098866-3Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

| | | | | | | | |
|---------------|----------|---------------------|---------------|-------------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Drug Ineffective | Health | Ritalin (Generic) | PS | Danbury | ORAL |
| 2 TABS @ 730A | | Educational Problem | Professional | | | | |
| PO; 1 1/2 TAB | | | | | | | |

@ 1130A PM;

1@4100 PO;

STRARTED

Date:06/24/98ISR Number: 3098870-5Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

| | | | | | | | |
|--------------|----------|-----------------------------------|---------------|-----------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper | Health | Methylphenidate | PS | Danbury | |
| 1@8A, | | Abnormal Behaviour | Professional | | | | |
| 1/2@4P;1@12N | 2 MON | Memory Impairment Restlessness | | | | | |

Date:06/24/98ISR Number: 3098871-7Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Methylphenidate | PS | Danbury | ORAL |
| 1@8A; 1/2 @3 | | Social Avoidant Behaviour | | | | | |
| PO | 2 | MON | | | | | |

Date:06/25/98ISR Number: 3098541-5Report Type:Expedited (15-DaCompany Report #83505
 Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-----------------------|---------------|---------------|------|--------------|-------|
| Hospitalization - | | Dehydration | Literature | Midazolam | PS | | ORAL |
| 20 MG 1 X ONE | | Drug Effect Decreased | | | | | |
| Initial or Prolonged | | Drug Ineffective | | Ritalin | SS | | |
| DOSE ORAL | | Drug Interaction | | | | | |
| 5 MG 2 X PER | | Lethargy | | Ketamine | SS | | |
| DAY | | Medication Error | | | | | |
| 60 MG 1 X PER | | Nausea | | Midazolam | | | |
| ONE DOSE | | Overdose | | Hydrochloride | SS | | |
| INTRAVENOUS | 5 MG 1 | Vomiting | | | | | |
| ONE DOSE | | | | | | | |
| INTRAVENOUS | | | | * | C | | |

Date:06/30/98ISR Number: 3100716-3Report Type:Expedited (15-DaCompany Report #98D-10222
 Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Thrombocythaemia | Foreign | Ritalin | PS | | ORAL |
| 15 MG, BID, | | | Health | | | | |
| ORAL | 40 | DAY | Professional | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/07/98ISR Number: 3102770-1Report Type:Expedited (15-DaCompany Report #98D--10317
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------|--|---------|------|--------------|-------|
| Hospitalization - 10 MG, TID, Initial or Prolonged ORAL | | Arthralgia | Foreign Health Professional Other | Ritalin | PS | | ORAL |

Date:07/07/98ISR Number: 3185379-3Report Type:Periodic Company Report #AR-1040
Age:40 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|---|---------------|---|-----------------------|----------------|-------|
| Other 40MG/DAY (ORAL) | | Blood Pressure Increased Chest Discomfort Drug Ineffective Hypoaesthesia Nausea Palpitations Panic Attack | Consumer | Methylphenidate Hci Tablets 10 Mg (Danbury/Schein) Prozac Clonipin Inhaler | PS C C C | Danbury/Schein | ORAL |

Date:07/08/98ISR Number: 3104178-1Report Type:Direct Company Report #
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|-----------------------|---------------|---------|------|--------------|-------|
| Other 25 MG BID PO | | Drug Effect Decreased | | Ritalin | PS | | ORAL |

Date:07/21/98ISR Number: 3108440-8Report Type:Direct Company Report #
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|--------|------------------|----------|----|---------|------|
| Other | Swelling | Ritalin | PS | Janssen | ORAL |
| PO BID | Weight Increased | Loxapine | C | | |

Date:07/28/98ISR Number: 3113159-3Report Type:Direct Company Report #
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------------------|---------------|---------|------|--------------|-------|
| Dose | | Drug Effect Decreased | | Ritalin | PS | | |
| 20MG 4 PER | | | | | | | |
| DAY | | | | | | | |

Date:07/31/98ISR Number: 3181709-7Report Type:Periodic Company Report #8-97364-028B
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------|-------------|------|--------------|-------|
| Dose | | Chest Pain | Consumer | Pondimin | PS | | ORAL |
| Other | | Dyspnoea | | Effexor | SS | | |
| ORAL | | | | Phentermine | SS | | |
| 150 MG | | | | Ritalin | SS | | |
| | | | | Erall | C | | |
| | | | | Effexor | C | | |
| | | | | Phentermine | C | | |
| | | | | Ritalin | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/03/98ISR Number: 3112492-9Report Type:Expedited (15-DaCompany Report #98USA10723
Age:17 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatinine | Health | Ritalin | PS | | ORAL |
| 20MG,BID,ORAL | | Increased | Professional | Pseudoephedrine | C | | |
| | | Nephritis Interstitial | | Ibuprofen | C | | |
| | | | | Ceftin | C | | |
| | | | | Zoloft | C | | |
| | | | | Growth Hormone | | | |
| | | | | Unknown | C | | |
| | | | | Zyrtec | C | | |
| | | | | Claritin | C | | |
| | | | | Sertraline | C | | |
| | | | | Loratadine | C | | |

Date:08/04/98ISR Number: 3112488-7Report Type:Expedited (15-DaCompany Report #98GB-10779
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Hepatic Neoplasm | Foreign | Ritalin | PS | | |
| DAILY, | | | Health | | | | |
| | | | Professional | | | | |
| | | | Other | | | | |

Date:08/04/98ISR Number: 3226773-1Report Type:Periodic Company Report #MPI-98182
Age:20 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Abuser | Consumer | Methylphenidate | | | |
| | | | | Hydrochloride | | | |
| | | | | Extended-Release | | | |
| | | | | Tablets Usp, 20 Mg | PS | | ORAL |

12 TABLETS

DAILY (240 MG

ER), PO 3.5

YEARS

Effexor

C

Date:08/05/98ISR Number: 3113328-2Report Type:Direct
Age:10 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | Health | Methylphenidate | PS | | ORAL |
| 20 MG SR PO | | | Professional | | | | |
| / 10MG PO | | | | | | | |

Date:08/09/98ISR Number: 3185364-1Report Type:Periodic
Age: Gender:Male I/FU:I

Company Report #9807623

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|----------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alopecia | Health | Zyrtec Tablets | PS | | ORAL |
| 10.00 MG | | Drug Interaction | Professional | | | | |
| TOTAL; DAILY; | | | Company | | | | |
| ORAL; SEVERAL | | | Representative | | | | |
| MONTHS | | | | Ritalin | SS | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------|---------------|----------|------|--------------|-------|
| Death | | Anorexia | Foreign | Ritalin | PS | | |
| 20 MG, DAILY | | Brain Herniation | Literature | Pemoline | SS | | |
| 37.5 MG, | | Brain Oedema | Health | | | | |
| DAILY | | Cholestasis | Professional | | | | |
| | | Encephalopathy | | | | | |
| | | Eosinophilia | | | | | |
| | | Fatigue | | | | | |
| | | Hepatic Necrosis | | | | | |
| | | Hepatomegaly | | | | | |
| | | Jaundice | | | | | |
| | | Liver Function Test | | | | | |
| | | Abnormal | | | | | |
| | | Liver Tenderness | | | | | |
| | | Liver Transplant | | | | | |
| | | Rejection | | | | | |
| | | Necrosis | | | | | |
| | | Renal Failure Acute | | | | | |
| | | Weight Decreased | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/27/98ISR Number: 3124026-3Report Type:Direct
 Age:9 YR Gender:Female I/FU:I

Company Report #

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|----------------------------------|------|--------------|-------|
| 1T AM | | Drug Ineffective | | Methylphenidate Hydrochloride Sr | PS | | |
| 2T 3:30PM | | | | Methylphenidite Hydrochloride | SS | | ORAL |

Date:08/28/98ISR Number: 3123480-0Report Type:Expedited (15-DaCompany Report #8-98187-014A
 Age:40 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------------|-------------------|------|--------------|-------|
| Required 150 MG THREE Intervention to TIMES DAILY Prevent Permanent Impairment/Damage 5 MG THREE TIMES DAILY ORAL | | Abortion Spontaneous Complications Of Maternal Exposure To Therapeutic Drugs | Health Professional | Effexor Xr | PS | | ORAL |
| 0.1 MG DAILY ORAL | | | | Ritalin | SS | | ORAL |
| | | | | Synthroid | SS | | ORAL |
| | | | | Ritalin Synthroid | C C | | |

Date:09/03/98ISR Number: 3125679-6Report Type:Direct
 Age: Gender: I/FU:I

Company Report #

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------|---------------|---------|------|--------------|-------|
| 1 PO TID | 2 YR | Abdominal Pain Upper | | Ritalin | PS | | ORAL |

Date:09/04/98ISR Number: 3126263-0Report Type:Expedited (15-DaCompany Report #98USA11254
Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|--------------------|---------------|-------------|------|--------------|-------|
| Hospitalization - 10 MG TID | | Aggression | Health | Ritalin | PS | | ORAL |
| Initial or Prolonged ORAL | | Emotional Disorder | Professional | | | | |
| 60 MG DAILY | | Psychotic Disorder | | Adderall 20 | SS | | ORAL |
| ORAL | | | | | | | |

Date:09/09/98ISR Number: 3126562-2Report Type:Direct Company Report #
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Other 20 MG SR, 1 Q | | Drug Ineffective | | Methylphenidate | PS | | |
| AM AND 10 MG | | | | | | | |
| AM + AFT | | | | | | | |

Date:09/11/98ISR Number: 3127686-6Report Type:Expedited (15-DaCompany Report #98USA11287
Age:91 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|----------|---------------------------|---------------|---------|------|--------------|-------|
| Hospitalization - DAILY, ORAL | | Urinary Tract Obstruction | Health | Ritalin | PS | | ORAL |
| Initial or Prolonged | | | Professional | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/14/98ISR Number: 3130221-XReport Type:Expedited (15-DaCompany Report #98USA 11335
 Age:40 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----------------------------------|---------------|-----------|------|--------------|-------|
| Other | | Abortion Spontaneous | Health | Ritalin | PS | | ORAL |
| 5 MG, TID, Required ORAL | | Complications Of Maternal | Professional | | | | |
| Intervention to .1MG, DAILY, Prevent Permanent ORAL | | Exposure To Therapeutic Drugs | Other | Synthroid | SS | | ORAL |
| Impairment/Damage 450 MG, DAILY, ORAL | | Pain | | Effexor | SS | | ORAL |

Date:09/18/98ISR Number: 3132770-7Report Type:Expedited (15-DaCompany Report #1998-09-0369
 Age:46 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------|---------------|------------|------|--------------|-------|
| Hospitalization - 3 MU TIW Initial or Prolonged 1200 MG QD ORAL | | Acute Psychosis | Study | Intron A | PS | | ORAL |
| | | Aggression | Health | Ribavirin | SS | | ORAL |
| | | Confusional State | Professional | | | | |
| | | Memory Impairment | | Ritalin | SS | | ORAL |
| | | Speech Disorder | | Prozac | SS | | ORAL |
| | | | | Buspar | SS | | ORAL |
| | | | | Ampicillin | C | | |

Date:09/18/98ISR Number: 3133033-6Report Type:Expedited (15-DaCompany Report #USA004414
 Age:40 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
|---------|----------|----|---------------|---------|------|--------------|-------|

| | | | | | |
|--|--|---|---|------------------------|------------------|
| Required 100 MCG OD PO Intervention to 5 MG TID PO Prevent Permanent 150 MG TID Impairment/Damage PO, 150 MG OD PO-SEE IMAGE | Abdominal Pain Lower Abortion Spontaneous Twin Pregnancy | Health Professional Other | Synthroid Ritalin Effexor | PS SS SS | ORAL ORAL |
|--|--|---|---|------------------------|------------------|

Date:09/21/98ISR Number: 3133873-3Report Type:Expedited (15-DaCompany Report #98USA11381
Age:14 YR Gender:Male I/FU:I

| Outcome Dose Duration Hospitalization - DAILY, ORAL Initial or Prolonged | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|---------------|---------|------|--------------|-------|
| | Amnesia | Health | Ritalin | PS | | ORAL |
| | Confusional State Laboratory Test Abnormal Mental Impairment | Professional | | | | |

Date:09/28/98ISR Number: 3233550-4Report Type:Periodic Company Report #9714665
Age:57 YR Gender:Male I/FU:F

| Outcome Dose Duration Other 5.00 MG TOTAL:DAILY:O RAL 15.00 MG TOTAL:TID:ORA L 15.00 MG TOTAL:TID:ORA L | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---|---------------|-----------------|------|--------------|-------|
| | Anxiety Attention Deficit/Hyperactivity Disorder | Consumer | Norvasc Tablets | PS | | ORAL |
| | Depression Hypertension Myalgia | | Ritalin | SS | | ORAL |
| | | | Dexedrine | SS | | ORAL |
| | | | Ativan | C | | |
| | | | Xanax | C | | |
| | | | Ventolin | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Zocor

C

Date:09/29/98ISR Number: 3136504-1Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|---------------|---------|------|--------------|-------|
| Dose | | | Health | Ritalin | PS | | |
| Other | | Attention | Professional | | | | |
| 7.5 MG QID | | Deficit/Hyperactivity Disorder Condition Aggravated Excitability | | | | | |

Date:09/29/98ISR Number: 3136589-2Report Type:Direct
Age:7 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | Methylphenidate | PS | Schein | |
| Other | | Drug Ineffective | | | | | |
| 2 GM, - 1 NOON, 1 @ 3 | | Psychomotor Hyperactivity | | | | | |

PM:NDC#0364-0

561-01

Date:10/01/98ISR Number: 3137282-2Report Type:Expedited (15-DaCompany Report #98D-10831
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------------------------------------|-----------------------|---------|------|--------------|-------|
| Dose | | | Foreign | Ritalin | PS | | ORAL |
| Hospitalization - 1 DF TID ORAL 3 MON | | Bronchospasm | Health | | | | |
| Initial or Prolonged | | Hallucination Status Asthmaticus | Professional Other | | | | |

Date:10/08/98ISR Number: 3140263-6Report Type:Expedited (15-DaCompany Report #98D-10860

Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Eyelid Oedema | Foreign | Ritalin | PS | | ORAL |
| 15 MG, DAILY, | | Face Oedema | Health | | | | |
| ORAL | | Rash Macular | Professional | | | | |

Date:10/08/98ISR Number: 3260757-2Report Type:Periodic Company Report #9828157

Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Zyrtec Tablets | PS | | ORAL |
| 10.00 MG | | Anorexia | | | | | |
| TOTAL;DAILY;O | | Diarrhoea | | | | | |
| RAL | | Drug Ineffective | | Ritalin | SS | | ORAL |
| 15.00 MG | | Thinking Abnormal | | | | | |
| TOTAL;TID;ORA | | | | Clonidine | C | | |
| L | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/98ISR Number: 3262241-9Report Type:Periodic Company Report #9807623
 Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alopecia | Health | Zyrtec Tablets | PS | | ORAL |
| 10.00 MG | | Drug Interaction | Professional | | | | |
| TOTAL:DAILY:0 | | | | | | | |
| RAL | | | | | | | |
| | | | | Ritalin | SS | | ORAL |
| 7.50 MG | | | | | | | |
| TOTAL:DAILY:0 | | | | | | | |
| RAL | | | | | | | |

Date:10/13/98ISR Number: 3141051-7Report Type:Expedited (15-DaCompany Report #98HQ-10359
 Age:42 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------------|---------------|---------|------|--------------|-------|
| Hospitalization - | | Anxiety | Foreign | Ritalin | PS | | ORAL |
| 120MG DAILY | | | | | | | |
| Initial or Prolonged | | Cerebral Atrophy | Literature | | | | |
| ORAL | | Depression | Health | | | | |
| | | Drug Dependence | Professional | | | | |
| | | Drug Withdrawal Syndrome | Other | | | | |
| | | Electroencephalogram | | | | | |
| | | Abnormal | | | | | |
| | | Malaise | | | | | |
| | | Movement Disorder | | | | | |
| | | Nuclear Magnetic | | | | | |
| | | Resonance Imaging | | | | | |
| | | Abnormal | | | | | |
| | | Palpitations | | | | | |
| | | Panic Attack | | | | | |
| | | Respiratory Distress | | | | | |
| | | Social Phobia | | | | | |
| | | Suicidal Ideation | | | | | |
| | | Thought Blocking | | | | | |

Date:10/19/98ISR Number: 3142785-0Report Type:Direct
Age:19 YR Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|------------|---------------|-----------|------|----------------|-------|
| Life-Threatening 5 MG | | Convulsion | | Ritalin | PS | Mfg: Ciba Gigy | |
| | | | | Dilantin | C | | |
| | | | | Phenobarb | C | | |
| | | | | Pepcid | C | | |

Date:10/19/98ISR Number: 3143306-9Report Type:Expedited (15-DaCompany Report #98D--10831
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|----------|--------------------|------------------------|---------|------|--------------|-------|
| Hospitalization - 25 MG DAILY | | Bronchospasm | Foreign | Ritalin | PS | | ORAL |
| Initial or Prolonged ORAL | 3 MON | Status Asthmaticus | Health Professional | | | | |

Date:10/19/98ISR Number: 3143903-0Report Type:Direct
Age:17 YR Gender: I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Other 1.5 TAB BID, 1 TAB AFTER | | Drug Ineffective | | Methylphenidate | PS | Schein | ORAL |

SCHOOL

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Impairment/Damage

Date:10/27/98ISR Number: 3243926-7Report Type:Periodic Company Report #9820743
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|--------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Apathy | Consumer | Zyrtec Syrup | PS | | ORAL |
| 5.00 MG | | Emotional Disorder | | | | | |
| TOTAL:PRN:ORA | | | | | | | |

| | | | | | | | |
|------|--|--|--|---------|----|--|------|
| L | | | | Ritalin | SS | | ORAL |
| ORAL | | | | | | | |

Date:10/30/98ISR Number: 3150426-1Report Type:Expedited (15-DaCompany Report #98USA11335
 Age:40 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------------|----------|----------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abortion Spontaneous | Health | Ritalin | PS | | ORAL |
| 10MG, TIDI, Required | | Pain | Professional | | | | |
| ORAL | | | | | | | |
| Intervention to | | | Other | Synthroid | SS | | ORAL |
| 1 MG, DAILY, Prevent Permanent | | | | | | | |
| ORAL | | | | | | | |
| Impairment/Damage | | | | Effexor | SS | | ORAL |
| 375 MG, DAILY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/98ISR Number: 3151245-2Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|--------------------------------|---------------|-----------------|------|--------------|-------|
| 5MG PO Q AM , | | Burning Sensation | | Methylphenidate | PS | | ORAL |
| 5 MG PO Q__ | | Dermatitis | | | | | |
| | | Rash Papular Rash Vesicular | | Aspirin | C | | |

Date:11/04/98ISR Number: 3152005-9Report Type:Direct
Age:10 MON Gender:Male I/FU:I

Company Report #

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|------------------|---------------|---------|------|--------------|-------|
| 10MG QID | | Drug Ineffective | | Ritalin | PS | | |

Date:11/17/98ISR Number: 3160554-2Report Type:Expedited (15-DaCompany Report #98USA11679
Age:47 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Burning Sensation Chest Wall Pain | Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG BID | | Liver Function Test | | | | | |
| ORAL | | Abnormal Odynophagia | | | | | |

Date:11/19/98ISR Number: 3161209-0Report Type:Direct
Age:41 YR Gender:Female I/FU:I

Company Report #

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------|----------|-----------|---------------|---------------------|------|--------------|-------|
| Disability 20 MG QID | | Agitation | | Methylphenidate Hcl | PS | Novartis | |

Other
(4X DA)

Anxiety

Asthenia
Depression
Disturbance In Attention
Drug Ineffective

Prozac C
Zyprexa C
Klonopin C

Date:11/23/98ISR Number: 3163255-XReport Type:Expedited (15-DaCompany Report #98USA11589

Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--|---------------|-----------------|------|--------------|-------|
| Other | | Body Height Below Normal | Health | Methylphenidate | PS | | ORAL |
| 65 MG, DAILY, ORAL | | Brain Damage | Professional | | | | |
| | | Headache Nausea Reading Disorder | | Tylenol Talbet | C | | |

Date:11/24/98ISR Number: 3162993-2Report Type:Direct Company Report #

Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|---------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | Psychomotor Hyperactivity | Health | Methylphenidate Hcl | PS | | |
| 15MG @ 800; 10MG @ 1200 & 1600 | | | Professional | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/01/98ISR Number: 3164971-6Report Type:Direct
Age:14 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin | PS | | ORAL |
| 15 MG PO BID | | | | | | | |

Date:12/02/98ISR Number: 3165975-XReport Type:Direct
Age:14 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Health | Ritalin | PS | | ORAL |
| 15MG PO BID | | | | | | | |
| Professional | | | | | | | |

Date:12/07/98ISR Number: 3168246-0Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| | | Drug Ineffective | Health | Ritalin | PS | | |
| Professional | | | | | | | |

Date:12/09/98ISR Number: 3169099-7Report Type:Expedited (15-DaCompany Report #98D--10860
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Eye lid Oedema | Foreign | Ritalin | PS | | ORAL |
| 15 MG, DAILY, | | | | | | | |
| ORAL | | | | | | | |
| | | Face Oedema | Health | | | | |
| | | Rash Generalised | Professional | | | | |
| | | Rash Macular | | | | | |

Date:12/16/98ISR Number: 3290754-2Report Type:Periodic
Age:34 YR Gender:Female I/FU:I

Company Report #93396

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Mental Impairment | Other | Valium (Diazepam) 5.000 Mg | PS | | ORAL |
| 5 MG DAILY | | | | | | | |
| ORAL | | | | | | | |
| | | | | Klonopin Tablets (Clonazepam) 1.000mg | SS | | ORAL |
| 1 MG DAILY | | | | | | | |
| ORAL | | | | | | | |
| | | | | Prozac (Fluoxetine) 20 Mg | SS | | ORAL |
| 20 MG DAILY | | | | | | | |
| ORAL | | | | | | | |
| | | | | Zoloft (Sertraline Hydrochloride) 100.00 Mg | SS | | ORAL |
| 100 MG 5 X | | | | | | | |
| PER DAY ORAL | | | | | | | |
| | | | | Paxil (Paroxetine) 20 Mg | SS | | ORAL |
| 10 MG DAILY | | | | | | | |
| ORAL | | | | | | | |
| | | | | Nortriptyline (Nortriptyline Hydrochloride) 50.00 Mg | SS | | ORAL |
| 50 MG DAILY | | | | | | | |
| ORAL | | | | | | | |
| | | | | Methylphenidate (Methylphenidate Hydrochloride) 10.00 Mg | SS | | ORAL |
| 10 MG DAILY | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

ORAL

Date:12/21/98ISR Number: 3172602-4Report Type:Expedited (15-DaCompany Report #98USA11815
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------|---------------|----------------|------|--------------|-------|
| Dose | | | Health | Ritalin-Sr | PS | | ORAL |
| Other | | Coma | Professional | | | | |
| 20 MG BID, | | Eye Rolling | | | | | |
| ORAL | | Syncope | | Remeron Tablet | C | | |
| | | | | .. | C | | |
| | | | | .. | C | | |

Date:01/07/99ISR Number: 3177675-0Report Type:Direct Company Report #
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | Ritalin | PS | | |
| 30 MG QD | | Drug Ineffective | | | | | |

Date:01/08/99ISR Number: 3179055-0Report Type:Direct Company Report #
 Age:14 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------------------|---------------|----------|------|--------------|-------|
| Dose | | | Health | Ritalin | PS | | ORAL |
| Other | | Anxiety | Professional | | | | |
| 5 MG Q AM + | | Depressed Level Of | | | | | |
| NOON | | Consciousness | | Depakote | C | | |
| | | Hallucination, Auditory | | Prozac | C | | |
| | | Headache | | | | | |
| | | Tremor | | | | | |
| | | Vision Blurred | | | | | |

Date:01/11/99ISR Number: 3179585-1Report Type:Expedited (15-DaCompany Report #98D--11041
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----------------------|--|---------|------|--------------|-------|
| Hospitalization - 10 MG DAILY, Initial or Prolonged ORAL Other | | Angioneurotic Oedema | Foreign Health Professional Other | Ritalin | PS | | ORAL |

Date:01/13/99ISR Number: 3180308-0Report Type:Expedited (15-DaCompany Report #99CDN10013
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|----------|----------|------------------|---------|------|--------------|-------|
| Disability 15MG, BID, ORAL | | Diplopia | Foreign Other | Ritalin | PS | | ORAL |

Date:01/15/99ISR Number: 3181050-2Report Type:Direct Company Report #
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|---------------------------------|---------------|-----------------|------|--------------|-------|
| TABLETS/ORAL 7 1/2MG AM & NOON | | Abnormal Behaviour Nightmare | | Methylphenidate | PS | Schien | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/99ISR Number: 3183216-4Report Type:Direct
 Age:10 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia | | Ritalin | PS | | |
| 20MG TID | | Crying | | | | | |
| BEGAN AT | | Depression | | | | | |
| 40MG-60MG | | Headache | | | | | |
| SEVERE | 3 MON | Nausea | | | | | |
| | | Weight Decreased | | | | | |

Date:01/21/99ISR Number: 3183735-0Report Type:Expedited (15-DaCompany Report #98D--11041
 Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Angioneurotic Oedema | Foreign | Ritalin | PS | | ORAL |
| 10 MG, DAILY, | | Oedema Peripheral | Health | | | | |
| Initial or Prolonged | | | Professional | | | | |
| ORAL | | | | | | | |
| Other | | | | | | | |

Date:01/22/99ISR Number: 3184611-XReport Type:Expedited (15-DaCompany Report #98USA10035
 Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Blood Creatine | Health | Ritalin Tablet | | | |
| Initial or Prolonged | | Phosphokinase Increased | Professional | (Methylphenidate | | | |
| | | Chest Pain | | Hydrochloride) | PS | | ORAL |
| DAILY ORAL | | | | | | | |

Date:01/25/99ISR Number: 3198616-6Report Type:Periodic
 Age: Gender:Female I/FU:F

Company Report #9820743

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|--------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Apathy | Consumer | Zyrtec Syrup | PS | | ORAL |
| 5.00 MG | | Emotional Disorder | Health | | | | |
| TOTAL:PRN:ORA | | | Professional | | | | |
| L | | | | Ritalin | SS | | ORAL |
| ORAL | | | | | | | |

Date:01/27/99ISR Number: 3186639-2Report Type:Direct Company Report #
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Tic | | Generic Ritalin | PS | Schien | |
| 5MG QAM | | | | | | | |

Date:01/27/99ISR Number: 3186812-3Report Type:Expedited (15-DaCompany Report #1999-000075
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Accommodation Disorder | Foreign | Clonidine | | | |
| PO | | Binocular Eye Movement | Other | Hydrochloride | PS | | ORAL |
| 5 MG PO | 39 MON | Disorder | | Ritalin | SS | | ORAL |
| | | Condition Aggravated | | | | | |
| | | Visual Disturbance | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/29/99ISR Number: 3188498-0Report Type:Expedited (15-DaCompany Report #1999-000075
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|------------------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Accommodation Disorder | Foreign | Clonidine | | | |
| PO | | Binocular Eye Movement | Other | Hydrochloride | PS | | ORAL |
| | | Disorder | | Ritalin | SS | | ORAL |
| 5 MG; PO | 39 MON | Condition Aggravated | | | | | |
| | | Visual Disturbance | | | | | |

Date:01/29/99ISR Number: 3188605-XReport Type:Expedited (15-DaCompany Report #99HQ-10010
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Drug Interaction | Literature | Carbamazepine | PS | | |
| 1000 MG, | | | Health | | | | |
| Initial or Prolonged | | | Professional | Methylphenidate | | | |
| DAILY | | | | Unknown | | | |
| | | | | (Methylphenidate) | SS | | |
| | | | | Thiothixene Unknown | C | | |

Date:02/01/99ISR Number: 3189575-0Report Type:Expedited (15-DaCompany Report #99USA10081
 Age:51 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Tinnitus | Health | Ritalin | PS | | ORAL |
| 10 MG QD ORAL | 2 WK | | Professional | | | | |

Date:02/01/99ISR Number: 3189577-4Report Type:Expedited (15-DaCompany Report #97USA11732
 Age:50 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|----------------------------------|---|--------------|---------|----|------|
| Life-Threatening 60 MG, QD | Cerebrovascular Accident | Health | Ritalin | PS | ORAL |
| Hospitalization - ORAL 14 MON | Haemorrhage Intracranial | Professional | | | |
| Initial or Prolonged | Hypertension Ruptured Cerebral Aneurysm | | | | |

Date:02/01/99 ISR Number: 3196882-4 Report Type:Periodic Company Report #7394727
 Age:27 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aspartate | Health | Abbott-Cylert | PS | Abbott | ORAL |
| 37.500 MG PO | | Aminotransferase | Professional | | | | |
| QD | | Increased | | Ritalin | SS | | |
| 20.000 MG QD | | Blood Lactate | | Claritin | C | | |
| | | Dehydrogenase Increased | | Ritalin | C | | |

Date:02/03/99 ISR Number: 3191349-1 Report Type:Expedited (15-Da Company Report #8-97199-009S
 Age:39 YR Gender:Female I/FU:F

| | |
|----------------------|------------------------------|
| Outcome | PT |
| Death | Abdominal Distension |
| Life-Threatening | Ascites |
| Hospitalization - | Cardiac Failure |
| Initial or Prolonged | Congestive Cardiac Murmur |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------|--------------------|------|--------------|-------|
| 60 MG DAILY | | Cardiogenic Shock Cardiomegaly Cough | Consumer | Pondimin | PS | | ORAL |
| ORAL | | Dyspnoea | | | | | |
| 20 MG THREE | | Dyspnoea Exertional | | | | | |
| TIMES DAILY | | Electrocardiogram St | | Ritalin | SS | | ORAL |
| ORAL | | Segment Abnormal | | | | | |
| | | Fatigue | | | | | |
| | | Hepatic Function Abnormal | | Cafergot | C | | |
| | | Hepatomegaly | | Estrogen | C | | |
| | | Hypoxia | | Klonopin | C | | |
| | | Malaise | | Lithium | C | | |
| | | Mania | | Methyltestosterone | C | | |
| | | Mitral Valve Incompetence | | Synthroid | C | | |
| | | Oedema Peripheral | | Triazolam | C | | |
| | | Orthopnoea | | | | | |
| | | Pneumonia | | | | | |
| | | Postnasal Drip | | | | | |
| | | Pulmonary Hypertension | | | | | |
| | | Pyrexia | | | | | |
| | | Respiratory Failure | | | | | |
| | | Right Ventricular Failure | | | | | |
| | | Sinusitis | | | | | |
| | | Tricuspid Valve | | | | | |
| | | Incompetence | | | | | |
| | | Weight Decreased | | | | | |

Date:02/04/99ISR Number: 3197993-XReport Type:Periodic
Age:5 YR Gender:Male I/FU:I

Company Report #98USA10490

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------|------------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Convulsion | Consumer Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY ORAL | | | | | | | |

Date:02/04/99ISR Number: 3197999-0Report Type:Periodic Company Report #98USA11678
Age:30 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------------------------------------|------------------------|-----------------------------------|--------|--------------|-------|
| Hospitalization - Initial or Prolonged 10 MG TID | | Aggression Euphoric Mood | Health Professional | Methylphenidate Tablet 10 Mg | PS | | ORAL |
| ORAL | | Jaundice | | | | | |
| | | Liver Disorder Psychotic Disorder | | Paxil Capsule Clonidine Tablet | C C | | |

Date:02/04/99ISR Number: 3404468-9Report Type:Periodic Company Report #98USA11402
Age:52 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|------------------------|---|-----------------------|--------------|-------|
| Dose | | Dizziness Hypertension Metanephrine Urine Increased | Health Professional | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | Palpitations | | Zolofl Tablet Effexor Tablet ///Zodone Tablet Buspar Tablet Iron Tablet | C C C C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3404474-4Report Type:Periodic Company Report #98USA11404
 Age: Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|---------------|--|------|--------------|-------|
| | | Psychotic Disorder | Other | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3404479-3Report Type:Periodic Company Report #98USA11405
 Age: Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|---------------|--|------|--------------|-------|
| | | Psychotic Disorder | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3404483-5Report Type:Periodic Company Report #98USA11406
 Age:47 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---|------------------------|--|------|--------------|-------|
| | | Bursitis Carpal Tunnel Syndrome Intervertebral Disc Disorder | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Xanax Tablet | C | | |
| | | | | Effexor Tablet | C | | |
| | | | | Zyrtec Tablet | C | | |
| | | | | Prilosec Tablet | C | | |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3404486-0Report Type:Periodic Company Report #98USA11409
 Age:6 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-----------|------------------------|---------------------------------|------|--------------|-------|
| | | Dysphonia | Health Professional | Ritalin Tablet (Methylphenidate | | | |

| | | | | | |
|---------------|--|--|--|----|------|
| 12.5 MG, TID, | | | Hydrochloride) | PS | ORAL |
| ORAL | | | | | |
| | | | Ritalin-Sr Slow Release Tablet 20 (Methylphenidate Hydrochloride) | SS | ORAL |
| 20 MG, DAILY, | | | | | |
| ORAL | | | Claritin Tablet | C | |

Date:02/04/99ISR Number: 3404488-4Report Type:Periodic Company Report #98USA11411
Age:23 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| | | Palpitations Restlessness Tachycardia | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3404491-4Report Type:Periodic Company Report #98USA11423
Age:48 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| | | Drug Level Above Therapeutic | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|--------------------|--|--|--|------------------|----|--|------|
| 5 MG, TID, ORAL | | | | Hydrochloride) | PS | | ORAL |
| | | | | Sudafed Tablet | C | | |
| | | | | Ibuprofen Tablet | C | | |

Date:02/04/99ISR Number: 3404493-8Report Type:Periodic Company Report #98USA11442
Age:65 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--|------------------------|---|------|--------------|-------|
| | | Hyponatraemia Inappropriate Antidiuretic Hormone | Health Professional | Methylphenidate Tablet 5 Mg (Methylphenidate) | PS | | ORAL |
| 5 MG, BID, ORAL | | Secretion | | Colace Capsule | C | | |
| | | | | Pepcid Tablet | C | | |

Date:02/04/99ISR Number: 3404495-1Report Type:Periodic Company Report #98USA11443
Age:47 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|----------------------------|------------------------|--|------|--------------|-------|
| | | Pelvic Pain Pollakiuria | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 30 MG, DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3404496-3Report Type:Periodic Company Report #98USA11445
Age:46 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|----------------------------------|------------------------|--|------|--------------|-------|
| | | Hypoaesthesia Joint Stiffness | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3404497-5Report Type:Periodic
Age:60 YR Gender:Female I/FU:I

Company Report #98USA11456

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------------------|---------------|--|------|--------------|-------|
| DAILY, ORAL | | Arthralgia Fatigue Headache | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | Nightmare Pain | | Imipramine Tablet (Imipramine) | SS | | ORAL |
| | | | | Alprazolam Tablet | C | | |

Date:02/04/99ISR Number: 3404500-2Report Type:Periodic
Age:10 YR Gender:Female I/FU:I

Company Report #98USA11457

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|------------------------|--|------|--------------|-------|
| 25 MG, BID, ORAL | | Decreased Appetite Nausea Weight Decreased | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |

Epistaxis

Health
Professional

Ritalin Tablet 20 Mg
(Methylphenidate
Hydrochloride)

PS

ORAL

20 MG, TID,

ORAL

Date:02/04/99ISR Number: 3404512-9Report Type:Periodic
Age:40 YR Gender:Female I/FU:I

Company Report #98USA11497

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|----------|------------------------|--|------|--------------|-------|
| | | Alopecia | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |

15 MG, BID,

ORAL

Zoloft Aerosol

C

Date:02/04/99ISR Number: 3404514-2Report Type:Periodic
Age:8 YR Gender:Male I/FU:I

Company Report #98USA11506

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|------------------|------------------------|--|------|--------------|-------|
| | | Trichotillomania | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |

25 MG, DAILY,

ORAL

18-Aug-2005 11:49 AM

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3404516-6Report Type:Periodic Company Report #98USA11508
 Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------|---------------------|--|------|--------------|-------|
| Dose | | Hypervigilance | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, ONCE, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3404519-1Report Type:Periodic Company Report #98USA11515
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-------------------|---------------------|--|------|--------------|-------|
| Dose | | Oedema Peripheral | Health Professional | Ritalin Tablet 15 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 15 MG, QD, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3405177-2Report Type:Periodic Company Report #98USA11059
 Age:84 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---|---------------------|--|------|--------------|-------|
| Dose | | Depressed Level Of Consciousness Sedation | Health Professional | Ritalin Tablet 5mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, QD, ORAL | | | | | | | |
| | | | | Remeron Tablet | C | | |
| | | | | Persantine Tablet | C | | |
| | | | | Lasix Tablet | C | | |
| | | | | K-Dur Tablet | C | | |
| | | | | Mvi | C | | |

Date:02/04/99ISR Number: 3405181-4Report Type:Periodic Company Report #98USA11146
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------------|--|------|--------------|-------|
| Dose | | Haematuria | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 30 MG, DAILY, | | | | | | | |
| ORAL | | | | No Comedication | C | | |

Date:02/04/99ISR Number: 3405182-6Report Type:Periodic Company Report #98USA11153
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------------------|--|------|--------------|-------|
| Dose | | Aggression | Health Professional Other | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | Claritin Tablet (Loratadine) | SS | | ORAL |
| 10 MG, DAILY, | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3405185-1Report Type:Periodic
Age:13 YR Gender:Female I/FU:I

Company Report #98USA11163

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--------------|---------------------|--|------|--------------|-------|
| Dose | | Eosinophilia | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, BID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3405189-9Report Type:Periodic
Age:42 YR Gender:Female I/FU:I

Company Report #98USA11168

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|-----------------|---------------------|--|------|--------------|-------|
| Dose | | Muscle Rigidity | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 70 MG, DAILY, ORAL | | | | | | | |

Klonopin Tablet C

Date:02/04/99ISR Number: 3405193-0Report Type:Periodic
Age:58 YR Gender:Male I/FU:I

Company Report #98USA11172

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|------------------|---------------------|---|------|--------------|-------|
| Dose | | Drug Ineffective | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, TID, ORAL | | | | | | | |

Xanax Tablet C
Ativan Tablet C
Lipitor Tablet C
Cardizem C

Date:02/04/99ISR Number: 3405195-4Report Type:Periodic Company Report #98USA11239
Age:50 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------|---------------------|--|------|--------------|-------|
| Dose | | Fatigue | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | Xanax Tablet | C | | |
| | | | | Activan Tablet | C | | |
| | | | | Lipitor | C | | |
| | | | | Cardizem | C | | |

Date:02/04/99ISR Number: 3405197-8Report Type:Periodic Company Report #98USA11242
Age:52 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------------------|---------------------|--|------|--------------|-------|
| Dose | | Laboratory Test Abnormal | Health Professional | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, QID, | | | | | | | |
| ORAL | | | | Cardizem Cd Capsule | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3405199-1Report Type:Periodic
Age:17 YR Gender:Female I/FU:I

Company Report #98USA11254

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--|------------------------|--|------|--------------|-------|
| 10 MG, TID, ORAL | | Aggression Emotional Disorder Psychotic Disorder | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 60 MG,DAILY, ORAL | | | | Adderall Tablet 20 Mg (Adderall) | SS | | ORAL |

Date:02/04/99ISR Number: 3405202-9Report Type:Periodic
Age:21 YR Gender:Female I/FU:I

Company Report #98USA11257

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------------|---|------------------------|--|------|--------------|-------|
| DAILY, ORAL RESPIRATORY (INHALATION) | INHALATION | Hallucination Insomnia Overdose Psychotic Disorder | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | Wellbutrin Tablet (Amfebutamone Hydrochloride) | SS | | ORAL |

Date:02/04/99ISR Number: 3405208-XReport Type:Periodic
Age:7 YR Gender:Male I/FU:I

Company Report #98USA11263

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|--------------------------|------------------------|---|------|--------------|-------|
| | | Dermatitis Haematuria | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate | | | |

7.5 MG, BID, ORAL
Liver Function Test
Abnormal
ORAL

Date:02/04/99ISR Number: 3405210-8Report Type:Periodic Company Report #98USA11303
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------|------------------------|---|------|--------------|-------|
| Dose | | Insomnia Tourette'S Disorder | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

15 MG, DAILY,

ORAL

Prozac C
Risperdal C

Date:02/04/99ISR Number: 3405211-XReport Type:Periodic Company Report #98USA11306
Age:53 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|------------------------|---|------|--------------|-------|
| Dose | | Hypoglycaemia | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

5 MG, BID,

ORAL

Insulin Suspension
For Injec C
Calcium Tablet C
Vitamins C
Prozac C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3405212-1Report Type:Periodic Company Report #98USA11307
 Age:9 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|------------------------|--|------|--------------|-------|
| 10 MG, BID, ORAL | | Liver Function Test Abnormal Muscle Spasms | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3405213-3Report Type:Periodic Company Report #98USA11342
 Age:10 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------|------------------------|--|------|--------------|-------|
| DAILY, ORAL | | Diplopia | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Laxatives | C | | |

Date:02/04/99ISR Number: 3405214-5Report Type:Periodic Company Report #98USA11344
 Age:10 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|----------|---------------|--|------|--------------|-------|
| 10 MG, TID, ORAL | | Dyspnoea | Consumer | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3405216-9Report Type:Periodic Company Report #98USA11347
 Age:9 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|----------------------|------|--------------|-------|
| | | Drug Ineffective | Health | Ritalin Tablet 10 Mg | | | |

| | | | | |
|------------|--------------|---------------------------------|----|------|
| 10 MG, QD, | Professional | (Methylphenidate Hydrochloride) | PS | ORAL |
| ORAL | | Ritalin-Sr | C | |

Date:02/04/99ISR Number: 3405217-0Report Type:Periodic Company Report #98USA11357
 Age:42 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------|---------------------|---|------|--------------|-------|
| Dose | | Vision Blurred | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, BID, | | | | | | | |
| ORAL | | | | | | | |

Date:02/04/99ISR Number: 3405218-2Report Type:Periodic Company Report #98USA11358
 Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------|---------------------|--|------|--------------|-------|
| Dose | | Hypertension | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, BID, | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3405219-4Report Type:Periodic Company Report #98USA11382
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-----------------|------------------------|---|------|--------------|-------|
| Dose | | Headache Tic | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, BID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3405891-9Report Type:Periodic Company Report #98USA10597
 Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------------------|------------------------------------|--|------|--------------|-------|
| Dose | | Eye Disorder Muscle Twitching | Consumer Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 7.5 MG, BID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3405896-8Report Type:Periodic Company Report #98USA10601
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|------------------|------------------------|--|------|--------------|-------|
| Dose | | Drug Ineffective | Health Professional | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, TID, ORAL | | | | | | | |
| | | | | Prevacid Capsule | C | | |

Date:02/04/99ISR Number: 3405901-9Report Type:Periodic Company Report #98USA10602
 Age:12 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|----------|---------------------|--|------|--------------|-------|
| | | Enuresis | Health Professional | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, BID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3405906-8Report Type:Periodic Company Report #98USA10603
 Age: Gender: I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------------|---------------------|--|------|--------------|-------|
| | | Photosensitivity Reaction | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3405912-3Report Type:Periodic Company Report #98USA10604
 Age:5 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|--|------|--------------|-------|
| | | Diarrhoea Headache Muscle Spasms Nausea | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3405918-4Report Type:Periodic Company Report #98USA10643
 Age:44 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------------|---------------------|--|------|--------------|-------|
| Dose | | Semen Abnormal | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3405925-1Report Type:Periodic Company Report #98USA10644
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-----------------------------------|---------------------|--|------|--------------|-------|
| Dose | | Drug Ineffective Medication Error | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10MG, BID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3405928-7Report Type:Periodic Company Report #98USA10658
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------------|--|------|--------------|-------|
| Dose | | Drug Ineffective Psychomotor Hyperactivity | Health Professional | Ritalin Tablet 5mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3405932-9Report Type:Periodic Company Report #98USA10661
 Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------|---------------------|---|------|--------------|-------|
| Dose | | Epistaxis | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, BID, | | | | | | | |

ORAL

Caffeine Unknown
(Caffeine) SS
Ephedrine Unknown
(Ephedrine) SS

Date:02/04/99ISR Number: 3405936-6Report Type:Periodic Company Report #98USA10679
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------------------------|------------------------|---|------|--------------|-------|
| Dose | | Crying Irritability Pollakiuria | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG BID, | | | | | | | |

ORAL

Date:02/04/99ISR Number: 3405939-1Report Type:Periodic Company Report #98USA10680
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|------------------------|--|------|--------------|-------|
| Dose | | Gynaecomastia | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 60 MG, DAILY, | | | | | | | |

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3405941-XReport Type:Periodic Company Report #98USA10703
 Age:8 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------------------------------|------------------------|---|------|--------------|-------|
| | | Inappropriate Affect Mood Swings | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

DAILY, ORAL

Date:02/04/99ISR Number: 3405962-7Report Type:Periodic Company Report #98USA10714
 Age:55 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------|---------------|--|------|--------------|-------|
| | | Headache | Consumer | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Elavil Tablet | C | | |

DAILY, ORAL

Date:02/04/99ISR Number: 3406028-2Report Type:Periodic Company Report #98USA10769
 Age:48 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------------------|---------------|--|------|--------------|-------|
| | | Headache Nausea Tremor | Consumer | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

DAILY, ORAL

Date:02/04/99ISR Number: 3406032-4Report Type:Periodic Company Report #98USA10793
 Age:12 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|------------------------|--|------|--------------|-------|
| | | Drug Ineffective | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

10MG, BID,

ORAL

Ritalin-Sr Slow
Release Tablet 20 Mg
(Methylphenidate
Hydrochloride) SS

ORAL

20 MG, DAILY,

ORAL

Date:02/04/99ISR Number: 3406034-8Report Type:Periodic
Age: Gender:Female I/FU:I

Company Report #98USA10803

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------------|--|------|--------------|-------|
| Dose | | Drug Ineffective | Health Professional | Ritalin Tablet 5mg (Methylphenidate Hydrochloride) | PS | | ORAL |

5MG, BID,

ORAL

Date:02/04/99ISR Number: 3406035-XReport Type:Periodic
Age:12 YR Gender:Male I/FU:I

Company Report #98USA10815

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|---------------------|---|------|--------------|-------|
| Dose | | Headache | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

5MG, BID,

ORAL

18-Aug-2005 11:49 AM

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3406037-3Report Type:Periodic Company Report #98USA10879
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|------------|---------------------|--|------|--------------|-------|
| Dose | | Ecchymosis | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10MG, BID, ORAL | | | | | | | |
| | | | | Lithium Tablet | C | | |

Date:02/04/99ISR Number: 3406045-2Report Type:Periodic Company Report #98USA10881
 Age:49 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------|---------------------|--|------|--------------|-------|
| Dose | | Muscle Spasms | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3406052-XReport Type:Periodic Company Report #98USA10908
 Age:47 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------|---------------------|--|------|--------------|-------|
| Dose | | Hypertension | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |
| | | | | Luvox Tablet | C | | |
| | | | | Klonopin Tablet | C | | |
| | | | | Buspar Tablet | C | | |

Date:02/04/99ISR Number: 3406064-6Report Type:Periodic Company Report #98USA11568
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|-------------|------------------|----------|--|----|------|
| | Drug Ineffective | Consumer | Methylphenidate Tablet 20 Mg (Methylphenidate) | PS | ORAL |
| 20 MG, QID, | | | | | |
| ORAL | | | Clonidine Tablet | C | |

Date:02/04/99ISR Number: 3406066-XReport Type:Periodic Company Report #98USA11569
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|--|------|--------------|-------|
| Dose | | Drug Ineffective | Consumer | Methylphenidate Tablet (Methylphenidate) | PS | | ORAL |
| 40 MG, QID, | | | | | | | |
| ORAL | | | | Clonidine Tablet | C | | |
| | | | | Trazodone Tablet | C | | |

Date:02/04/99ISR Number: 3406071-3Report Type:Periodic Company Report #98USA11587
 Age:61 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|---------------|--|------|--------------|-------|
| Dose | | Abdominal Pain Headache Vaginal Haemorrhage | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Dexedrine Tablet C
 Premarin Tablet C
 Trental Tablet C
 Lipitor Tablet C
 Synthroid Tablet C
 Vitamins Tablet C

Date:02/04/99ISR Number: 3406092-0Report Type:Periodic Company Report #98USA11594
 Age:46 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|--|------|--------------|-------|
| Dose | | Drug Ineffective | Consumer | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, TID, | | | | | | | |
| ORAL | | | | Zoloft Tablet | C | | |

Date:02/04/99ISR Number: 3406094-4Report Type:Periodic Company Report #98USA11595
 Age:19 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------|------------------------|--|------|--------------|-------|
| Dose | | Eosinophilia | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 40 MG, DAILY, | | | | | | | |
| ORAL | | | | | | | |

Date:02/04/99ISR Number: 3406097-XReport Type:Periodic Company Report #98USA11596
 Age:36 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|------------------------|--|------|--------------|-------|
| Dose | | Anxiety Headache Liver Function Test | Health Professional | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, TID, | | | | | | | |

Abnormal

ORAL

| | |
|------------------|---|
| Buspar Tablet | C |
| Zyprexa Tablet | C |
| Depakote Tablet | C |
| Neurontin Tablet | C |
| Claritin Tablet | C |

Date:02/04/99ISR Number: 3406105-6Report Type:Periodic
 Age:25 YR Gender:Female I/FU:I

Company Report #98USA11597

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|---------------|--|------|--------------|-------|
| Dose | | Pregnancy | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | Klonopin Tablet | C | | |

Date:02/04/99ISR Number: 3406106-8Report Type:Periodic
 Age:16 YR Gender:Female I/FU:I

Company Report #98USA11645

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|------------------------|--|------|--------------|-------|
| Dose | | Pregnancy | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Flagyl Tablet C
Zithromax Tablet C

Date:02/04/99ISR Number: 3406108-1Report Type:Periodic Company Report #98USA11646
Age:20 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------|---------------------|--|------|--------------|-------|
| | | Alopecia | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3406109-3Report Type:Periodic Company Report #98USA11694
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|---------------------|--|------|--------------|-------|
| | | Anorexia Disturbance In Attention Insomnia | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, BID, ORAL | | | | | | | |
| | | Irritability | | | | | |
| | | Nervousness | | | | | |

Date:02/04/99ISR Number: 3407533-5Report Type:Periodic Company Report #98USA10333
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|-----------------------------------|---------------------|--|------|--------------|-------|
| | | Dermatitis Peripheral Coldness | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, BID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407534-7Report Type:Periodic Company Report #98USA10334
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----|------------------------------|---|------|--------------|-------|
| Dose | | Tic | Consumer Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG , BID, | | | | | | | |
| ORAL | 6 | WK | | | | | |

Date:02/04/99ISR Number: 3407535-9Report Type:Periodic Company Report #98USA10366
Age:5 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------------------|---------------------|---|--------|--------------|-------|
| Dose | | Bronchospasm Cough Sneezing | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | |
| DAILY, | | | | | | | |
| UNKNOWN | | | | Vanceril Solution Aerosol Met Albuterol Unknown | C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3407536-0Report Type:Periodic
 Age:45 YR Gender:Female I/FU:I

Company Report #98USA10367

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--------------------|------------------------|---|------|--------------|-------|
| Dose | | Arthralgia Gout | Health Professional | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG , QD, ORAL | | | | Ritalin-Sr Slow Release Tablet 20 Mg (Methylphenidate Hydrochloride) | SS | | ORAL |
| 40 MG, DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407537-2Report Type:Periodic
 Age:45 YR Gender:Male I/FU:I

Company Report #98USA10383

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|------------|------------------------|---|------|--------------|-------|
| Dose | | Arthralgia | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, BID, ORAL | 3 MON | | | | | | |

Date:02/04/99ISR Number: 3407538-4Report Type:Periodic
 Age:9 YR Gender:Male I/FU:I

Company Report #98USA10384

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|-----|------------------------|--|------|--------------|-------|
| Dose | | Tic | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 25 MG, DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407539-6Report Type:Periodic Company Report #98USA10387
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----|---------------------|--|------|--------------|-------|
| Dose | | Tic | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, BID, | | | | | | | |
| ORAL | | | | Zoloft Tablet 50 Mg | C | | |

Date:02/04/99ISR Number: 3407540-2Report Type:Periodic Company Report #98USA10404
Age:33 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------|---------------------|--|------|--------------|-------|
| Dose | | Alopecia | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, TID, | | | | | | | |
| ORAL | | | | Prozac Unknown | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3407541-4Report Type:Periodic
Age:33 YR Gender:Female I/FU:I

Company Report #98USA10419

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---------------------------------------|---------------|---|------|--------------|-------|
| 10 MG, TID, ORAL | | Alopecia Blood Uric Acid Decreased | Consumer | Ritalin Tablet 10mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3407542-6Report Type:Periodic
Age:65 YR Gender:Female I/FU:I

Company Report #98USA10446

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|------------|------------------------|--|------|--------------|-------|
| 10 MG, 5QD, ORAL | | Convulsion | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3407543-8Report Type:Periodic
Age:10 YR Gender:Male I/FU:I

Company Report #98USA10465

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|----------|------------------------|---|------|--------------|-------|
| 5 MG, TID, ORAL | | Headache | Health Professional | Ritalin Tablet 5.0 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3407544-XReport Type:Periodic
Age:7 YR Gender:Male I/FU:I

Company Report #98USA10477

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----|---------------|---------|------|--------------|-------|
|--------------|----------|----|---------------|---------|------|--------------|-------|

| | | | | | |
|-------------|--------------------|--------------|------------------|----|------|
| | Abnormal Behaviour | Health | Ritalin Tablet | | |
| | Anger | Professional | (Methylphenidate | | |
| | Emotional Disorder | | Hydrochloride) | PS | ORAL |
| 15 MG, TID, | | | | | |
| ORAL | | | | | |

Date:02/04/99ISR Number: 3407545-1Report Type:Periodic Company Report #98USA10501
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|---------------|---------------------|------|--------------|-------|
| Dose | | Sneezing | Consumer | Ritalin Tablet 5.0 | | | |
| | | Urticaria | Health | Mg (Methylphenidate | | | |
| | | | Professional | Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407546-3Report Type:Periodic Company Report #98USA10503
 Age:23 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|----------------------|------|--------------|-------|
| Dose | | Drug Ineffective | Consumer | Ritalin Tablet 10 Mg | | | |
| | | | | (Methylphenidate | | | |
| | | | | Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3407547-5Report Type:Periodic Company Report #98USA10516
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|------------|-----------------------------------|--|------|--------------|-------|
| Dose | | Haematuria | Health Professional User Facility | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, BID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407548-7Report Type:Periodic Company Report #98USA10530
 Age:56 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|----------------------|---------------------|--|------|--------------|-------|
| Dose | | Ejaculation Disorder | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 15 MG, BID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407549-9Report Type:Periodic Company Report #98USA10531
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|------------------------------|--|------|--------------|-------|
| Dose | | Aggression Agitation Depression | Health Professional Other | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, BID, ORAL | | | | | | | |
| | 2 DAY | Emotional Disorder Nervousness Psychotic Disorder Suicidal Ideation | | | | | |

Date:02/04/99ISR Number: 3407550-5Report Type:Periodic Company Report #98USA10537
 Age:18 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--|------------------------|---|------|--------------|-------|
| 10 MG, QD, ORAL | | Abnormal Behaviour Drug Interaction Irritability | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, DAILY, ORAL | | | | Ritalin-Sr Slow Release Tablet 20 Mg (Methylphenidate Hydrochloride) | SS | | ORAL |
| INHALATION | | | | Marijuana Unknown (Cannabis) | SS | | |

Date:02/04/99ISR Number: 3407551-7Report Type:Periodic Company Report #98USA10544
Age:8 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|----------|------------------------|--|--------|--------------|-------|
| 20 MG, QD, ORAL | | Alopecia | Health Professional | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Prednisone Tablet Amoxicillin Unknown | C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3407553-0Report Type:Periodic Company Report #98USA10596
 Age:48 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|--|------------------------|--|------|--------------|-------|
| 600 MG, DAILY, ORAL | | Abnormal Behaviour Dry Skin Erythema | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3407586-4Report Type:Periodic Company Report #98USA10137
 Age:10 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|----------------------|------------------------|--|------|--------------|-------|
| 10 MG TID ORAL | | Raynaud'S Phenomenon | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Tofranil Tablet | C | | |

Date:02/04/99ISR Number: 3407588-8Report Type:Periodic Company Report #98USA10138
 Age:12 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|------------------------|---|------|--------------|-------|
| 5 MG TID ORAL | | Visual Disturbance | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3407591-8Report Type:Periodic Company Report #98USA10157
 Age:11 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------|---------------|--------------------|------|--------------|-------|
| | | Anxiety | Consumer | Ritalin Tablet 5mg | | | |

Chest Pain

(Methylphenidate
Hydrochloride)

PS

ORAL

5 MG BID ORAL

Date:02/04/99ISR Number: 3407594-3Report Type:Periodic
Age:19 YR Gender:Female I/FU:I

Company Report #98USA10181

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------------|---|------|--------------|-------|
| Dose | | Abdominal Pain | Health Professional | Ritalin Tablet 10mg (Methylphenidate Hydrochloride) | PS | | ORAL |

10 MG TID

ORAL

Date:02/04/99ISR Number: 3407596-7Report Type:Periodic
Age:54 YR Gender:Male I/FU:I

Company Report #98USA10182

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------------|---|------|--------------|-------|
| Dose | | Arthralgia Neck Pain | Health Professional | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |

60 MG DAILY

ORAL

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3407599-2Report Type:Periodic Company Report #98USA10183
 Age:43 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------|---------------------|--|------|--------------|-------|
| DAILY ORAL | | Lethargy | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Prevacid Capsule | C | | |

Date:02/04/99ISR Number: 3407601-8Report Type:Periodic Company Report #98USA10225
 Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|----------|---------------------|--|------|--------------|-------|
| 10 MG TID ORAL | | Alopecia | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3407603-1Report Type:Periodic Company Report #98USA10237
 Age:43 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---|---------------|---|------|--------------|-------|
| 15 MG TID ORAL | | Drug Effect Decreased Drug Interaction | Consumer | Ritalin Tablet 10mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | 9 DAY | | | Suprax Tablet (Cefixime) | SS | | ORAL |
| | | | | Nordette Tablet | C | | |
| | | | | Pred Forte | C | | |

Date:02/04/99ISR Number: 3407606-7Report Type:Periodic Company Report #98USA10247
Age:45 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------------------|---------------------|--|------|--------------|-------|
| | | Liver Function Test Abnormal | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |

DAILY ORAL

Date:02/04/99ISR Number: 3407608-0Report Type:Periodic Company Report #98USA10254
Age:9 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------------------|---------------------|--|------|--------------|-------|
| | | Liver Function Test Abnormal | Health Professional | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |

DAILY ORAL

Date:02/04/99ISR Number: 3407610-9Report Type:Periodic Company Report #98USA10257
Age:30 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------------|--|------|--------------|-------|
| | | Infertility Male | Health Professional | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

20 MG QD ORAL

Antacid C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3407613-4Report Type:Periodic
Age:7 YR Gender:Male I/FU:I

Company Report #98USA10269

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------|---------------|---|------|--------------|-------|
| Dose | | Drug Ineffective | Consumer | Ritalin Tablet 10mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG BID | | | | | | | |
| ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407615-8Report Type:Periodic
Age:32 YR Gender:Female I/FU:I

Company Report #98USA10272

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------|------------------------|---|------|--------------|-------|
| Dose | | Drug Ineffective | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY ORAL | | | | Ritalin-Sr Slow Release Tablet 20 Mg (Methylphenidate Hydrochloride) | SS | | ORAL |
| ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407617-1Report Type:Periodic
Age:22 YR Gender:Male I/FU:I

Company Report #98USA10273

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|------------------------|--|------|--------------|-------|
| Dose | | Alopecia | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG QD ORAL | | | | Zoloft | C | | |

Date:02/04/99ISR Number: 3407620-1Report Type:Periodic
Age:53 YR Gender:Female I/FU:I

Company Report #98USA10290

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|----------|---------------------|--|------|--------------|-------|
| Dose | | Alopecia | Health Professional | Ritalin Tablet 5mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG PRN | ORAL | | | Zoloft | C | | |
| | | | | Wellbutrin | C | | |

Date:02/04/99ISR Number: 3407622-5Report Type:Periodic Company Report #98USA10292
 Age:21 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|--|------|--------------|-------|
| Dose | | Drug Ineffective Feeling Jittery Nausea | Consumer | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG TID | | | | | | | |
| ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407624-9Report Type:Periodic Company Report #98USA10293
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------|---------------------|--|------|--------------|-------|
| Dose | | Halitosis | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG BID | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3407626-2Report Type:Periodic Company Report #98USA10306
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------------|---|------|--------------|-------|
| Dose | | Dermatitis | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG BID ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407629-8Report Type:Periodic Company Report #98USA10308
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------|---------------------|--|------|--------------|-------|
| Dose | | Dysuria | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 12.5 MG DAILY | | | | | | | |

ORAL

Date:02/04/99ISR Number: 3407631-6Report Type:Periodic Company Report #98USA10325
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------------|---------------|--|------|--------------|-------|
| Dose | | Headache Nausea | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 15 MG DAILY | | | | | | | |

ORAL

Date:02/04/99ISR Number: 3407818-2Report Type:Periodic Company Report #97USA12165
 Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------|---------------------|------------------------|------|--------------|-------|
| Dose | | Pyrexia | Health Professional | Ritalin Tablet Unknown | | | |

(Methylphenidate Hydrochloride) PS ORAL
DAILY, ORAL

Date:02/04/99ISR Number: 3407824-8Report Type:Periodic Company Report #97USA12170
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------------|--|------|--------------|-------|
| Dose | | Abdominal Discomfort | Health Professional | Ritalin Tablet 10 (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, QD, | | | | | | | |
| ORAL | | | | | | | |
| | | | | Ritalin-Sr Slow Release Tablet 20 Mg (Methylphenidate Hydrochloride) | SS | | ORAL |
| 20 MG, DAILY, | | | | | | | |
| ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407826-1Report Type:Periodic Company Report #97USA12198
Age:40 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------------|---------------|--|------|--------------|-------|
| Dose | | Anxiety Drug Ineffective | Consumer | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, TID, | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3407829-7Report Type:Periodic Company Report #97USA12201
 Age:9 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------|---------------------|---|------|--------------|-------|
| | | Abdominal Pain | Health Professional | Ritalin Tablet 12.5 (Methylphenidate Hydrochloride) | PS | | ORAL |
| 12.5 MG, QD, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407832-7Report Type:Periodic Company Report #97USA12298
 Age: Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------------------|------------------------------|--|------|--------------|-------|
| | | Dizziness Drug Interaction | Health Professional Other | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |
| | | | | Claritin Tablet 10mg (Loratadine) | SS | | ORAL |
| 10 MG DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407835-2Report Type:Periodic Company Report #97USA12304
 Age:23 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|------------------------|---------------------|---|------|--------------|-------|
| | | Depression Insomnia | Health Professional | Ritalin Tablet 5.0 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, QD, ORAL | | | | | | | |
| | | | | Zoloft | C | | |

Date:02/04/99ISR Number: 3407838-8Report Type:Periodic Company Report #97USA12306
Age:20 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------|---------------------|--|------|--------------|-------|
| Dose | | Hypertension | Health Professional | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407842-XReport Type:Periodic Company Report #97USA12346
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|---------------------|--|------|--------------|-------|
| Dose | | Diarrhoea | Health Professional | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407844-3Report Type:Periodic Company Report #97USA12350
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|------------------------------|---------------------|--|------|--------------|-------|
| Dose | | Liver Function Test Abnormal | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, TID, ORAL | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Paxil

C

Date:02/04/99ISR Number: 3407847-9Report Type:Periodic
Age:19 YR Gender:Male I/FU:I

Company Report #97USA12364

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|------------------------|--|------|--------------|-------|
| Dose | | Decreased Appetite Erectile Dysfunction | Health Professional | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, TID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407851-0Report Type:Periodic
Age:5 YR Gender:Male I/FU:I

Company Report #97USA12365

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--|------------------------|---|------|--------------|-------|
| Dose | | Flushing Peripheral Coldness Pyrexia | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407854-6Report Type:Periodic
Age: Gender:Male I/FU:I

Company Report #97USA12424

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------|------------------------|---|------|--------------|-------|
| Dose | | Rash Macular | Health Professional | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407856-XReport Type:Periodic
Age:10 YR Gender:Male I/FU:I

Company Report #97USA12442

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-------------------------|---------------------|--|------|--------------|-------|
| | | Salivary Hypersecretion | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 15 MG, QID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407858-3Report Type:Periodic Company Report #97USA12450
 Age:6 YR Gender: I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--------------------------------------|---------------------|--|------|--------------|-------|
| | | Blood Alkaline Phosphatase Increased | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 35 MG, DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407861-3Report Type:Periodic Company Report #98USA10034
 Age: Gender: I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------|---------------------|--|------|--------------|-------|
| | | Chest Pain | Health Professional | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3407864-9Report Type:Periodic Company Report #98USA10051
 Age:69 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------|---------------|---|------|--------------|-------|
| | | Cough | Consumer | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407867-4Report Type:Periodic Company Report #98USA10085
 Age: Gender: I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------|------------------------|--|------|--------------|-------|
| | | Alopecia | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407870-4Report Type:Periodic Company Report #98USA10086
 Age: Gender: I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|------------------------|---|------|--------------|-------|
| | | Drug Ineffective | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3407873-XReport Type:Periodic Company Report #98USA10117
 Age: Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--------------------|---------------|---|------|--------------|-------|
| | | Psychotic Disorder | Consumer | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL 30 DAY | | | | | | | |

Date:02/04/99ISR Number: 3407875-3Report Type:Periodic Company Report #98USA10126
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------|---------------------|--|------|--------------|-------|
| Dose | | Leukopenia | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 15 MG, BID, | | | | | | | |
| ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408045-5Report Type:Periodic Company Report #98USA11715
Age:48 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|---------------|--|------|--------------|-------|
| Dose | | Anxiety Headache Muscle Rigidity | Consumer | Ritalin Tablet 5mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5MG, BID, | | Muscle Spasms | | | | | |
| ORAL | | Nausea | | Premarin | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3408052-2Report Type:Periodic Company Report #98USA11716
 Age:7 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|------------------|---------------|--|------|--------------|-------|
| 10 MG, BID, ORAL | | Weight Decreased | Consumer | Ritalin Tablet 10mg (Methylphenidate) Hydrochlore) | PS | | ORAL |

Date:02/04/99ISR Number: 3408054-6Report Type:Periodic Company Report #98USA11717
 Age:7 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------------------------|------------------------|--|------|--------------|-------|
| DAILY, ORAL | | Drug Ineffective Drug Interaction | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | Claritin Tablet (Loratadine) | SS | | ORAL |

Date:02/04/99ISR Number: 3408056-XReport Type:Periodic Company Report #98USA11718
 Age:16 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|------------------------|--|------|--------------|-------|
| DAILY, ORAL | | Drug Interaction | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Claritin Tablet (Loratadine) | SS | | |
| | | | | Depakote | C | | |

Date:02/04/99ISR Number: 3408058-3Report Type:Periodic Company Report #98USA11719
 Age:10 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|----------|--------------------------------------|---------------------|---|------|--------------|-------|
| | | Drug Ineffective Drug Interaction | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |
| ORAL | | | | | | | |
| Claritin Tablet (Loratadine) | | | | | | | |
| SS | | | | | | | |
| ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408061-3Report Type:Periodic Company Report #98USA11726
 Age:47 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------|---------------|---|------|--------------|-------|
| | | Hypertension | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408063-7Report Type:Periodic Company Report #98USA11753
 Age:21 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|---------------------|---|------|--------------|-------|
| | | Abdominal Pain Asthenia Diarrhoea | Health Professional | Ritalin Tablet 5mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |
| Nausea Vomiting | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3408068-6Report Type:Periodic
Age:43 YR Gender:Male I/FU:I

Company Report #98USA11759

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------------|---------------------|--|------|--------------|-------|
| DAILY ORAL | | Drug Tolerance Increased | Health Professional | Ritalin Tablet 420mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Prozac | C | | |
| | | | | Flexeril | C | | |
| | | | | Vicodin | C | | |

Date:02/04/99ISR Number: 3408072-8Report Type:Periodic
Age:12 YR Gender:Female I/FU:I

Company Report #98USA11761

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|---------------|---|------|--------------|-------|
| 10 MG, QID, ORAL | | Abnormal Behaviour Drug Ineffective | Consumer | Ritalin Tablet 10mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Atrohist Syrup | C | | |

Date:02/04/99ISR Number: 3408076-5Report Type:Periodic
Age:55 YR Gender:Female I/FU:I

Company Report #98USA11771

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|----------------|---------------------|--|------|--------------|-------|
| 5 MG TID, ORAL | | Vision Blurred | Health Professional | Ritalin Tablet 5mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3408078-9Report Type:Periodic
Age:6 YR Gender:Female I/FU:I

Company Report #98USA11773

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|------------------------|------------------------|---|------|--------------|-------|
| Dose | | Dyskinesia Insomnia | Health Professional | Ritalin Tablet 40mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 40 MG, QD, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408080-7Report Type:Periodic Company Report #97USA11956
 Age:57 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--|---------------|---|------|--------------|-------|
| Dose | | Drug Interaction Drug Tolerance Decreased | Consumer | Ritalin Tablet 15mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 15 MG, DAILY, ORAL | | | | | | | |
| | | | | Ativan | C | | |

Date:02/04/99ISR Number: 3408083-2Report Type:Periodic Company Report #97USA11990
 Age:7 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|----------|----------------------|------------------------|---|------|--------------|-------|
| Dose | | Urinary Incontinence | Health Professional | Ritalin Tablet 10.0 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MGM BID, ORAL | | | | | | | |
| | | 4 YR | | | | | |
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Ddavp

C

Date:02/04/99ISR Number: 3408251-XReport Type:Periodic
Age:13 YR Gender:Male I/FU:I

Company Report #98USA10910

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|--------------------|---------------------|---|------|--------------|-------|
| | | Abnormal Behaviour | Health Professional | Ritalin Tablet Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408255-7Report Type:Periodic
Age:49 YR Gender:Male I/FU:I

Company Report #98USA10920

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|---|---------------------|--|------|--------------|-------|
| | | Blood Thyroid Stimulating Hormone Increased Lymphadenopathy | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408261-2Report Type:Periodic
Age:16 YR Gender:Male I/FU:I

Company Report #98USA10922

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---------------------------------------|---------------------|---|------|--------------|-------|
| | | Blood Bilirubin Increased Jaundice | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, QD, ORAL | | | | | | | |

Prozac

C

Date:02/04/99ISR Number: 3408265-XReport Type:Periodic
Age:8 YR Gender:Male I/FU:I

Company Report #98USA10923

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--------------------|---------------|---|------|--------------|-------|
| Dose | | Amnesia Aphasia | Consumer | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG, QD, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408268-5Report Type:Periodic Company Report #98USA10950
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|-----|------------------------|--|------|--------------|-------|
| Dose | | Tic | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, BID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408271-5Report Type:Periodic Company Report #98USA10953
 Age:72 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|----------------------|------------------------|--|------|--------------|-------|
| Dose | | Dyspnoea Insomnia | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, QD, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Theophylline C
 Lasix C
 Acetazolamide C

Date:02/04/99ISR Number: 3408299-5Report Type:Periodic Company Report #98USA10960
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-----------|---------------------|--|------|--------------|-------|
| Dose | | Epistaxis | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, TID, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408301-0Report Type:Periodic Company Report #98USA10964
 Age:21 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------|---------------------|--|------|--------------|-------|
| Dose | | Nausea | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408303-4Report Type:Periodic Company Report #98USA11014
 Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------------|---------------------|--|------|--------------|-------|
| Dose | | Hypothyroidism | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |
| | | | | Ritalin-Sr Slow Release | C | | |
| | | | | Clonidine Tablet | C | | |

Date:02/04/99ISR Number: 3408305-8Report Type:Periodic Company Report #98USA11038
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------|---------------------|--|------|--------------|-------|
| Dose | | Alopecia | Health Professional | Ritalin Tablet Unk (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:02/04/99ISR Number: 3408307-1Report Type:Periodic Company Report #97USA12046
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------------|--|------|--------------|-------|
| Dose | | Confusional State Motor Dysfunction | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |
| | | | | Depakote Tablet | C | | |
| | | | | Tenex Tablet | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3408311-3Report Type:Periodic Company Report #97USA12048
 Age:5 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--------------------------|------------------------|---|------|--------------|-------|
| 5 MG, BID, ORAL | 3 DAY | Face Oedema Urticaria | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3408314-9Report Type:Periodic Company Report #97USA12054
 Age:6 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|------------------|------------------------|---|------|--------------|-------|
| 5 MG, BID, ORAL | | Drug Ineffective | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3408319-8Report Type:Periodic Company Report #97USA12077
 Age: Gender:Unknown I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------|------------------------|---|------|--------------|-------|
| DAILY, ORAL | | Alopecia | Health Professional | Ritalin Tablet Ukn (Methylpenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3408322-8Report Type:Periodic Company Report #97USA12078
 Age: Gender:Unknown I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------|------------------------|---------------------------------------|------|--------------|-------|
| | | Ecchymosis | Health Professional | Ritalin Tablet Ukn (Methylpenidate | | | |

| | | | | | | | |
|--|-------------|---------------------|----------------------------|--|------|--------------|-------|
| RAILY, ORAL | | | Hydrochloride) | PS | ORAL | | |
| Date:02/04/99ISR Number: 3408328-9Report Type:Periodic | | | Company Report #97USA12109 | | | | |
| Age:6 YR | Gender:Male | I/FU:I | | | | | |
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Erythema Multiforme | Health Professional | Ritalin Tablet Uknown (Methylpenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | 5 | MON | | | | | |

| | | | | | | | |
|--|----------------|---------|----------------------------|---|------|--------------|-------|
| Date:02/04/99ISR Number: 3408332-0Report Type:Periodic | | | Company Report #97USA12110 | | | | |
| Age: | Gender:Unknown | I/FU:I | | | | | |
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Anaemia | Health Professional | Ritalin Tablet Ukn Own (Methylpenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/99ISR Number: 3408335-6Report Type:Periodic
Age:10 YR Gender:Male I/FU:I

Company Report #97USA12131

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|----------------------------------|------------------------|---|------|--------------|-------|
| 10 MG, BID, ORAL | 4 MON | Erythema Multiforme Urticaria | Health Professional | Ritalin Tablet 10 Mg (Methylpenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3408340-XReport Type:Periodic
Age: Gender:Unknown I/FU:I

Company Report #97USA12136

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------|------------------------|--|------|--------------|-------|
| DAILY, ORAL | | Pollakiuria | Health Professional | Ritalin Tablet Unknown (Methylpenidate Hydrochloride) | PS | | ORAL |

Date:02/04/99ISR Number: 3408345-9Report Type:Periodic
Age:12 YR Gender:Male I/FU:I

Company Report #97USA12164

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------|------------------------|--|------|--------------|-------|
| DAILY, ORAL | | Abdominal Pain | Health Professional | Ritalin Tablet Unknown (Methylpenidate Hydrochloride) | PS | | ORAL |

Date:02/05/99ISR Number: 3199100-6Report Type:Periodic
Age:8 YR Gender:Male I/FU:I

Company Report #FLUV002980049

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|------------------------------|------------------------|--------------------------------------|------|--------------|-------|
| | | Alopecia Drug Interaction | Health Professional | Luvox Tablets 50 Mg (Fluvoxamine) | | | |

10 MG , PER Maleate) PS ORAL
 ORAL
 15 MG PER Ritalin (Methylphenidate Hydrochloride) SS ORAL
 ORAL ; 1YR

Date:02/10/99ISR Number: 3195467-3Report Type:Expedited (15-DaCompany Report #99USA10109
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Vasculitis | Health | Ritalin-Sr | PS | | ORAL |
| TABLET, | | Wegener'S Granulomatosis | Professional | | | | |
| DAILY, ORAL | | | | | | | |

Date:02/12/99ISR Number: 3203031-2Report Type:Expedited (15-DaCompany Report #99USA10109
 Age:30 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|--------------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Malaise | Health | Ritalin-Sr | PS | | ORAL |
| 20 MG,QD, | | Vasculitis | Professional | | | | |
| ORAL | | Wegener'S Granulomatosis | | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | SS | | ORAL |
| 20 MG, DAILY, | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/18/99ISR Number: 3203028-2Report Type:Expedited (15-DaCompany Report #99USA10179
Age:35 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Antinuclear Antibody | Health | Ritalin-Sr | PS | | ORAL |
| 20 MG, BID, | | Positive | Professional | | | | |
| ORAL | | Asthma | | Nortriptyline | | | |
| | | Gastrointestinal Disorder | | Capsule | C | | |
| | | Medication Error | | Citrucel Dry Powder | C | | |
| | | Mucous Membrane Disorder | | | | | |
| | | Night Sweats | | | | | |
| | | Systemic Lupus | | | | | |
| | | Erythematosis | | | | | |

Date:02/23/99ISR Number: 3204642-0Report Type:Expedited (15-DaCompany Report #MPI-97418(1)
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Aggression | Health | Methylphenidate | | | |
| Initial or Prolonged | | Agitation | Professional | Tablets 10 Mg | | | |
| | | Intermittent Explosive | | (Methylphenidate | | | |
| | | Disorder | | Hydrochloride 10 Mg) | PS | | ORAL |
| 55 MG, PO | | Memory Impairment | | Clonidine | | | |
| | | Parent-Child Problem | | Hydrochloride | | | |
| | | | | (Clonidine | | | |
| | | | | Hydrochloride) | SS | | ORAL |
| 0.1 MG PO | | | | Bupropion | | | |
| | | | | (Amfebutamone) | SS | | ORAL |
| 150 MG PO | | | | | | | |

Date:02/25/99ISR Number: 3207887-9Report Type:Periodic Company Report #9726880
Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Catatonia | Consumer | Zoloft Tablets | PS | | ORAL |
| | | Social Problem | | Ritalin | SS | | ORAL |

Tenex SS ORAL
Risperdal SS ORAL

Date:02/25/99ISR Number: 3209993-1Report Type:Periodic Company Report #9828259
Age:18 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Amnesia | Consumer | Zoloft Tablets | PS | | ORAL |
| 50.00MG TOTAL | | Confusional State | | | | | |
| DAILY ORAL | | Coordination Abnormal | | Ritalin | SS | | ORAL |
| 60.00MG TOTAL | | Insomnia | | | | | |
| DAILY ORAL | | | | Birth Control Pills | SS | | ORAL |
| ORAL | | | | Synthroid | C | | |

Date:02/25/99ISR Number: 3211473-4Report Type:Periodic Company Report #9808200
Age:28 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypoaesthesia | Health | Zoloft Tablets | PS | | ORAL |
| 200.00 MG | | Oedema Peripheral | Professional | | | | |
| TOTAL; DAILY; | | | | | | | |
| ORAL | | | | Ritalin | SS | | ORAL |
| 30.00 MG | | | | | | | |
| TOTAL; TID; | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

ORAL

Vitamin C C
 Vitamin D C
 Antioxidants C

Date:02/25/99ISR Number: 3211929-4Report Type:Periodic Company Report #9804561
 Age:38 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Abuser | Consumer | Zoloft Tablets | PS | | ORAL |
| 100.00 MG | | Drug Interaction | Health | | | | |
| TOTAL:DAILY:0 | | | Professional | | | | |

RAL

Ritalin SS ORAL

40.00 MG

TOTAL:DAILY:0

RAL

Marijuana SS

Date:02/25/99ISR Number: 3212214-7Report Type:Periodic Company Report #9802532
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depersonalisation | Consumer | Zoloft Tablets | PS | | ORAL |
| 50.00 MG | | Hallucination | Health | | | | |
| TOTAL: DAILY: | | Thinking Abnormal | Professional | | | | |

ORAL

Accutane SS ORAL

40.00 MG

TOTAL: DAILY

: ORAL

Ritalin SS ORAL

10.00 MG

TOTAL: DAILY:

ORAL

Date:02/25/99ISR Number: 3212730-8Report Type:Periodic Company Report #9803621

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia | Consumer | Zoloft Tablets | PS | | ORAL |
| 150.00 MG | | Depression | | | | | |

TOTAL:DAILY:0

RAL

ORAL

| | | | | | | | |
|--|--|--------------------|--|-----------|----|--|------|
| | | Drug Ineffective | | | | | |
| | | Intentional Misuse | | Ritalin | SS | | ORAL |
| | | Libido Decreased | | Vitamin E | C | | |
| | | Pollakiuria | | | | | |

Date:02/25/99ISR Number: 3216492-XReport Type:Periodic Company Report #9803250

Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Choreoathetosis | Health | Zoloft Tablets | PS | | ORAL |
| 50.00MG TOTAL | | Drug Interaction | Professional | | | | |
| DAILY ORAL | | Tardive Dyskinesia | | Ritalin | SS | | ORAL |
| ORAL | | | | Dexedrine | SS | | ORAL |

ORAL

Date:02/25/99ISR Number: 3217091-6Report Type:Periodic Company Report #9812057

Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Interaction | Health | Zoloft Tablets | PS | | ORAL |
| 25 MG TOTAL | | Ecchymosis | Professional | | | | |

DAILYORAL

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

15 MG TOTAL Ritalin SS ORAL

TID ORAL Clonidine C

Date:02/26/99ISR Number: 3214260-6Report Type:Periodic Company Report #8-98128-002T
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | Consumer | Effexor | PS | | ORAL |
| 150 MG | | Dyspnoea | | Phentermine | SS | | |
| | | | | Pondimin | SS | | ORAL |
| | | | | Ritalin | SS | | |
| | | | | Adderall | C | | |
| | | | | Phentermine | C | | |
| | | | | Pondimin Oral | C | | |
| | | | | Ritalin | C | | |

Date:03/01/99ISR Number: 3209268-0Report Type:Expedited (15-DaCompany Report #99NZ-10005
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Haemorrhagic Stroke | Foreign Health Professional | Ritalin Unknown (Methylphenidate Hydrochloride) | PS | | |
| INTRAVENOUS | DAILY, | | Other | | | | |
| INTRAVENOUS | | | | | | | |

Date:03/01/99ISR Number: 3209324-7Report Type:Expedited (15-DaCompany Report #99USA10226
 Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---------------------------|---------------------|---------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Drug Interaction Lethargy | Health Professional | Ritalin Tablet 15 Mg (Methylphenidate | | | |

15 MG, QD, Stupor Hydrochloride) PS

UNKNOWN

Depakote Tablet C
Klonopin Tablet C
Tegretol Tablet C
Augmentin Tablet C

Date:03/01/99ISR Number: 3432298-0Report Type:Periodic Company Report #MPI-98055
Age:8 YR Gender:Female I/FU:F

Outcome Dose Duration PT Personality Disorder Report Source Health Professional Product Methylphenidate Hcl Role PS Manufacturer Md Pharmaceutical Inc Route ORAL
10 MG DAILY,
PO

Date:03/01/99ISR Number: 3432301-8Report Type:Periodic Company Report #MPI-98056
Age:9 YR Gender:Male I/FU:F

Outcome Dose Duration PT Muscle Twitching Report Source Consumer Product Methylphenidate Hcl Role PS Manufacturer Md Pharmaceutical Inc Route ORAL
10 MG BID, PO

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/01/99ISR Number: 3432308-0Report Type:Periodic
 Age:9 YR Gender:Male I/FU:F

Company Report #MPI-98179

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------------|------------------------|---------------------|------|--------------------------|-------|
| Dose | | Asthenia Drug Ineffective | Health Professional | Methylphenidate Hcl | PS | Md Pharmaceutical Inc | ORAL |
| 15 MG TID, PO | | | | Clonadine | C | | |

Date:03/01/99ISR Number: 3432314-6Report Type:Periodic
 Age:45 YR Gender:Female I/FU:F

Company Report #MPI-98181

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|------------------------------------|------|--------------------------|-------|
| Dose | | Drug Effect Decreased Drug Ineffective | Consumer | Methylphenidate Hcl | PS | Md Pharmaceutical Inc | ORAL |
| 10 MG QID, PO | | | | Estrogen (Estrogenic Substance) | C | | |
| | | | | Vasotec (Enalapril Maleate) | C | | |

Date:03/01/99ISR Number: 3440908-7Report Type:Periodic
 Age:11 YR Gender:Female I/FU:I

Company Report #98USA10258

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|----------------|------------------------|--|------|--------------|-------|
| Dose | | Hypothyroidism | Health Professional | Anafranil Capsule 25 Mg (Clomipramine Hydrochloride) | PS | | ORAL |
| 25 MG, QD, ORAL | | | | Ritalin Tablet (Methylphenidrate Hydrochloride) | SS | | ORAL |
| 40 MG, DAILY, ORAL | | | | | | | |

Date:03/02/99ISR Number: 3209329-6Report Type:Expedited (15-DaCompany Report #99USA10225

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Intentional Misuse Medication Error | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | |
| UNK, DAILY, | | | | | | | |
| INTRANASAL | | | | | | | |

Date:03/03/99ISR Number: 3211815-XReport Type:Expedited (15-DaCompany Report #WAES 99020288

Age:7 YR Gender:Male I/FU:F

| Outcome | PT |
|---|--|
| Hospitalization - Initial or Prolonged | Anorexia Attention Deficit/Hyperactivity Disorder Blood Cortisol Increased Conjunctivitis Cushingoid Cystitis Encephalopathy Haematuria Hyperreflexia Hypertension Labile Blood Pressure |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------|----------|--|------------------------|----------------------|------|--------------|-------|
| | | Nephritis Interstitial Proteinuria Pyrexia | Health | Crixivan | PS | | ORAL |
| PO | | Pyuria | Professional | Megace | SS | | ORAL |
| PO | | Renal Tubular Acidosis | Company Representative | Ritalin | SS | | ORAL |
| PO | | | | Lamivudine | C | | |
| | | | | Sulfamethoxazole (+) | C | | |
| | | | | Trimethopril | C | | |
| | | | | Zidovudine | C | | |

Date:03/05/99ISR Number: 3214371-5Report Type:Expedited (15-DaCompany Report #99USA10246
Age:50 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|-------------------------|---------------------|---|------|--------------|-------|
| Life-Threatening | | Ventricular Tachycardia | Health Professional | Ritalin Tablet 10mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, TID, ORAL | 1 YR | | | Tiazac | C | | |

Date:03/12/99ISR Number: 3218855-5Report Type:Direct Company Report #
Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------------|----------|--|---------------|---------|------|--------------|-------|
| Other 20MG AM 10MG NOON 30# | | Headache Jaw Disorder Muscle Twitching | Professional | Ritalin | PS | | |

Date:03/17/99ISR Number: 3222278-2Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|---------------|---------|------|--------------|-------|
| 1 5 MG TAB Q | | Abnormal Behaviour | | Ritalin | PS | | ORAL |
| AM AND 1 Q | | | | | | | |
| NOON | | | | | | | |

Date:03/22/99ISR Number: 3224116-0Report Type:Expedited (15-DaCompany Report #9904511
 Age:35 YR Gender:Female I/FU:F

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------|---------------|----------------|------|--------------|-------|
| Required 100.00 MG | | Breast Discharge | Health | Zoloft Tablets | PS | | ORAL |
| Intervention to | | Breast Haemorrhage | Professional | | | | |
| TOTAL: DAILY: | | Fatigue | | | | | |
| Prevent Permanent ORAL Impairment/Damage 30.00 MG | | Mastitis | | Ritalin | SS | | ORAL |
| TOTAL: TID: | | Staphylococcal Infection | | | | | |
| ORAL | | | | | | | |

Date:03/22/99ISR Number: 3224294-3Report Type:Expedited (15-DaCompany Report #99USA10246
 Age:50 YR Gender:Male I/FU:F

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|---|------------------------|--|------|--------------|-------|
| Life-Threatening 10 MG, TID | 1 YR | Chest Pain Exercise Test Abnormal Ventricular Tachycardia | Health Professional | Ritalin Tablet 10 Mg (Methyphenidate Hydrochloride) | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/24/99ISR Number: 3319281-0Report Type:Periodic Company Report #WAES 98101346
 Age:11 YR Gender:Female I/FU:F

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|--------------------|------|--------------|-------|
| | | Attention | Health | Tab Singulair 5 Mg | PS | | ORAL |
| PO | | Deficit/Hyperactivity Disorder Drug Interaction | Professional | Ritalin Unk | SS | | |

Date:03/30/99ISR Number: 3418515-1Report Type:Periodic Company Report #AR-1199
 Age:8 YR Gender:Male I/FU:F

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|------------------|---------------|---|------|-----------------------|-------|
| | | Drug Ineffective | Other | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | ORAL |
| 10MG/DAY (ORAL) | | | | Methylphenidate Hcl Tablets, 5mg (Danbury/Schein) | SS | Danbury/Schein | ORAL |
| 5 MG/DAY (ORAL) | | | | | | | |

Date:03/30/99ISR Number: 3418521-7Report Type:Periodic Company Report #AR-1235
 Age: Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------|---------------|---------------------|------|-----------------------|-------|
| | | Drug Ineffective | Other | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | ORAL |
| 10 MG AT 8:00A.M. (ORAL) ,10 MG AT NOON (ORAL) , | | | | | | | |

7.5 MG AT

Date:03/30/99ISR Number: 3418528-XReport Type:Periodic Company Report #AR-1236
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-----------------------|-----------------|---------------------|------|-----------------------|-------|
| Dose | | Drug Effect Decreased | Consumer Health | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | ORAL |
| 3 TABS. | 6:00 | | Professional | | | | |
| A.M. (ORAL); | | | | | | | |
| 3 TABS. | 10:30 | | | | | | |
| A.M. (ORAL); | | | | | | | |
| 3 TABS. | 3:00 | | | | | | |
| | | | | Vanceril | C | | |
| | | | | Vancenase | C | | |
| | | | | Claritin | C | | |
| | | | | Albuterol | C | | |

Date:03/30/99ISR Number: 3418535-7Report Type:Periodic Company Report #AR-1237
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|---------------------|------|-----------------------|-------|
| Dose | | Drug Ineffective | Other | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | ORAL |
| 10 MG IN A.M. | | | | | | | |
| (ORAL) | | | | | | | |
| | | | | Methylphenidate Hcl | | | |
| | | | | Tablets, 5 Mg | | | |
| | | | | (Danbury/Schein) | SS | | ORAL |
| 5 MG AT LUNCH | | | | | | | |
| (ORAL) | | | | | | | |

18-Aug-2005 11:49 AM

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/30/99ISR Number: 3418546-1Report Type:Periodic Company Report #AR -1239
 Age:48 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-----------------------|------------------------|---------------------|------|-----------------------|-------|
| | | Drug Effect Decreased | Company Representative | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | ORAL |
| 25 MG PO OD | 5 YR | | | Anaprox | C | | |

Date:03/30/99ISR Number: 3418550-3Report Type:Periodic Company Report #AR - 1240
 Age:11 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|-----------------------|------------------------------|----------------------------|------|-----------------------|-------|
| | | Drug Effect Decreased | Consumer Health Professional | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | |
| 15 MG AM, 10 MG NOON, 10MG 4PM | | | | Methylphenidate Tabs 10 Mg | SS | | |

Date:03/30/99ISR Number: 3418552-7Report Type:Periodic Company Report #AR - 1241
 Age: Gender:Unknown I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------------|---------------------|------|-----------------------|-------|
| | | Drug Ineffective | Health Professional | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | |

Date:04/05/99ISR Number: 3232860-4Report Type:Expedited (15-DaCompany Report #99D--10259
 Age:6 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----------------------|----------------|---------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Anaemia Leukocytosis | Foreign Health | Ritalin Tablet (Methylphenidate | | | |

| | | | | | |
|-------------|-------------------------|--------------|----------------|----|------|
| 1.5 DF, | Pyrexia | Professional | Hydrochloride) | PS | ORAL |
| DAILY, ORAL | Thrombocythaemia | Other | | | |
| | Urinary Tract Infection | | | | |

Date:04/07/99ISR Number: 3234266-0Report Type:Direct Company Report #
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Ritalin (Methylphenidate Hydrochloride) | PS | Danbury Pharmacol, Inc. | |
| | | | | Ritalin (Methylphenidate Hydrochloride) | SS | Medeva Pharmaceuticals | |

Date:04/15/99ISR Number: 3240721-XReport Type:Expedited (15-DaCompany Report #98HQ-10217
 Age:10 YR Gender:Male I/FU:F

| | |
|---------|----------------------|
| Outcome | PT |
| Death | Arrhythmia |
| | Condition Aggravated |
| | Dizziness |
| | Grand Mal Convulsion |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Psychomotor Hyperactivity Syncope Tic | Report Source | Product | Role | Manufacturer | Route |
|-------|----------|---|--------------------------------------|---|------|--------------|-------|
| DAILY | | Transient Ischaemic Attack | Literature Health Professional | Ritalin Unknown (Methylphenidate Hydrochloride) | PS | | |
| | | | | Clonidine Unknown (Clonidine) | SS | | |

Date:04/15/99ISR Number: 3240724-5Report Type:Expedited (15-DaCompany Report #96USA13072
Age:10 YR Gender:Male I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------|----------|---|--------------------------------------|--|------|--------------|-------|
| Death | 20 MG, DAILY | , ORAL | Arrhythmia Grand Mal Convulsion Psychomotor Hyperactivity | Literature Health Professional | Methylphenidate Tablet (Methylphenidate) | PS | | ORAL |
| | | | Syncope | | | | | |
| | | | Tic Transient Ischaemic Attack | | Clonidine Trans-Therapeutic System | SS | | ORAL |

Date:04/19/99ISR Number: 3242995-8Report Type:Expedited (15-DaCompany Report #96J-10255
Age:18 MON Gender:Female I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------------|----------|--|---------------------------------|--|------|--------------|-------|
| Life-Threatening Hospitalization - Initial or Prolonged | 3 MG DAILY | | Blood Creatine Phosphokinase Increased Cellulitis | Foreign Literature Health | Methylphenidate Tablet (Methylphenidate) | PS | | ORAL |
| | | | Face Oedema Hyperhidrosis Hypertension Hypertonia Leukocytosis Muscle Rigidity Neuroleptic Malignant | Professional Other | Amoxicillin | C | | |

Syndrome
Opisthotonus
Otitis Media
Pseudobulbar Palsy
Pyrexia
Quadriplegia
Tachycardia
Tachypnoea

Date:04/22/99ISR Number: 3244544-7Report Type:Direct
Age:10 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Decreased Appetite | | Ritalin | PS | | |
| 2TABS 8AM 1 | | Dermatitis | | | | | |
| 1/2 TABS 12 | | Headache | | | | | |
| NOON & 1 TAB | | Nausea | | | | | |
| 3PM | | Nervousness | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/99ISR Number: 3245749-1Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Methylphenidate | | | |
| | PS | ORAL | 10MG ORAL | | | | |
| -TWICE DAY | | | | | | | |

Date:04/27/99ISR Number: 3247542-2Report Type:Expedited (15-DaCompany Report #99USA10443
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------------|--|---------------------|---|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Monocyte Count Increased Platelet Count Decreased White Blood Cell Count | Health Professional | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| | 20 MG, QD, ORAL | Decreased | | Albuterol Aerosol Multivitamin With M Tablet | C C | | |

Date:04/28/99ISR Number: 3248421-7Report Type:Direct
 Age: Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Mental Disorder | | Ritalin | PS | | |
| | 3 DAY | Paraesthesia | | | | | |

Date:04/30/99ISR Number: 3250846-0Report Type:Expedited (15-DaCompany Report #99NL-10016
 Age:26 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|----------------|-------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abortion | Foreign Health | Ritalin Unknown (Methylphenidate | | | |

30 MG, Professional Hydrochloride) PS ORAL
 DAILY, ORAL Other

Date:05/17/99ISR Number: 3263693-0Report Type:Expedited (15-DaCompany Report #99USA10510
 Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Aggression Pyromania | Health Professional | Ritalin Tablet (Methlphenidate Hydrochloride) | PS | | |
| 25 MG, QD, | | | | Depakote Tablet | C | | |

Date:05/24/99ISR Number: 3269217-6Report Type:Expedited (15-DaCompany Report #99D--10259
 Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Anaemia Blood Iron Decreased Haemoglobin Decreased | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, DAILY, ORAL | | Iron Deficiency Leukocytosis Pyrexia Thrombocythaemia Urinary Tract Infection | Other | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/28/99ISR Number: 3272815-7Report Type:Direct
 Age:38 YR Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|---------------|----------------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Feeling Jittery | | Methylphenidate 5 Mg | | | |
| | | Gastrointestinal Disorder | | Tablets | PS | Danbury / Schein | |
| 3 TABS | 3X/DAY | | | Thyroid Tablets | C | | |

Date:05/28/99ISR Number: 3274100-6Report Type:Periodic
 Age: Gender:Female I/FU:F

Company Report #98USA10571

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Insomnia | Health | Ritalin-Sr Slow | | | |
| Initial or Prolonged | | Overdose | Professional | Release Tablet 20mg | | | |
| | | Psychotic Disorder | | (Methylphenidate | PS | | ORAL |
| | | | | Hydrochloride) | | | |
| 20 MG, | QD, | | | | | | |
| ORAL | | | | | | | |
| | | | | Ritalin Tablet 5.0 | | | |
| | | | | Mg (Methylphenidate | SS | | ORAL |
| | | | | Hydrochloride) | | | |
| 5 MG, | DAILY, | | | | | | |
| ORAL | | | | | | | |
| | | | | Tavist-D Tablets | C | | |
| | | | | Armour Thyroid | | | |
| | | | | Tablet 60mg | C | | |
| | | | | Insomnia | C | | |

Date:06/03/99ISR Number: 3275255-XReport Type:Direct
 Age:8 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| | | Feeling Abnormal | | Ritalin 5mg (Generic | | | |
| | | Sedation | | Brand) | PS | | |
| 1 MONTH | 1 | MON | | | | | |

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|-------------|---|---------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Cough Drug Dependence Dyspnoea | Foreign Literature Health | Ritalin Unknown (Methylphenidate Hydrochloride) | PS | | |
| INTRAVENOUS | UNK, DAILY, | Emphysema | Professional | | | | |
| INTRAVENOUS | | Lung Disorder Lung Transplant Respiratory Failure Rhinorrhoea Septic Embolus Silicon Granuloma | Other | | | | |

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose 25 MG TID | | Drug Ineffective | | Methylphenidate | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/07/99ISR Number: 3277798-1Report Type:Expedited (15-DaCompany Report #99USA10649
Age:21 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Bilirubin Increased Blood Lactate Dehydrogenase Increased | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, QD, ORAL | | Haemolytic Anaemia Jaundice Splenomegaly | | | | | |

Date:06/10/99ISR Number: 3280427-4Report Type:Expedited (15-DaCompany Report #99USA10656
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Bipolar Disorder Depressed Level Of Consciousness | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY ORAL | | Drug Withdrawal Syndrome Dysphonia Hearing Impaired Libido Increased Muscle Disorder Myalgia Pain Suicide Attempt Ulcer Haemorrhage | | | | | |

Date:06/10/99ISR Number: 3281899-1Report Type:Periodic Company Report #1998-07-0504
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------------------|------------------------|----------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Drug Interaction | Health Professional | Claritin (Loratadine) Tablets | PS | | ORAL |
| 10 MG QD ORAL | | | Company | Ritalin Tablets | SS | | ORAL |
| UNKNOWN ORAL | | | | | | | |

Representative

Allergy
Desensitization
Medication

C

Date:06/11/99ISR Number: 3281234-9Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Ritalin 20 Mg Sr Each Am | PS | | ORAL |
| 20 MG PO EACH | | | | | | | |
| AM | | | | | | | |
| | | | | Ritalin 5 Mg Am, Noon, Pm | SS | | ORAL |
| 5 MG PO AM, | | | | | | | |
| NOON, PM | | | | | | | |

Date:06/16/99ISR Number: 3284273-7Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| 25 MG TID | | Drug Ineffective | | Methylphenidate | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/16/99ISR Number: 3285829-8Report Type:Direct
 Age: Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-----------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | Health | Ritalin | PS | | ORAL |
| 10MG 3AM, 2Q | | | Professional | | | | |
| NOON | | | | | | | |

Date:06/16/99ISR Number: 3285845-6Report Type:Direct
 Age:7 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Ritalin (Generic) | PS | | ORAL |
| PO TID | | | | | | | |

Date:06/16/99ISR Number: 3285846-8Report Type:Direct
 Age:10 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin | PS | | ORAL |
| 10MG PO QAM; | | | | | | | |
| 5MG PO TID | | | | | | | |

Date:06/17/99ISR Number: 3286223-6Report Type:Expedited (15-DaCompany Report #99GB-10262
 Age:10 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Arrhythmia | Foreign | Ritalin Tablet | | | |
| | | Cardiac Murmur | Health | (Methylphenidate | | | |
| | | Heart Rate Irregular | Professional | Hydrochloride) | PS | | ORAL |
| 10 MG, BID, | | Palpitations | Other | | | | |
| ORAL | 20 MON | | | | | | |

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-------------------------|---------------|--------------------|------|--------------|-------|
| Dose | Duration | | | | | |
| Life-Threatening | Aggression | Health | Lamictal Tablet | PS | | ORAL |
| SINGLE DOSE | | | | | | |
| Hospitalization - | Aspiration | Professional | Cabapentin Capsule | SS | | ORAL |
| SINGLE DOSE | | | | | | |
| Initial or Prolonged | Electrocardiogram Qrs | | Fluoxetine | | | |
| Other | Complex Prolonged | | Hydrochloride | SS | | ORAL |
| | Intentional Misuse | | Risperidone | SS | | ORAL |
| | Lung Infiltration | | Methylphenidate | SS | | ORAL |
| | Suicide Attempt | | Thioridazine | SS | | |
| | Tachypnoea | | Ethanol | SS | | ORAL |
| | Ventricular Tachycardia | | | | | |
| | Vomiting | | | | | |

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------------|---------------|------------------|------|--------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - | Aggression | Health | Ritalin Tablet | | | |
| Initial or Prolonged | Pyromania | Professional | (Methylphenidate | PS | | |
| | | | Hydrochloride) | | | |
| 25 MG, QD | | | Depakote Tablet | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/99ISR Number: 3286460-0Report Type:Direct
 Age:8 YR Gender: I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Decreased Appetite | | Ritalin | PS | | ORAL |
| 5MG TID ORAL | | Erection Increased | | | | | |
| | | Weight Decreased | | | | | |

Date:06/22/99ISR Number: 3288939-4Report Type:Expedited (15-DaCompany Report #1191252A
 Age:39 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|--------------------------------|-------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Analgesic Drug Level Above Therapeutic Completed Suicide | Literature Health Professional | Unknown Acetaminophen Product | PS | | ORAL |
| UNKNOWN DOSE, | | Intentional Misuse | | | | | |
| PO | | | | Salicylate | SS | | ORAL |
| UNKNOWN DOSE, | | | | | | | |
| PO | | | | Methylphenidate | SS | | ORAL |
| UNKNOWN DOSE, | | | | | | | |
| PO | | | | | | | |

Date:06/24/99ISR Number: 3290928-0Report Type:Expedited (15-DaCompany Report #208382
 Age:29 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Agitation Anxiety Ecchymosis | Foreign Other | Laroxyl (Amitriptyline Hydrochloride) 25 Mg | PS | | ORAL |
| 250 MG 1 PER | | | | | | | |
| 1 ONE DOSE | | Fall | | | | | |
| | | Hallucination | | Zoloft (Sertraline | | | |

| | | | | |
|--------------|----------|--|----|------|
| 1.4 GRAM 1 | Overdose | Hydrochloride) | SS | ORAL |
| PER 1 ONE | | | | |
| DOSE | | | | |
| 600 MG 1 PER | | Ritalin (Methylphenidate Hydrochloride | SS | ORAL |
| 1 ONE DOSE | | | | |
| 400 MG 1 PER | | Stilnox (Zolpidem Tartrate) | SS | ORAL |
| 1 ONE DOSE | | | | |
| | | Tranxene (Clorazepate Dipotassium) | C | |
| | | Vivalan (Viloxazine Hydrochloride) | C | |
| | | Athymil (Mianserin Hydrochoride) | C | |

Date:06/28/99ISR Number: 3292921-0Report Type:Expedited (15-DaCompany Report #99D-10497
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|-----------|--|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Attention Deficit/Hyperactivity Disorder | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| UNK, DAILY, ORAL | 56 MON | Condition Aggravated Syncope | Other | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/28/99ISR Number: 3292935-0Report Type:Expedited (15-DaCompany Report #99F--10541
 Age:29 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------------------|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Agitation Anxiety Ecchymosis | Foreign Health Professional | Ritaline Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 600 MG, ONCE, ORAL | 1 | Fall DAY | Other | | | | |
| | | Hallucination Intentional Misuse | | Laroxyl Tablet (Amitriptyline Hydrochloride) | SS | | ORAL |
| 250 MG, ONCE, ORAL | 1 | DAY | | | | | |
| | | | | Tranxene Tablet (Dipotassium Clorazepate) | SS | | ORAL |
| UNK, UNK, ORAL | | | | | | | |
| | | | | Athymil Tablet (Mianserin Hydrochloride) | SS | | ORAL |
| UNK, UNK, ORAL | | | | | | | |
| | | | | Vivalan Tablet (Viloxazine Hydrochloride) | SS | | ORAL |
| UNK, UNK, ORAL | 1 | DAY | | | | | |
| | | | | Stilnox Tablet (Zolpidem) | SS | | ORAL |
| 400 MG, ONCE, ORAL | | | | | | | |
| | | | | Zoloft Tablet (Sertraline Hydrochloride) | SS | | ORAL |
| 1.4 G, ONCE, ORAL | 1 | DAY | | | | | |

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---------------|--|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Lower Conjunctivitis Convulsion | Foreign Health Professional | Ritalin Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| 70 MG, DAILY, ORAL | | Dermatitis | Other | | | | |
| TRANSDERMAL | 10 MG, DAILY, | Dermatitis Bullous Diverticulum Genital Ulceration Stevens-Johnson Syndrome | | Nitriderm Tts Trans-Therapeutic-Sy stem (Glyceryl Trinitrate) | SS | | |
| TRANSDERMAL | 4 DAY | Syncope Urinary Tract Infection Vomiting | | Clamoxyl Solution For Injection (Amoxicillin) | SS | | |
| INTRAVENOUS | 3 G, DAILY, | | | | | | |
| INTRAVENOUS | | | | | | | |
| 3 G, DAILY, ORAL | | | | Clamoxyl Tablet (Amoxicillin) | SS | | ORAL |
| RECTAL | UNK, UNK, | | | Gastrografin Solution (Gastrografin) | SS | | |
| RECTAL | | | | | | | |
| 200 MG, DAILY, ORAL | | | | Triflucan Capsule (Fluconazole) | SS | | ORAL |
| | | | | Amlor Capsule Insulatard | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Suspension For Inj C
 Digoxine Tablet C
 Solupsan Tablet C
 Lasilix Tablet C
 Alpress Tablet C
 Mopral Unknown C

Date:06/30/99ISR Number: 3295090-6Report Type:Expedited (15-DaCompany Report #9926807

Age:29 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------------------|---------------|--|------------------|--------------|-------|
| Dose Duration Hospitalization - 1400.00 MG Initial or Prolonged TOTAL:DAILY:O | Agitation | Foreign | Zoloft Tablets | PS | | ORAL |
| RAL | Ecchymosis | Professional | | | | |
| 400.00 MG TOTAL:DAILY:O | Fall | Other | Zolpidem | SS | | ORAL |
| RAL | Hallucination | | | | | |
| 600.00 MG TOTAL:DAILY:O | Medication Error | | | | | |
| RAL | Overdose | | Methylphenidate | SS | | ORAL |
| 250.00 MG TOTAL:DAILY:O | | | Amitriptyline | SS | | ORAL |
| RAL | | | Potassium Clorazepate Viloxazine Mianserine | C C C C | | |

Date:07/01/99ISR Number: 3294960-2Report Type:Expedited (15-DaCompany Report #AR-1238

Age:8 YR Gender:Male I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|------|----------|------------------|---------------|---|------|------------------|-------|
| | | | Drug Ineffective | Other | Methylphenidate Hcl Tablets, 5mg (Danbury/Schein) | PS | Danbury / Schein | ORAL |
| 4 TABS/DAY | | | | | | | | |
| ORAL | | | | | Risperdal | C | | |

Date:07/06/99ISR Number: 3298013-9Report Type:Expedited (15-DaCompany Report #99D--10497
 Age:15 YR Gender: I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------|----------|--|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | | Attention Deficit/Hyperactivity Disorder | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 50 MG | QD | | Rebound Effect | | | | | |
| ORAL | | 57 MON | Shock Syncope | | | | | |

Date:07/07/99ISR Number: 3297512-3Report Type:Direct Company Report #
 Age: Gender:Female I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------|----------|---|---------------|-----------------|------|--------------|-------|
| Other 5MG 1/2 TAB | | | Abnormal Behaviour | | Methlyphenidate | PS | | |
| TID | | | Aggression | | | | | |
| | | | Condition Aggravated Impulsive Behaviour | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/07/99ISR Number: 3298032-2Report Type:Direct
 Age:5.5 YR Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------------|----------|---|---------------|----------------------------------|------|--------------|-------|
| Dose Other 5MG 1/2 TAB TID | | Abnormal Behaviour Aggression Impulsive Behaviour | | (Ritalin)-Methylin Malincroft | PS | Malinccott | |

Date:07/12/99ISR Number: 3301507-0Report Type:Expedited (15-DaCompany Report #9714665
 Age:57 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------|---|---|--------------|------------------------------|
| Required 5.00 MG Intervention to TOTAL:DAILY:0 Prevent Permanent RAL Impairment/Damage 15.00 MG TOTAL:TID:ORA L 15.00 MG TOTAL:TID:ORA L | | Angioplasty Anxiety Condition Aggravated Drug Ineffective Drug Interaction Gastrointestinal Motility Disorder Myalgia Pain In Extremity Psychomotor Hyperactivity | Consumer | Norvasc Tablets Ritalin Dexedrine Ativan Xanax Ventolin Zocor Fioricet Tylenol #3 Aspirin Bethanechol Benzodiazepine | PS SS SS C C C C C C C C C | | ORAL ORAL ORAL |

Date:07/12/99ISR Number: 3301622-1Report Type:Expedited (15-DaCompany Report #9828259

Age:18 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|-------------------------|---------------|---------------------|------|--------------|-------|
| Required | | Amnesia | Consumer | Zoloft Tablets | PS | | ORAL |
| 50.00 MG | | | | | | | |
| Intervention to | | Confusional State | Health | | | | |
| TOTAL:DAILY:0 | | | | | | | |
| Prevent Permanent | | Drug Interaction | Professional | | | | |
| RAL | | | | | | | |
| Impairment/Damage | | Insomnia | | Ritalin | SS | | ORAL |
| 60.00 MG | | | | | | | |
| TOTAL:DAILY:0 | | Medication Error | | | | | |
| RAL | | Movement Disorder | | | | | |
| ORAL | | Nervous System Disorder | | Birth Control Pills | SS | | ORAL |
| | | | | Synthroid | C | | |

Date:07/13/99ISR Number: 3302540-5Report Type:Expedited (15-DaCompany Report #95USA10000

Age:19 YR Gender:Male I/FU:F

| Outcome | PT |
|---------|---------------------------|
| Death | Alcohol Poisoning |
| | Arrhythmia |
| | Blood Creatine |
| | Phosphokinase Mb |
| | Increased |
| | Brain Hypoxia |
| | Cardiac Arrest |
| | Cardiac Disorder |
| | Cardio-Respiratory Arrest |
| | Cardiomyopathy |
| | Circulatory Collapse |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---|--------------------------------------|--|------|--------------|-------|
| | | Ejection Fraction Abnormal Fall | | | | | |
| | | Head Injury Hypokinesia Hypotension | Literature Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | |
| DAILY, INTRANASAL | | Loss Of Consciousness Myocardial Infarction Myocardial Ischaemia Overdose Pyrexia Tachycardia Toxicologic Test Abnormal | | | | | |

Date:07/13/99ISR Number: 3357958-1Report Type:Periodic Company Report #M0206-99
Age:20 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|------------------|---------------|-------------------------------|--------|--------------|-------|
| Dose | | Drug Interaction | Health | Remeron | PS | | ORAL |
| 14-45 MG/DAY PO | | Dyspnoea | Professional | | | | |
| 2.5-20 MG PO | | Tachycardia | | Ritalin | SS | | ORAL |
| | | | | Depakote Lithium Carbonate | C C | | |

Date:07/14/99ISR Number: 3303992-7Report Type:Expedited (15-DaCompany Report #A0094748
Age:31 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------------|----------|-----------------------|---------------|--------------------|------|--------------|-------|
| Life-Threatening SINGLE DOSE | | Aggression | Health | Lamictal Tablet | PS | | ORAL |
| Hospitalization - ORAL | | Aspiration | Professional | | | | |
| Initial or Prolonged SINGLE DOSE | | Electrocardiogram Qrs | | Gabapentin Capsule | SS | | ORAL |

| | | | | |
|---------------|--|---|----|------|
| Other ORAL | Complex Prolonged | | | |
| ORAL | Intentional Misuse Lung Infiltration Suicide Attempt Tachypnoea | Fluoxetine Hydrochloride (Formulation Unknown) | SS | ORAL |
| ORAL | Ventricular Tachycardia Vomiting | Risperidone (Formulation Unknown) | SS | ORAL |
| ORAL | | Methylphenidate (Formulation Unknown) | SS | ORAL |
| ORAL | | Thioridazine (Formulation Unknown) | SS | ORAL |
| ORAL | | Ethanol (Formulation Unknown) | SS | ORAL |

Date:07/14/99ISR Number: 3304026-0Report Type:Expedited (15-DaCompany Report #A0094619
Age:31 YR Gender:Male I/FU:F

Outcome PT
Hospitalization - Aggression
Initial or Prolonged Aspiration
Other Electrocardiogram Qrs
Complex Prolonged
Intentional Misuse
Lung Infiltration

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--|---------------|-----------------------------|------|--------------|-------|
| ORAL | | Suicide Attempt Ventricular Tachycardia Vomiting | Health | Lamictal Tablet | PS | | ORAL |
| SINGLE DOSE/ ORAL | | | Professional | Gabapentin | SS | | ORAL |
| | | | | Fluoxetine Hydrochloride | SS | | |
| | | | | Risperidone | SS | | |
| | | | | Thioridazine | SS | | |
| | | | | Methylphenidate | SS | | |
| | | | | Ethanol | SS | | |

Date:07/19/99ISR Number: 3306831-3Report Type:Expedited (15-DaCompany Report #1191252A

Age:39 YR Gender:Female I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|----------|--|----------------------|-------------------------------------|------|--------------|-------|
| Death | 10 G, PO | | Completed Suicide Drug Level Above Therapeutic | Literature Health | Regular Strength Tylenol Tablets | PS | | ORAL |
| UNKNOWN DOSE, PO | | | | Professional | Salicylate | SS | | ORAL |
| 1.2 G PO | | | | | Methylphenidate | SS | | ORAL |
| 12 G PO | | | | | Ibuprofen | SS | | ORAL |

Date:07/26/99ISR Number: 3310951-7Report Type:Expedited (15-DaCompany Report #99D--10621

Age:10 YR Gender:Female I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|-------------|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | 15 MG , QD, | | Abdominal Pain Upper Blood Amylase Increased Lipase Increased | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |

ORAL 6 WK Nausea
Pancreatitis
Pyrexia

Other

Date:07/26/99ISR Number: 3311949-5Report Type:Periodic Company Report #CEPH-1538-99-5082
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---------------------------------------|------------------------|---------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged 11,800MG PO | | Bradycardia Diarrhoea | Health Professional | Provigil 200mg Tablets | PS | | ORAL |
| AT ONCE | | Insomnia Nausea Suicide Attempt | | Ritalin Tablet | SS | | |

Date:07/27/99ISR Number: 3313038-2Report Type:Periodic Company Report #9903183
Age:40 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-----------------------------------|---------------|----------------|------|--------------|-------|
| Other 50.00 MG | | Attention | Health | Viagra Tablets | PS | | ORAL |
| TOTAL:PRN:ORA | | Deficit/Hyperactivity Disorder | Professional | | | | |
| L NOT SPECIFIED | | Drug Interaction | | Ritalin | SS | | |
| | | Headache Rhinitis | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/03/99ISR Number: 3317611-7Report Type:Expedited (15-DaCompany Report #MPI-1999-01603 (0)
 Age:15 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Conversion Disorder Crying Depersonalisation Depression | Consumer | Methylphenidate Tablets 5mg (Methylphenidate Hydrochloride 5mg) | PS | | |
| SEE IMAGE | | | | | | | |
| STARTED | | Intentional Self-Injury | | | | | |
| 3-4 WEEKS AGO | | Laceration | | | | | |
| SEE IMAGE | | Paranoia Speech Disorder | | Methylphenidate Tablets 10 Mg (Methylphenidate Hydrochloride 10 Mg) | SS | | |

Date:08/04/99ISR Number: 3319410-9Report Type:Expedited (15-DaCompany Report #8-97345-009L
 Age:38 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------|--|----------------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged 20 MG DAILY Required Intervention to 5 MG TWICE Prevent Permanent DAILY Impairment/Damage | | Arthralgia Atrioventricular Block Complete Cardiac Arrest Cardiac Pacemaker Insertion Chest Pain Dyspnoea Ejaculation Disorder Erectile Dysfunction Fatigue Gastrooesophageal Reflux Disease Hypertension Libido Decreased Mitral Valve Incompetence Prostatitis | Consumer | Redux Prozac (Fluoxetine) Ritalin (Methylphenidate) | PS SS SS | | ORAL |

Pulmonary Valve
Incompetence
Sinus Bradycardia
Sleep Apnoea Syndrome
Sleep Disorder
Tachycardia
Tricuspid Valve
Incompetence

Date:08/05/99ISR Number: 3321958-8Report Type:Direct
Age:7 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | Health | Ritalin | PS | | ORAL |
| ORAL - NO | | Dysphonia | Professional | | | | |
| DOSAGE DATA | | Tic | | Cylert | C | | |
| | | | | Imipramine | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/11/99ISR Number: 3324016-1Report Type:Expedited (15-DaCompany Report #19990800145
 Age:67 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|--------------------|------|--------------|-------|
| Death | | Confusional State | Foreign | Xylocaine Jell | PS | | |
| TOPICAL | TOPICAL | Hallucination | Other | Gastrogel | SS | | |
| | | | | Panadol | SS | | |
| | | | | Ciprofloxacin | SS | | |
| | | | | Coloxyl With Senna | SS | | |
| | | | | Ms Contin Tab | SS | | |
| | | | | Slow-K | SS | | |
| | | | | Dothiepin | SS | | |
| | | | | Ritalin Tab | SS | | |
| | | | | Dexamethasone | C | | |
| | | | | Metoclopramide | C | | |

Date:08/12/99ISR Number: 3324856-9Report Type:Expedited (15-DaCompany Report #99HQ-10325
 Age:22 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------|--------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Mania | Literature Health Professional | Methylphenidate Unknown (Methylphenidate) | PS | | |
| 15 MG, DAILY | | | | Venlafaxine Unknown (Venlafaxine) | SS | | |
| 187.5 MG, | | | | | | | |
| DAILY | | | | | | | |

Date:08/18/99ISR Number: 3328625-5Report Type:Expedited (15-DaCompany Report #J/99/02235/MEL
 Age:23 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent | | Abdominal Pain Blood Amylase Increased Cardiac Arrest Coma Electrocardiogram | Foreign Health Professional | Melleril (Thioridazine Hydrochloride) Anafranil (Clomipramine) | PS | | |

| | | | |
|-------------------|-----------------------|----------------------|----|
| Impairment/Damage | Abnormal | Hydrochloride) | SS |
| | Hypothermia | Lexotan (Bromazepam) | SS |
| | Intentional Misuse | Pyrethia | |
| | Mydriasis | (Promethazine | |
| | Oedema | Hydrochloride) | SS |
| | Pancreatic Pseudocyst | Vegetamin-A | |
| | Pancreatitis Acute | (Vegetamin A) | SS |
| | Suicide Attempt | Hirnamin | |
| | | (Levomepromazine) | SS |
| | | Isomytal | |
| | | (Amobarbital) | SS |
| | | Halcion (Triazolam) | SS |
| | | Ritalin | |
| | | (Methylphenidate | |
| | | Hydrochloride) | SS |

Date:08/20/99ISR Number: 3330904-2Report Type:Expedited (15-DaCompany Report #99NZ-10075

Age: Gender:Female I/FU:F

| | | |
|----------------------|-------------------|---------------|
| Outcome | PT | Report Source |
| Hospitalization - | Convulsion | Foreign |
| Initial or Prolonged | Syncope | Health |
| | Syncope Vasovagal | Professional |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

| Dose | Duration | Product | Role | Manufacturer | Route |
|-----------------------|----------|---|------|--------------|-------|
| 70 MG, DAILY, ORAL | | Ritalin Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:08/24/99ISR Number: 3333417-7Report Type:Expedited (15-DaCompany Report #99D--10724
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose Other DAILY, ORAL | | Convulsion Drug Interaction Drug Level Above | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | Therapeutic Hallucination Sedation | Other | Tofranil Mite Sugar-Coated Table | C | | |

Date:08/30/99ISR Number: 3337715-2Report Type:Expedited (15-DaCompany Report #1999-08-0877
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|---|---|---|----------|--------------|--------------|
| Dose Other ORAL ORAL | | Drug Interaction Electrocardiogram Qt Prolonged | Health Professional Company Representative | Claritin (Loratadine) Ritalin Tablets | PS SS | | ORAL ORAL |

Date:08/30/99ISR Number: 3339376-5Report Type:Expedited (15-DaCompany Report #99USA10970
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|---|---|------------------------|---|----|------|
| Hospitalization - Initial or Prolonged | Fatigue Feeling Abnormal Gait Disturbance Sedation | Health Professional | Ritalin-Sr Slow Release Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | ORAL |
| 20 MG, QD, ORAL | Viral Infection | | | | |
| 5 MG, DAILY, ORAL | | | Ritalin Tablet 5 Mg (Methylphenidate Hydrochloride) | SS | ORAL |

Date:09/01/99ISR Number: 3339334-0Report Type:Expedited (15-DaCompany Report #99F--10782
Age:7 YR Gender:Male I/FU:I

| Outcome Dose Hospitalization - Initial or Prolonged | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|---|------|--------------|-------|
| 10 MG, DAILY, ORAL | | Agitation Clonic Convulsion Electroencephalogram Abnormal Epilepsy | Foreign Health Professional Other | Ritaline Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/03/99ISR Number: 3341479-6Report Type:Expedited (15-DaCompany Report #99HQ-10348
Age:9 YR Gender:Male I/FU:I

| Outcome Dose Hospitalization - Initial or Prolonged Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--|--------------------------------------|---|------|--------------|-------|
| 30 MG, DAILY, ORAL | Blood Pressure Systolic Increased Bradycardia Coma | Literature Health Professional | Methylphenidate Unknown (Methylphenidate) | PS | | ORAL |
| 180 MG, DAILY, ORAL | Confusional State Difficulty In Walking Hypoglycaemia Pupil Fixed | | Propranolol Unknown (Propranolol) | SS | | ORAL |

Date:09/03/99ISR Number: 3341481-4Report Type:Expedited (15-DaCompany Report #99HQ-10349
Age:6 YR Gender:Female I/FU:I

| Outcome Dose Hospitalization - Initial or Prolonged Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|---|--------------------------------------|--|------|--------------|-------|
| 20 MG, DAILY, ORAL | Blood Pressure Increased Coma Depressed Level Of Consciousness | Literature Health Professional | Methylphenidate Unknown (Methylphenidate) | PS | | ORAL |
| 240 MG, DAILY, ORAL | Heart Rate Decreased Hypoglycaemia | | Propranolol Unknown | SS | | ORAL |
| 1 MG DAILY, ORAL | Hypoventilation Respiratory Rate Decreased | | Guanfacine Hydrochloride Unknown (Guanfacine Hydrochloride) | SS | | ORAL |

Date:09/07/99ISR Number: 3341951-9Report Type:Expedited (15-DaCompany Report #99USA11007
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------|---------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Drug Abuser Stupor | Health Professional Other | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | NASAL |
| DAILY, INTRANASAL | | | | Ativan Tablet (Lorazepam) | SS | | NASAL |
| INTRANASAL | | | | | | | |

Date:09/09/99ISR Number: 3343224-7Report Type:Direct Company Report #
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---|------------------------|---------|------|--------------|-------|
| Other 15MG BID PO | 1 YR | Abnormal Behaviour Anger Anorexia Nervosa Obsessive-Compulsive Disorder | Health Professional | Ritalin | PS | | ORAL |

Date:09/14/99ISR Number: 3347407-1Report Type:Expedited (15-DaCompany Report #MPI-1999-01847(0)
Age:1 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------------------|--------------------------------------|---|------|--------------|-------|
| Other | | Neuroleptic Malignant Syndrome | Literature Health Professional | Methylphenidate Tablets (Unspecified) (Methylphenidate | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hydrochloride) PS

Date:09/20/99ISR Number: 3352444-7Report Type:Expedited (15-DaCompany Report #99HQ-10373

Age:36 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|-------------------|------|--------------|-------|
| Death | | Completed Suicide | Literature | Methylphenidate | | | |
| | | Hypothermia | Health | Unknown | | | |
| | | Intentional Misuse | Professional | (Methylphenidate) | PS | | |
| DAILY | | | | Lorazepam | C | | |
| | | | | L-Thyroxine | C | | |
| | | | | Alprazolam | C | | |

Date:09/20/99ISR Number: 3352445-9Report Type:Expedited (15-DaCompany Report #99HQ-10374

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------|---------------|--------------------|------|--------------|-------|
| Death | | Intentional Misuse | Literature | Methylphenidate | | | |
| | | | Health | Tablet | | | |
| | | | Professional | (Methylphenidate) | PS | | ORAL |
| DAILY ORAL | | | | Desipramine Tablet | | | |
| | | | | (Desipramine) | SS | | ORAL |

ORAL

Date:09/21/99ISR Number: 3353239-0Report Type:Expedited (15-DaCompany Report #8-99222-001A

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------|---------------|-----------------------------------|------|--------------|-------|
| Hospitalization - OVERDOSE | | Drug Abuser | | Ativan Tablets | PS | | ORAL |
| Initial or Prolonged AMOUNT ORAL | | Stupor | | | | | |
| Other Required Intervention to OVERDOSE | | | | Ritalin (Methylphenidate) Tablets | SS | | ORAL |

Prevent Permanent
AMOUNT ORAL
Impairment/Damage

Ritalin

C

Date:09/23/99ISR Number: 3355682-2Report Type:Direct
Age:9 YR Gender: I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------|---------------|---------|------|--------------|-------|
| Dose | | Malabsorption | Health | Ritalin | PS | | ORAL |
| 10MG PO TID | | | Professional | | | | |

Date:10/05/99ISR Number: 3363618-3Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|---------|------|--------------|-------|
| Dose | | Drug Effect Decreased | Health | Ritalin | PS | | |
| | | | Professional | | | | |

Date:10/14/99ISR Number: 3372702-XReport Type:Expedited (15-DaCompany Report #99D--10902
Age:35 YR Gender:Female I/FU:I

| Outcome | PT |
|----------------------|---------------------------|
| Life-Threatening | Arrhythmia |
| Hospitalization - | Cardio-Respiratory Arrest |
| Initial or Prolonged | Coma |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Coordination Abnormal Intentional Misuse Mental Disorder Due To A | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|-----------------------------------|--|------|--------------|-------|
| DAILY, ORAL | | General Medical Condition Suicide Attempt | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | Other | Alcohol Unknown (Ethanol) | SS | | ORAL |
| ORAL | | | | Trevilor Unknown (Venlafaxine Hydrochloride) | SS | | ORAL |

Date:10/25/99ISR Number: 3395686-7Report Type:Periodic Company Report #CEPH-1538-99-5141
Age:48 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|--------------------------------|--------------------|---------------------------|------|--------------|-------|
| 100-200MG PO | | Arthralgia Joint Stiffness | Consumer Health | Provigil 200mg Tablets | PS | | ORAL |
| ONCE | | Nasopharyngitis Pharyngitis | Professional | Ritalin 5mg | SS | | |

Date:10/27/99ISR Number: 3383045-2Report Type:Expedited (15-DaCompany Report #9944977
Age:1 DY Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|---|-----------------------|--------------------|------|--------------|-------|
| Congenital Anomaly ORAL | | Complications Of Maternal | Foreign | Zithromax Capsules | PS | | ORAL |
| ORAL | | Exposure To Therapeutic | Health | Methylphenidate | SS | | ORAL |
| | | Drugs Polydactyly Pregnancy Syndactyly | Professional Other | Cannabis | SS | | |

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|---------------|---|-----------------------------|---|------|--------------|-------|
| Congenital Anomaly | | Complications Of Maternal Exposure To Therapeutic Drugs | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | |
| TRANSPLACENTAL | TRANSPLACENTA | Congenital Foot Malformation | Other | | | | |
| L | | Congenital Hand Malformation | | Azithromycin Dihydrate Unknown (Azithromycin Dihydrate) | SS | | |
| TRANSPLACENTAL | TRANSPLACENTA | Polydactyly | | | | | |
| L | | Syndactyly | | | | | |
| | | | | Cannabis | C | | |

Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|----------------------------|------|--------------|-------|
| Other | | Abdominal Pain | | Methylphenidite / Novartis | PS | Novartis | |
| 20MG AM & PM, | | Diarrhoea | | | | | |
| WEEKLY | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/99ISR Number: 3390230-2Report Type:Periodic Company Report #077-99
 Age:32 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|---------------|-----------------|------|--------------|-------|
| Other | | Aortic Valve Incompetence | Other | Phentermine Hcl | PS | | |
| 30 MG | | Chest Pain | | Pondimin | SS | | |
| | | Dizziness | | Redux | SS | | |
| | | Dysphagia | | Ritalin | SS | | |
| | | Headache | | Zoloft | SS | | |
| | | Nausea | | | | | |
| | | Palpitations | | | | | |
| | | Restlessness | | | | | |
| | | Sedation | | | | | |

Date:11/04/99ISR Number: 3389048-6Report Type:Expedited (15-DaCompany Report #99GB-10745
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-----------|---------------|---------------------|------|--------------|-------|
| Hospitalization - | | Coma | Foreign | Ritalin Unknown | | | |
| Initial or Prolonged | | Hypotonia | Health | (Methylprednisolone | | | |
| 20 MG QD PO | | Vomiting | Professional | Hydrochloride) | PS | | ORAL |
| | | | Other | | | | |

Date:11/08/99ISR Number: 3391522-3Report Type:Expedited (15-DaCompany Report #J/99/02235/MEL
 Age:23 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------|---------------|----------------------|------|--------------|-------|
| Hospitalization - | | Abdominal Pain | Foreign | Melleril | | | |
| Initial or Prolonged | | Cardiac Arrest | Health | (Thioridazine | | | |
| Required | | Depressed Level Of | Professional | Hydrochloride) | PS | | |
| UNSPECIFIED | | | | | | | |
| Intervention to | | Consciousness | | Anafranil | | | |
| Prevent Permanent | | Hypothermia | | (Clomipramine | | | |
| Impairment/Damage | | Mydriasis | | Hydrochloride) | SS | | |
| UNSPECIFIED | | | | | | | |
| | | Oedema | | Lexotan (Bromazepam) | SS | | |
| UNSPECIFIED | | | | | | | |
| | | Overdose | | Pyrethia | | | |

| | | | |
|-------------|---|---|----|
| UNSPECIFIED | Pancreatic Pseudocyst Pancreatitis | (Promethazine Hydrochloride) | SS |
| UNSPECIFIED | Pancreatitis Acute Pupillary Reflex Impaired | Vegetamin-A (Vegetamin A) | SS |
| UNSPECIFIED | Respiratory Disorder Stupor | Hirnamin (Levomepromazine) | SS |
| UNSPECIFIED | Suicide Attempt | Isomytal (Amobarbital) | SS |
| UNSPECIFIED | | Halcion (Triazolam) | SS |
| UNSPECIFIED | | Ritalin (Methylphenidate Hydrochloride) | SS |

Date:11/10/99ISR Number: 3394020-6Report Type:Expedited (15-DaCompany Report #99CH-10068
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Priapism | Foreign Health Professional | Ritalin Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG DAILY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/12/99ISR Number: 3394739-7Report Type:Direct
Age: Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|------------------------------------|------|--------------|-------|
| Dose | | Drug Ineffective | | Metnylphenidate 5mg Twice A Day | PS | | |

Date:11/15/99ISR Number: 3397378-7Report Type:Expedited (15-DaCompany Report #99D--11002
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | Glomerulonephritis Haematuria Proteinuria | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| Other | 20 MG, DAILY | | Other | | | | |

Date:11/15/99ISR Number: 3397778-5Report Type:Expedited (15-DaCompany Report #99USA11278
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------------------|---------------------------------------|------------------------|---|------|--------------|-------|
| Dose | | Henoch-Schonlein Purpura Petechiae | Health Professional | Ritalin Tablet 200 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| Other | 200 MG, BID, ORAL | | | | | | |

Date:11/22/99ISR Number: 3405379-5Report Type:Expedited (15-DaCompany Report #99USA11295
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------------|------------------------|--|------|--------------|-------|
| Dose | | B-Cell Type Acute Leukaemia | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | |
| Other | DAILY | | | Risperdal Tablet | C | | |

Date:11/24/99ISR Number: 3406913-1Report Type:Direct
 Age: Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|----------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Therapeutic Response | Health | Generic Ritalin | PS | | |
| 10MG TID | | Unexpected | Professional | | | | |

Date:11/29/99ISR Number: 3410334-5Report Type:Expedited (15-DaCompany Report #MPI-1999-02971(0)
 Age:36 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--------------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Delusional Disorder, Persecutory Type Medication Error | Literature Health Professional | Methylphenidate Tablets 10 Mg (Methylphenidate Hydrochloride) | PS | | |

INTRAVENOUS SEE IMAGE FOR

DOSAGE/AND

THERAPY DATES

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/29/99ISR Number: 3410337-0Report Type:Expedited (15-DaCompany Report #MPI-1999-02973(0)
 Age:28 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---------------|---|--------------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Delusion Depression Hallucination Medication Error | Literature Health Professional | Methylphenidate Tablets 10 Mg (Methylphenidate Hydrochloride) | | | |
| INTRAVENOUS | SEE IMAGE FOR | | | | PS | | |
| DOSAGE /AND | | | | | | | |
| THERAPY DATES | | | | | | | |

Date:12/02/99ISR Number: 3411898-8Report Type:Direct Company Report #
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|---------|------|--------------|-------|
| 10MG 1T TAB Q | | Drug Effect Decreased | | Ritalin | PS | | |
| AM; 20MG SR | | | | | | | |
| 1T TAB Q | | | | | | | |
| 1015A | | | | | | | |

Date:12/02/99ISR Number: 3412577-3Report Type:Direct Company Report #
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|------------------------|---------------------------------|------|--------------|-------|
| 20MG SR | | Drug Effect Decreased | Health Professional | Methyphenidate 20 Mg Sr 0730 | PS | | |
| 5 MG | | | | | | | |
| | | | | Methylphenidate 5mg | C | | |

Date:12/03/99ISR Number: 3413475-1Report Type:Expedited (15-DaCompany Report #99A--10016

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Choreoathetosis | Foreign Other | Ritalin Unknown (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:12/08/99ISR Number: 3416579-2Report Type:Expedited (15-DaCompany Report #9949846

Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Blood Pressure Increased | Literature | Zoloft Tablets | PS | | ORAL |
| 50.00 MG | | | | | | | |
| Initial or Prolonged | | Chest Pain | Health | | | | |
| TOTAL:DAILY:O | | | | | | | |
| RAL | | Dyspnoea | Professional | | | | |
| | | Dyspnoea Exertional | | Methylphenidate | SS | | ORAL |
| 30.00 MG | | | | | | | |
| TOTAL:BID:ORA | | Hyperhidrosis | | | | | |
| L | | Nodal Arrhythmia | | | | | |
| | | Palpitations | | Adderall | SS | | ORAL |
| 10.00 MG | | | | | | | |
| TOTAL:DAILY:O | | Paraesthesia | | | | | |
| RAL | | Tachycardia | | | | | |

Date:12/09/99ISR Number: 3417864-0Report Type:Expedited (15-DaCompany Report #99CDN10751

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------|---------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Compartment Syndrome | Foreign | Ritalin Tablet | | | |
| Initial or Prolonged | | Muscle Atrophy | Consumer | (Methylphenidate Hydrochloride) | PS | | ORAL |
| Disability | | Wheelchair User | | | | | |
| 15 MG BID | 1 YR | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

20 MG, DAILY 1 YR
 Ritalin-Sr Slow Release Tablet 20 Mg (Methylphenidate Hydrochloride) SS ORAL

Date:12/13/99ISR Number: 3420463-8Report Type:Expedited (15-DaCompany Report #99USA11392
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-----------------------------------|---------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Constipation Urinary Retention | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:12/17/99ISR Number: 3425635-4Report Type:Periodic Company Report #9912251
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-----------------------------|---------------------|-------------------------------------|------|--------------|-------|
| Other | | Abdominal Pain Dysgeusia | Health Professional | Zithromax Pediatric Oral Suspension | PS | | ORAL |
| ORAL | | | | | | | |
| Muscle Twitching | | | | Ritalin | SS | | ORAL |
| TID: ORAL | | | | | | | |
| | | | | Flovent | C | | |
| | | | | Ativan | C | | |

Date:12/20/99ISR Number: 3425966-8Report Type:Expedited (15-DaCompany Report #99D--11076
 Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|-----------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Arthralgia Henoch-Schonlein Purpura Otitis Media | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, DAILY, | | | | | | | |
| ORAL | | | | | | | |
| Other | | | | | | | |

Date:12/21/99ISR Number: 3426768-9Report Type:Expedited (15-DaCompany Report #MPI-1999-03009 (0)
Age:41 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|------------------------|---|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Halo Vision Headache Retinal Artery Thrombosis Visual Acuity Reduced | Health Professional | Methylphenidate Tablets 10mg (Methylphenidate Hydrochloride 10 Mg) | PS | | |
| 10 MG | | | | Ibuprofen Asa | C C | | |

Date:12/22/99ISR Number: 3428384-1Report Type:Expedited (15-DaCompany Report #99USA11278
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Henoch-Schonlein Purpura Petechiae Rash Generalised | Health Professional | Ritalin-Sr Slow Release Tablet 20 Mg (Methyphenidate Hydrochloride) | PS | | ORAL |
| 20 MG BID | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/22/99ISR Number: 3428577-3Report Type:Expedited (15-DaCompany Report #99USA11442
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Discomfort Cough Depression | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 7.5 MG BID | | | | | | | |
| ORAL | | Headache | | | | | |
| | | Suicidal Ideation | | Paxil Tablet | C | | |

Date:12/22/99ISR Number: 3428581-5Report Type:Expedited (15-DaCompany Report #99HQ-10540
Age:84 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------------------------------|--------------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Eye Disorder Fibrosis Retinal | Literature Health Professional | Methylphenidate Unknown (Methylphenidate) | PS | | ORAL |
| UNK, DAILY, | | | | | | | |
| ORAL | | Neovascularisation | | | | | |

Date:12/22/99ISR Number: 3428591-8Report Type:Expedited (15-DaCompany Report #99AUS10330
Age:37 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Amylase Increased Pancreatitis Relapsing | Foreign Health Professional | Ritalin Tablet (Methyphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, BID, | | | | | | | |
| ORAL | | | Other | | | | |
| | | | | Lithicare | C | | |
| | | | | Aropax | C | | |
| | | | | Kapanol | C | | |
| | | | | Entocort | C | | |

Date:12/23/99ISR Number: 3432580-7Report Type:Expedited (15-DaCompany Report #99HQ-10540
Age:64 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|----------------------|--------------------------------------|------|--------------|-------|
| Disability | | Drug Abuser Fibrosis | Literature Health | Methylphenidate (Methylphenidate) | PS | | ORAL |
| DAILY, ORAL | | Fundoscopy Abnormal Retinal Ischaemia Retinal Neovascularisation Visual Acuity Reduced | Professional | | | | |

Date:01/20/00ISR Number: 3446728-1Report Type:Expedited (15-DaCompany Report #00USA10062
Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------|---------------|--|------|--------------|-------|
| Death | | Tachycardia | Other | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/27/00ISR Number: 3447327-8Report Type:Expedited (15-DaCompany Report #00GB-10053

Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Retinopathy | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |
| Other | | | | | | | |

Date:01/27/00ISR Number: 3447328-XReport Type:Expedited (15-DaCompany Report #00GB-10044

Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pulmonary Hypertension | Foreign Health Professional | Ritalin Unknown (Methylphenidate Hydrochloride) | PS | | |
| DAILY | | | | | | | |
| Other | | | | | | | |

Date:02/02/00ISR Number: 3455582-3Report Type:Periodic Company Report #99USA10011

Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------|---------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Leukopenia | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydorchloride) | PS | | ORAL |
| 10 MG, TID | | | | | | | |
| ORAL | | | | | | | |

Date:02/02/00ISR Number: 3455583-5Report Type:Periodic Company Report #99USA10182

Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Arrhythmia Ecchymosis | Consumer | Ritalin Tablet 5 Mg (Methylphenidate | | | |

| | | | | | | |
|---|------------------|---------------|----------------------|------|--------------|-------|
| 5 MG TID, | Headache | | Hydrochloride) | PS | ORAL | |
| | Weight Decreased | | | | | |
| ORAL | | | | | | |
| Date:02/02/00ISR Number: 3455584-7Report Type:Periodic Company Report #99USA10673 | | | | | | |
| Age: | Gender:Male | I/FU:I | | | | |
| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | |
| Hospitalization - | Bradycardia | Health | Ritalin Tablet | | | |
| Initial or Prolonged | Diarrhoea | Professional | (Methylphenidate | | | |
| | Insomnia | Other | Hydrochloride) | PS | | ORAL |
| ORAL | | | | | | |
| | Nausea | | Modafinil Tablet 200 | | | |
| | | | Mg (Modafinil) | SS | | ORAL |
| ORAL | | | | | | |

| | | | | | | |
|---|---------------------|---------------|----------------------|------|--------------|-------|
| Date:02/02/00ISR Number: 3455585-9Report Type:Periodic Company Report #99USA10710 | | | | | | |
| Age: | Gender:Female | I/FU:I | | | | |
| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | |
| Hospitalization - | Erythema Multiforme | Consumer | Ritalin Tablet 20 Mg | | | |
| Initial or Prolonged | | | (Methylphenidate | | | |
| | | | Hydrochloride) | PS | | ORAL |
| 20 MG, TID, | | | | | | |
| ORAL | | | | | | |
| | | | Cynocobalamin | | | |
| | | | Ampoule | C | | |
| | | | Prilosec | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Celebrex C
 Prozac C
 Propulsid C
 Librax C
 Effexor C
 Xanax C
 Phenergan C

Date:02/02/00ISR Number: 3455586-0Report Type:Periodic Company Report #99USA11070
 Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|------------------------|--|------|--------------|-------|
| Dose Other | | Sinus Arrhythmia Ventricular Extrasystoles | Health Professional | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, QD, ORAL | | | | Hydroxyzine | C | | |

Date:02/02/00ISR Number: 3455587-2Report Type:Periodic Company Report #99USA11131
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|------------------------|--|------|--------------|-------|
| Dose Other | | Hallucination, Visual Psychotic Disorder | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 50 MG, QD, ORAL | | | | Prozac | C | | |
| | | | | Depakote | C | | |
| | | | | Tofranil | C | | |

Date:02/02/00ISR Number: 3455588-4Report Type:Periodic Company Report #99USA11147
 Age:54 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|---|----------------------|----------|--|----|------|
| Hospitalization - Initial or Prolonged | Grand Mal Convulsion | Consumer | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | ORAL |
| 17.5 MG, QD, | | | | | |
| ORAL | 9 YR | | Claritin | C | |

Date:02/07/00ISR Number: 3453563-7Report Type:Expedited (15-DaCompany Report #99GB-10716
Age:14 YR Gender:Male I/FU:I

| Outcome Dose Duration Hospitalization - Initial or Prolonged Other | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|-----------------------------------|--|------|--------------|-------|
| 40 MG, FAILY, ORAL | Blood Alkaline Phosphatase Increased Blood Bilirubin Increased Jaundice | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/10/00ISR Number: 3456366-2Report Type:Expedited (15-DaCompany Report #00USA10140
Age:55 YR Gender:Female I/FU:I

| Outcome Dose Duration Other | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|--------------|------------------------|--|------|--------------|-------|
| 60 MG, QD, PO | Pericarditis | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Ambien C
Prinivil C

Date:02/10/00ISR Number: 3456407-2Report Type:Expedited (15-DaCompany Report #00GB-10044
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|-----------------------------|--|------|--------------|-------|
| Other | | Pulmonary Hypertension | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 40 MG, DAILY, | | | Other | | | | |
| ORAL | | | | | | | |

Date:02/11/00ISR Number: 3456996-8Report Type:Expedited (15-DaCompany Report #99D--11024
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---------------|-----------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hypoglycaemia | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, BID, | | | Other | | | | |
| ORAL | | | | | | | |

Date:02/22/00ISR Number: 3460653-1Report Type:Expedited (15-DaCompany Report #99CDN10751
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|-----------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Compartment Syndrome Muscle Atrophy Post Procedural | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 15 MG, BID | | Complication | Other | | | | |
| ORAL | 1 YR | Wheelchair User | | Ritalin-Sr Slow Release Tablet 20 Mg (Methylphenidate | | | |

20 MG, DAILY, Hydrochloride) SS ORAL

ORAL 1 YR

Date:02/22/00ISR Number: 3460768-8Report Type:Expedited (15-DaCompany Report #99D--11024
 Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Blood Glucose Decreased | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, BID, | | | Other | | | | |
| ORAL | | | | | | | |

Date:02/23/00ISR Number: 3461462-XReport Type:Direct Company Report #
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Other | | Drug Ineffective | | Ritalin Generic | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/23/00ISR Number: 3461727-1Report Type:Expedited (15-DaCompany Report #MPI-1999-03009 (1)
 Age:41 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|---|------------------------|--|--------|--------------|-------|
| Dose Other | | Halo Vision Headache Retinal Artery Thrombosis Visual Acuity Reduced | Health Professional | Methyphenidate Tablets 10mg (Methylphenidate Hydrochloride) | | | |
| 10 MG, UNKNOWN, UNK | | | | | PS | | |
| | | | | Ibuprofen (Ibuprofen) Asa (Acetylsalicylic Acid) | C C | | |

Date:02/23/00ISR Number: 3461824-0Report Type:Expedited (15-DaCompany Report #MPI-2000-00696 (0)
 Age:64 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|--------------------------------------|--|--------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Alcoholic Anxiety Delusional Disorder, Persecutory Type | Literature Health Professional | Methlphenidate Tablets (Unspecified)(Methyl phenidate Hydrochloride) | | | PS |
| UP TO 200 MG PER DAY/ FIVE YRS PRIOR TO ADMISSION | | Depression Disturbance In Attention Drug Abuser Feelings Of Worthlessness Hallucination, Auditory Insomnia Loose Associations Medication Error Persecutory Delusion Suicidal Ideation Tangentiality | | Protriptyline(Protri ptyline) Alcohol (Ethanol) | C C | | |

Date:02/23/00ISR Number: 3462399-2Report Type:Periodic Company Report #9905148
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Laboratory Test Abnormal | Health | Zoloft Tablets | PS | | ORAL |
| 50.00 MG | | Personality Disorder | Professional | | | | |
| TOTAL: DAILY: | | | | | | | |
| ORAL | | | | | | | |
| | | | | Ritalin | SS | | |

Date:02/23/00ISR Number: 3467364-7Report Type:Periodic Company Report #9911172
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alopecia | Health | Zoloft Tablets | PS | | ORAL |
| 100.00 MG | | | Professional | | | | |
| TOTAL:DAILY:0 | | | | | | | |
| RAL | | | | | | | |
| ORAL | | | | | | | |
| | | | | Ritalin | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/00ISR Number: 3463980-7Report Type:Expedited (15-DaCompany Report #00CDN10125
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | Foreign | Ritalin | PS | | ORAL |
| DAILY, ORAL | | Aggression | Consumer | Ritalin-Sr | SS | | ORAL |
| ORAL | | Amnesia | Other | Luvox | C | | |
| | | Bipolar I Disorder | | Risperdal | C | | |
| | | Psychotic Disorder | | | | | |
| | | Suicidal Ideation | | | | | |

Date:02/25/00ISR Number: 3464240-0Report Type:Expedited (15-DaCompany Report #99GB-10262
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Arrhythmia | Foreign | Ritalin Tablet | | | |
| | | Cardiac Murmur | Health | (Methylphenidate | | | |
| 10 MG, BID, | | Heart Rate Increased | Professional | Hydrochloride) | PS | | ORAL |
| ORAL | 20 MON | Palpitations | Other | | | | |

Date:02/28/00ISR Number: 3464430-7Report Type:Expedited (15-DaCompany Report #00HQ-10097
Age:37 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Lung Transplant | Foreign | Ritalin Unknown | | | |
| Initial or Prolonged | | Pneumoconiosis | Literature | (Methylphenidate | | | |
| Disability | | Progressive Massive | Health | Hydrochloride) | PS | | |
| INTRAVENOUS | DAILY, | Fibrosis | Professional | | | | |
| INTRAVENOUS | | Respiratory Depression | Other | | | | |

Date:03/01/00ISR Number: 3466997-1Report Type:Expedited (15-DaCompany Report #00USA10248
Age:35 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|---------------|---|------|--------------|-------|
| Dose Other | | Catatonia Confusional State Insomnia | Consumer | Ritalin (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, QD, ORAL | | Logorrhoea | | | | | |
| ORAL | 5 YR | Neurosis Oral Intake Reduced Psychotic Disorder | | Valium | SS | | ORAL |

Date:03/08/00ISR Number: 3472172-7Report Type:Expedited (15-DaCompany Report #00CDN10161
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------------|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Drug Abuser Loss Of Consciousness | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | |
| DAILY | | | | | | | |
| INTRANASAL | | | | Methadon Tablet | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/08/00ISR Number: 3472177-6Report Type:Expedited (15-DaCompany Report #00USA10278
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--------------------------|---------------|--|------|--------------|-------|
| Dose Other | | Hypoaesthesia Syncope | Consumer | Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, TID, ORAL | 2 YR | | | | | | |

Date:03/10/00ISR Number: 3474517-0Report Type:Expedited (15-DaCompany Report #A007267
 Age:18 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---|---|----------------|--------------|-------|
| Hospitalization - Initial or Prolonged Required 5.00 MG Intervention to TOTAL; DAILY; Prevent Permanent ORAL Impairment/Damage | | Bone Marrow Depression Drug Interaction Infection In An Immunocompromised Host Leukopenia Varicella Vomiting | Health Professional Company Representative | Glucotrol Xl Extended Release Tablets Wellbutin Ritalin | PS SS SS | | ORAL |

Date:03/13/00ISR Number: 3473931-7Report Type:Expedited (15-DaCompany Report #99USA11278
 Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---------------------------------------|------------------------|---|------|--------------|-------|
| Dose Other | | Henoch-Schonlein Purpura Petechiae | Health Professional | Ritalin-Sr Slow Release Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, BID, ORAL | | | | | | | |

Date:03/14/00ISR Number: 3544072-5Report Type:Periodic Company Report #14375-00M/1272
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|---------------|---------------------|------|------------------|-------|
| Dose | | | | | | | |
| ORAL | | Hair Disorder | Consumer | Methylphenidate Hcl | PS | Mallinckrodt Inc | ORAL |

Date:03/16/00ISR Number: 3476257-0Report Type:Direct Company Report #
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------------------|---------------------|--------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression | Health Professional | Ritalin Sr 20 Mg Generic | PS | | ORAL |
| 1 PO QD PO | | | | | | | |

Date:03/17/00ISR Number: 3476455-6Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------------------------|---------------|-------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression | | Methylphenidate 10mg Morning & Noon | PS | | |
| 10MG MORNING | | | | | | | |
| & NOON | | | | | | | |
| 4MG 4PM | | | | Methylphenidate 5mg 4pm | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/20/00ISR Number: 3477601-0Report Type:Expedited (15-DaCompany Report #00D--10326
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------------|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Headache Speech Disorder | Foreign Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 1 DF, TID, ORAL | | | Other | | | | |

Date:03/21/00ISR Number: 3477728-3Report Type:Direct Company Report #
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|--|------------------------------------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Upper Blood Creatine Phosphokinase Increased Confusional State Dyskinesia Loss Of Consciousness Neuroleptic Malignant Syndrome Pallor Refusal Of Treatment By Patient Respiratory Rate Increased Speech Disorder Urinary Incontinence Weight Gain Poor | | Clozapine Trifluoperazine Ritalin Lopid (Gemfibrozol) Docusate Sodium Metamucil Multivitamin | PS SS SS C C C C | | |

Date:03/23/00ISR Number: 3479000-4Report Type:Direct Company Report #
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|------------------|---------------|----------------------|------|--------------|-------|
| Other 10 MG 2X DAY ORAL | | Drug Ineffective | | Ritalin 10 Mg Schein | PS | Schein | ORAL |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------------------------------|---|---|------|--------------|-------|
| Dose Required Intervention to Prevent Permanent Impairment/Damage | | Chest Pain Drug Interaction | Health Professional Company Representative | Bupropion Hydrochloride Tablet-Controlled Release (Bupropion Hydrochloride) | PS | | ORAL |
| 100 | | | | | | | |
| MG/VARIABLE | | | | | | | |
| DOSE/ORAL | | | | | | | |
| ORAL | | | | Pemoline Unspecified Tablet (Pemoline) | SS | | ORAL |
| 5 MG TWICE | | | | Methylphenidate Hcl Tablet | SS | | ORAL |
| PER DAY ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/27/00ISR Number: 3480286-0Report Type:Direct
 Age:8 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Methylphenidate | PS | | |
| 10 MG DAILY | | Dermatitis Exfoliative Eye Movement Disorder Hallucination Hallucination, Auditory Nightmare Paraesthesia Paranoia Phobia Pruritus Rash Erythematous Strabismus Tic | | | | | |

Date:03/28/00ISR Number: 3480945-XReport Type:Expedited (15-DaCompany Report #00GB-10156
 Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abortion Spontaneous | Foreign | Ritalin Unknown | | | |
| | | Haemorrhage | Health | (Methylphenidate | | | |
| | | Pain | Professional | Hydrochloride) | PS | | |
| 90 MG, DAILY | | | Other | | | | |

Date:03/30/00ISR Number: 3482408-4Report Type:Expedited (15-DaCompany Report #00USA10364
 Age:47 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hepatic Neoplasm | Health | Ritalin Tablet | | | |
| | | | Professional | (Methylphenidate | | | |
| | | | | Hydrochloride) | PS | | ORAL |
| 60 MG, DAILY, | | | | | | | |
| ORAL | | | | Climara | | | |

Date:04/04/00ISR Number: 3483595-4Report Type:Direct
 Age:8 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------|---------------|---------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged HALF TAB TID | | Crying Neurological Symptom | | Methylphenidate 10 Mg Schein | PS | Schein | ORAL |
| Other ORAL | | Torticollis | | | | | |
| | | Trismus Vision Blurred | | Methylphenidate 5 Mg Schein | SS | Schein | ORAL |
| HALF TAB TID | | | | | | | |
| ORAL | | | | | | | |

Date:04/17/00ISR Number: 3488913-9Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|-------------------|------|--------------|-------|
| Dose | | Drug Effect Decreased | | Ritalin (Generic) | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/18/00ISR Number: 3489120-6Report Type:Direct
 Age:14 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------------------|---------------|------------------------------|------|--------------|-------|
| Death | | Coronary Artery Disease | | Ritalin (Methylphenidate) | PS | | |
| 20 MG TID; | | | | | | | |
| CONTINUOUSLY | | | | | | | |
| SINCE AGE OF | | | | | | | |
| FOUR | | | | | | | |

Date:04/18/00ISR Number: 3558459-8Report Type:Periodic
 Age:30 YR Gender:Male I/FU:I

Company Report #US002553

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------|---------------|---------------|------|--------------|-------|
| | | Dizziness | Health | Provigil | PS | Cephalon Inc | ORAL |
| 200 MG QAM | | | | | | | |
| ORAL | | | | | | | |
| 10 MG BID | | | | | | | |
| | | | Professional | Ritalin | SS | | |
| | | | | Ephedrine | SS | | |
| | | | | Caffeine | SS | | |
| | | | | Wellbutrin Sr | C | | |

Date:04/20/00ISR Number: 3490634-3Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------------|------|--------------|-------|
| | | Drug Ineffective | | Ritalin Generic | PS | | |

Date:04/24/00ISR Number: 3491839-8Report Type:Expedited (15-DaCompany Report #00CDN10247
 Age:16 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------|----------|----------------------|-----------------------------------|--|------|--------------|-------|
| Death | | | Cold Exposure Injury | Foreign Health Professional Other | Ritalin-Sr Slow Release Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | | | | | |

Date:04/24/00ISR Number: 3491848-9Report Type:Expedited (15-DaCompany Report #00GB-10044
 Age:14 YR Gender:Male I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|------|----------|--------------------------------|-----------------------------------|--|------|--------------|-------|
| Other | | | Malaise Pulmonary Hypertension | Foreign Health Professional Other | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 40 MGF, | | | | | | | | |
| DAILY, ORAL | | | | | | | | |

Date:04/24/00ISR Number: 3491856-8Report Type:Expedited (15-DaCompany Report #00HQ-10193
 Age:14 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------|----------|---|------------------|---|------|--------------|-------|
| Death | | | Coronary Artery Disease Myocardial Infarction | Literature Other | Ritalin (Methylphenidate Hydrochloride) | PS | | |
| DAILY | | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/28/00ISR Number: 3494278-9Report Type:Expedited (15-DaCompany Report #00HQ-10193
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------------|---|------|--------------|-------|
| Death | | Coronary Artery Disease Myocardial Infarction | Literature Other | Ritalin Unknown (Methylphenidate Hydrochloride) | PS | | |
| DAILY | | | | | | | |

Date:05/01/00ISR Number: 3495529-7Report Type:Expedited (15-DaCompany Report #00USA10444
Age:76 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------------------|------------------------|--|------|---------------------|-------|
| Hospitalization - Initial or Prolonged | | Blister Dermatitis Pemphigoid | Health Professional | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | | ORAL |
| 40 MG, DAILY, ORAL | | | | | | | |
| | | | | | | Steroids Nos Tablet | C |

Date:05/01/00ISR Number: 3495530-3Report Type:Expedited (15-DaCompany Report #00USA10248
Age:35 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------------------------------|--|------|--------------|-------|
| Other | | Catatonia Confusional State Eating Disorder | Consumer | Ritalin Tablet 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG, QD, PO | | | | | | | |
| | | Insomnia Neurosis | | Valium Tablet 40 Mg (Diazepam) | SS | | ORAL |
| ORAL | | 5 YR | Psychotic Disorder Speech Disorder | | | | |

Date:05/12/00ISR Number: 3499710-2Report Type:Expedited (15-DaCompany Report #00D--10581
Age:3 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|------------------------------|--|------|----------------------------------|-------|
| Dose Other | | Visual Acuity Reduced | Foreign Consumer Other | Ritalin Tablet (Methylphenidate Hydrochloride) | PS | Novartis Pharmaceuticals Corp | ORAL |

DAILY , ORAL

Date:05/15/00ISR Number: 3500493-8Report Type:Expedited (15-DaCompany Report #00GB-10290
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--|-------------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged 5 MG, BID, ORAL | | Abdominal Pain Anorexia Circulatory Collapse Nausea Pallor | Foreign Health Professional Other | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:05/15/00ISR Number: 3501204-2Report Type:Expedited (15-DaCompany Report #00P-163-0089665-00(0)
Age:42 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------|------------------------|----------------------------|------|---|-------|
| Required Intervention to Prevent Permanent PER ORAL Impairment/Damage | | Chest Pain Drug Interaction | Health Professional | Cylert Amfebutamone | PS | Abbott Laboratories Pharmaceutical Products Div | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | |
|---------------------------------------|--|-----------|-------------|
| <p>400 MG, 1 IN 1 D, PER ORAL</p> | <p>Hydrochloride (Amfebutamone Hydrochloride)</p> | <p>SS</p> | <p>ORAL</p> |
| <p>5 MG, 2 IN 1 D, PER ORAL</p> | <p>Methylphenidate Hydrochloride (Methylphenidate Hydrochloride)</p> | <p>SS</p> | <p>ORAL</p> |

Date:05/18/00ISR Number: 3501382-5Report Type:Direct Company Report #USP 081278
Age: Gender: I/FU:I

| | | | | | | | |
|---------|----------|------------------|---------------|---|----------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Medication Error | | Ritalin (Methlylphenidate) Methlylphenidate | PS SS | Novartis | |

Date:05/18/00ISR Number: 3501383-7Report Type:Direct Company Report #USP 081277
Age: Gender: I/FU:I

| | | | | | | | |
|---------|----------|------------------|---------------|---|----------|-------------------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Medication Error | | Ritalin (Methlylphenidate) Methlylphenidate | PS SS | Novartis Mallunkrodt | |

Date:05/18/00ISR Number: 3501826-9Report Type:Expedited (15-DaCompany Report #00D--10618
Age: Gender:Unknown I/FU:I

| | | | | | | | |
|-------------|----------|------------------|-------------------|---------|------|----------------------------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Disability | | Hearing Impaired | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | |
| INTRAVENOUS | DAILY, | | Professional | | | | |
| INTRAVENOUS | | | | | | | |

Other

Date:05/19/00ISR Number: 3503435-4Report Type:Expedited (15-DaCompany Report #20000500303
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|-----------------------------|-----------|------|----------------|-------|
| Dose | | | | Toprol-Xl | PS | Astrazeneca Lp | |
| Other | | Retinal Artery Thrombosis | Foreign Health Professional | Ritalin | SS | | |

Date:05/22/00ISR Number: 3502832-0Report Type:Expedited (15-DaCompany Report #00USA10364
Age:47 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------------|---------|------|-------------------------------|-------|
| Dose | | | | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| Other | | Benign Hepatic Neoplasm | Health Professional | | | | |

60 MG, DAILY,

ORAL

Climara
Trans-Therapeutic C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/22/00ISR Number: 3503423-8Report Type:Expedited (15-DaCompany Report #00D--10627
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------------------------|-----------------------|-------------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | | Aphasia Cerebral Infarction | Foreign Health | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| DAILY, ORAL | | Hemiplegia | Professional Other | | | | |

Date:05/30/00ISR Number: 3505737-4Report Type:Expedited (15-DaCompany Report #00N--10021
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------|---------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Cholesterol Increased | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | |
| DAILY | | Hypoproteinaemia Nephrotic Syndrome | Professional Other | | | | |

Date:06/02/00ISR Number: 3507662-1Report Type:Expedited (15-DaCompany Report #00D--10627
Age:12 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----------------------------------|-----------------------|-------------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged 1 DF. QD. | | Aphasia Cerebral Infarction | Foreign Health | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| Other ORAL | 4 MON | Cerebral Ischaemia Hemiplegia | Professional Other | | | | |

Date:06/05/00ISR Number: 3508414-9Report Type:Expedited (15-DaCompany Report #00GB-10290
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|----------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Abdominal Pain | Foreign | Ritalin | PS | Novartis | |

| | | | | |
|----------------------|----------------------|--------------|----------------------|------|
| Initial or Prolonged | Anorexia | Health | Pharmaceuticals Corp | ORAL |
| 5 MG, BID, | | | | |
| Other | Circulatory Collapse | Professional | | |
| ORAL | 25 DAY | | | |
| | Gait Disturbance | Other | | |
| | Nausea | | | |
| | Pallor | | | |
| | Parkinson'S Disease | | | |
| | Weight Decreased | | | |

Date:06/05/00ISR Number: 3509918-5Report Type:Expedited (15-DaCompany Report #00CDN10247
Age:17 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------|----------------|------------------|------|-------------------------------|-------|
| Death | | Death | Foreign Health | Ritalin-Sr | PS | Novartis Pharmaceuticals Corp | ORAL |
| 40 MG, DAILY, | | | Professional | | | | |
| ORAL | 2 YR | | Other | Risperdal Tablet | C | | |

Date:06/06/00ISR Number: 3508822-6Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|-------------------|------|--------------|-------|
| Required | | Blood Creatine | Health | Ritalin 20 Mg Tid | PS | | ORAL |
| 20MG TID PO | 5 YR | | | | | | |
| Intervention to Prevent Permanent Impairment/Damage | | Phosphokinase Increased Liver Function Test Abnormal | Professional | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/07/00ISR Number: 3509562-XReport Type:Direct
 Age:10 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----|---------------|---------|------|--------------|-------|
| Dose Other 5MG 3X DAY (2X DAY) | 3 YR | Tic | | Ritalin | PS | | |

Date:06/08/00ISR Number: 3510563-6Report Type:Expedited (15-DaCompany Report #A007267
 Age:18 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|---|------------------------|--------------|-------|
| Hospitalization - 10.00 MG Initial or Prolonged TOTAL; DAILY; Required ORAL Intervention to 200.00 MG Prevent Permanent TOTAL; BID Impairment/Damage 100.00 MG TOTAL; QID | | Bone Marrow Depression Diabetes Mellitus Inadequate Control Drug Interaction Fatigue Herpes Zoster Leukopenia Urine Glucose False Positive Vomiting | Health Professional | Glucotrol Xl Wellbutrin Ritalin | PS SS SS | Pfizer Inc | ORAL |

Date:06/08/00ISR Number: 3510757-XReport Type:Expedited (15-DaCompany Report #97GB-10373
 Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|--------------------------------|--|---------|------|----------------------------------|-------|
| Dose Other DAILY, ORAL | | Haemorrhage Spinal Disorder | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:06/09/00ISR Number: 3511614-5Report Type:Expedited (15-DaCompany Report #00ZA-10015
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-----------------|--|---------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged 10 MG DAILY | | Coma Fatigue | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | |

Date:06/12/00ISR Number: 3512311-2Report Type:Expedited (15-DaCompany Report #MPI-2000-04548(0)
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------|----------|--|----------------------|----------------------------|------|--------------------------|-------|
| Other 80 MG, DAY | | Blood Ph Decreased Decreased Appetite | Literature Health | Methylphenidate Hcl | PS | Md Pharmaceutical Inc | |
| 25 MG, | 7 DAY | Grand Mal Convulsion Hyperphagia | Professional | Sertraline (Sertraline) | SS | | |
| 50 MG | 1 WK | | | Sertraline (Sertraline) | SS | | |

Date:06/15/00ISR Number: 3513628-8Report Type:Direct Company Report #USP 53123
Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------------|------|-----------------------------|-------|
| | | Medication Error | | Methylphenidate | PS | Medeva/Danbury Pharmacal | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Chlorpheniramine SS Goldline

Date:06/19/00ISR Number: 3515543-2Report Type:Expedited (15-DaCompany Report #MPI-2000-04567 (0)
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---------------------------|---------------|---------------------|------|-------------------|-------|
| Dose | | | | | | | |
| Other | | | | | | | |
| Required | | | | | | | |
| AGE 5- AGE 8 | | | | | | | |
| Intervention to | | | | | | | |
| Prevent Permanent | | | | | | | |
| Impairment/Damage | | | | | | | |
| | | Abnormal Behaviour | Literature | Methylphenidate Hcl | PS | Md Pharmaceutical | |
| | | Aggression | Health | | | Inc | |
| | | Anxiety | Professional | | | | |
| | | Condition Aggravated | | | | | |
| | | Depression | | | | | |
| | | Disturbance In Attention | | | | | |
| | | Drug Withdrawal Syndrome | | | | | |
| | | Irritability | | | | | |
| | | Paranoia | | | | | |
| | | Psychomotor Hyperactivity | | | | | |
| | | Psychotic Disorder | | | | | |
| | | Relationship Breakdown | | | | | |
| | | Suicidal Ideation | | | | | |

Date:06/21/00ISR Number: 3517289-3Report Type:Expedited (15-DaCompany Report #00ZA-10015
 Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|----------------------|---------------|---------|------|----------------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | | | | | | |
| 10 MG, BID; | | | | | | | |
| ORAL | | | | | | | |
| | | Circulatory Collapse | Foreign | Ritalin | PS | Novartis | |
| | | Coma | Health | | | Pharmaceuticals Corp | ORAL |
| | | Diarrhoea | Professional | | | | |
| | | Fatigue | Other | | | | |
| | | Sedation | | | | | |
| | | Vomiting | | | | | |

Date:06/22/00ISR Number: 3517799-9Report Type:Periodic Company Report #14550-00M/1514
 Age:48 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------|----------|-----------------------|------------------------|---------------------|------|------------------|-------|
| Other 10 MG BID TO | | | Drug Ineffective | Health Professional | Methylphenidate Hcl | PS | Mallinckrodt Inc | ORAL |
| QI ORAL | | | | | Ritalin | C | | |
| Date:06/22/00ISR Number: 3517801-4Report Type:Periodic Company Report #14549-00M/1513 | | | | | | | | |
| Age:20 YR Gender:Male I/FU:I | | | | | | | | |
| Other 10 MG BID | | | Drug Ineffective | Health Professional | Methylphenidate Hcl | PS | Mallinckrodt Inc | ORAL |
| ORAL | | | | | | | | |
| Date:06/22/00ISR Number: 3517802-6Report Type:Periodic Company Report #14562-00M/1529 | | | | | | | | |
| Age:7.5 YR Gender:Male I/FU:I | | | | | | | | |
| Other 10 MG AM & | | | Drug Effect Decreased | Health Professional | Methylphenidate Hcl | PS | Mallinckrodt Inc | ORAL |
| NOON ORAL | | | Medication Error | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/22/00ISR Number: 3517806-3Report Type:Periodic Company Report #14489-00M/1415
 Age:8.5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-----------------------|---------------|---------------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | Health | Methylphenidate Hcl | PS | Mallinckrodt Inc | ORAL |
| 5MG TID ORAL | | Educational Problem | Professional | | | | |

Date:06/26/00ISR Number: 3519104-0Report Type:Direct Company Report #
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Unevaluable Event | | Generic Ritalin | PS | | |
| 10MG TID | | | | | | | |

Date:06/26/00ISR Number: 3519997-7Report Type:Expedited (15-DaCompany Report #00D--10581
 Age:3 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------|--------------------|---------|------|-------------------------------|-------|
| Dose | | | | | | | |
| Other | | Visual Acuity Reduced | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| DAILY, ORAL | | | Professional Other | | | | |

Date:06/27/00ISR Number: 3520172-0Report Type:Direct Company Report #
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Headache | Consumer | Ritalin | PS | | |
| 1 PILL EVERY MORN | | | | Quanfacnie | SS | | |
| 1 PILL EVERY MORNING | | | | | | | |

Date:06/27/00ISR Number: 3520431-1Report Type:Expedited (15-DaCompany Report #MPI-2000-04574(0)
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|---------------------|------|--------------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine Phosphokinase Increased | Literature | Methylphenidate Hcl | PS | Md Pharmaceutical Inc | |
| 100MG/DAY, THREE TIMES A DAY IN THREE DOSES | | Blood Creatine Phosphokinase Mb Increased Chest Pain Emotional Distress Hypertension Intermittent Claudication Myocardial Ischaemia Tachycardia | | | | | |

Date:06/28/00ISR Number: 3521047-3Report Type:Direct Company Report #
Age:19 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|--|---------|--------------|-------|
| Dose | | | | | | | |
| 10MG BID ORAL | | Attention Deficit/Hyperactivity Disorder Condition Aggravated | | (Geneva) Methylphenidate 10 Mg Prozac | PS C | Geneva | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/30/00ISR Number: 3523158-5Report Type:Expedited (15-DaCompany Report #00GB-10368
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|-----------------------|-------------------|------------------------------------|--------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | | Rash Pustular Scab | Foreign Health | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| 20 MG, DAILY, ORAL | | Skin Lesion | Professional | | | | |
| | | | Other | Salbutamol Pulmicort Turbohaler | C C | | |

Date:07/03/00ISR Number: 3525243-0Report Type:Periodic Company Report #212938
Age:62 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|-------------------|---------------|---|--------|--------------------------|-------|
| Dose | | | | | | | |
| Death | | Completed Suicide | Other | Klonopin | PS | Hoffmann La Roche Inc | ORAL |
| 1 MG 1 PER 8 HOUR ORAL | | | | | | | |
| | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |
| 10 MG 2 PER DAY ORAL | | | | | | | |
| | | | | Paxil (Paroxetine) Pavabid (Papaverine Hydrochloride) | C C | | |

Date:07/03/00ISR Number: 3583856-4Report Type:Periodic Company Report #AR-1373
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|------------------------|------------------------|---------------------|------|--------------------------|-------|
| Dose | | | | | | | |
| | | Agitation Dizziness | Health Professional | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | ORAL |
| 10 MG A.M. 5 MG AT NOON | | Nausea | | | | | |

(ORAL) Sedation
Vomiting

Date:07/03/00ISR Number: 3583857-6Report Type:Periodic Company Report #AR-1374
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|------------------------|---------------------|------|--------------------------|-------|
| Dose | | Abnormal Behaviour Condition Aggravated | Health Professional | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | ORAL |
| 10 MG | 6:30 | | | | | | |
| | A.M., | | | | | | |
| | 9:30 | | | | | | |
| | A.M., | | | | | | |
| | 1 TAB. | | | | | | |
| | AT NOON | | | | | | |

(ORAL)

Date:07/03/00ISR Number: 3583859-XReport Type:Periodic Company Report #AR-1375
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|--|------------------------|---------------------|------|--------------------------|-------|
| Dose | | Abnormal Behaviour Condition Aggravated | Health Professional | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | ORAL |
| 10 MG | | Disturbance In Attention | | | | | |
| | BREAKFAST AND | Headache | | | | | |
| | LUNCH (ORAL) | | | Guanfacine (Sic) | C | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/03/00ISR Number: 3583861-8Report Type:Periodic Company Report #AR-1376
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------|---------------------|---------------------|------|-----------------------|-------|
| Dose | | Abnormal Behaviour | Health Professional | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | ORAL |
| 20 MG AM, 15 MG 10:30 AM AND 15 MG 1:30 PM (ORAL) | | | | | | | |
| | | | | Guafacine (Sic) | C | | |

Date:07/03/00ISR Number: 3583864-3Report Type:Periodic Company Report #AR-1377
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|---------------|---------------------|------|-----------------------|-------|
| Dose | | Abnormal Behaviour Condition Aggravated | Other | Methylphenidate Hcl | PS | Danbury Pharmacal Inc | |
| 15 MG DOSE | | | | | | | |
| | | | | Celexa | C | | |

Date:07/10/00ISR Number: 3527266-4Report Type:Expedited (15-DaCompany Report #00GB-10507
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---------------------------|-----------------------------------|---------------------------|------|-------------------------------|-------|
| Hospitalization - Initial or Prolonged | | Drug Interaction Priapism | Foreign Health Professional Other | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| DAILY , ORAL | | | | | | | |
| | | | | Risperidone (Risperidone) | SS | | |

Date:07/10/00ISR Number: 3527271-8Report Type:Expedited (15-DaCompany Report #99NZ-10075
 Age:23 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|-------------|-----------------------|-------------------|---------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged | 70 MG DAILY | Convulsion Syncope | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| ORAL | | Syncope Vasovagal | Professional | | | | |
| | | | Other | | | | |

Date:07/18/00ISR Number: 3531187-0Report Type:Expedited (15-DaCompany Report #MPI-2000-04610 (0)
Age:55 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|---|----------------------|--|---------------------|--------------------------|-------|
| Other | 30-100MG, DAY | Choreoathetosis Drug Abuser | Literature Health | Methylphenidate Hcl | PS | Md Pharmaceutical Inc | |
| | | Dry Mouth Dyskinesia Hypomania Movement Disorder Pupillary Reflex Impaired Tachycardia | Professional | Lithium (Lithium) Methapyrilene (Methapyrilene) Antipsychotic Medication (Antipsychotics) | C C C | | |

Date:07/21/00ISR Number: 3533745-6Report Type:Expedited (15-DaCompany Report #A024623
Age: Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Required Intervention to Prevent Permanent Dose Impairment/Damage | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------|---------------|-----------------|------|----------------------------|-------|
| 50.00 MG | | Asthma | Consumer | Zoloft | PS | Pfizer Pharmaceuticals Inc | ORAL |
| TOTAL:DAILY:0 | | Fatigue | | | | | |
| RAL | | Road Traffic Accident | | Methylphenidate | SS | | ORAL |
| ORAL | | | | Ventolin | C | | |

Date:07/24/00ISR Number: 3534488-5Report Type:Expedited (15-DaCompany Report #00GB-10507
 Age:13 YR Gender:Male I/FU:F

| Outcome Dose Hospitalization - Initial or Prolonged | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------|----------------|--|------|-------------------------------|-------|
| 30 MG, DAILY, | | Drug Interaction | Foreign Health | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| ORAL | 1 MON | Priapism | Professional | | | | |
| 20 MG, DAILY, | | | Other | Ritalin-Sr Slow Release Tablet (Methylphenidate Hydrochloride) | SS | | ORAL |
| ORAL | 1 MON | | | Clonidine | C | | |
| | | | | Risperdal | C | | |

Date:07/25/00ISR Number: 3534561-1Report Type:Direct Company Report #
 Age: Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------|---------------|---------|------|--------------|-------|
| | | Antisocial Behaviour | | Ritalin | PS | | |
| | | Personality Change | | | | | |

Date:07/25/00ISR Number: 3534580-5Report Type:Direct
Age: Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|--|---------------|--|------|--------------|-------|
| Life-Threatening | | Bundle Branch Block Cardiac Disorder Cardiac Failure | | Ritalin (Beginning Dosage 5 Mg - Increased To 60 Mg) | PS | | |
| ONCE A DAY | | Hypertension Myocardial Infarction | | | | | |

Date:07/31/00ISR Number: 3537461-6Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|-----------------|------|--------------|-------|
| P.O | | Reaction To Medical Agent Preservatives | | Ritalin-Generic | PS | | ORAL |

Date:07/31/00ISR Number: 3538816-6Report Type:Expedited (15-DaCompany Report #JACGBR2000000458
Age:13 YR Gender:Male I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
Disability

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Required Intervention to Prevent Permanent Dose Impairment/Damage | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--------------|--|-----------------------------|--|------|--|-------|
| 1 MG, 1 IN 1 | DAY(S), ORAL | Drug Interaction Priapism Sedation | Foreign Health Professional | Risperdal | PS | Janssen Research Fdn Div Johnson And Johnson | ORAL |
| 20 MG , 1 IN | 1 DAY(S), 10 | | | Ritalin Sr (Methylphenidate Hydrochloride) | SS | | |
| MG , 3 IN 1 | DAY(S) | | | Clonidine | C | | |

Date:08/04/00ISR Number: 3541248-8Report Type:Direct
Age:8 YR Gender:Male I/FU:I

Company Report #

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--|---------------|------------------|------|--------------|-------|
| 10 MG TID | | Aggression | Consumer | Ritalin (5-10mg) | PS | | ORAL |
| ORAL | | Growth Retardation | | | | | |
| 0.2 MG BID | | Insomnia | | Clonidine | SS | | ORAL |
| ORAL | | Obsessive-Compulsive Disorder Weight Decreased | | | | | |

Date:08/07/00ISR Number: 3543520-4Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----|---------------|---------|------|--------------|-------|
|--------------|----------|----|---------------|---------|------|--------------|-------|

| | | | | | |
|---------------|------------------------|-------------------------------------|--------|-----|------|
| Other | No Adverse Drug Effect | Ritalin 20mg Tablets (Bno) | PS | Bno | ORAL |
| 1T BID ORALLY | | | | | |
| SINCE 4/99 | | Generic Ritalin Generic Adderall | C C | | |

| | | | | | |
|---------------|-----------------------|--------------------|------------------|------|--------------|
| Date:08/08/00 | ISR Number: 3544624-2 | Report Type:Direct | Company Report # | | |
| Age: | Gender:Male | I/FU:I | | | |
| Outcome | PT | Report Source | Product | Role | Manufacturer |
| Dose | Duration | | | | Route |
| | Drug Ineffective | | Methylphenidate | PS | |

| | | | | | |
|-------------------|-------------------------|--------------------|------------------|------|--------------|
| Date:08/10/00 | ISR Number: 3546986-9 | Report Type:Direct | Company Report # | | |
| Age: | Gender:Male | I/FU:I | | | |
| Outcome | PT | Report Source | Product | Role | Manufacturer |
| Dose | Duration | | | | Route |
| Required | Blood Creatine | Health | Ritalin 20mg Tid | PS | ORAL |
| 20MG TID PO 5 YR | | | | | |
| Intervention to | Phosphokinase Increased | Professional | | | |
| Prevent Permanent | Liver Function Test | | | | |
| Impairment/Damage | Abnormal | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/14/00ISR Number: 3550521-9Report Type:Expedited (15-DaCompany Report #MPI-2000-04658 (0)
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|----------------------|---------------------|------|--------------------------|-------|
| Dose Other | | Angiogram Cerebral Abnormal | Literature Health | Methylphenidate Hcl | PS | Md Pharmaceutical Inc | |
| 20 MG PER DAY | | Cerebellar Syndrome Cerebral Arteritis Computerised Tomogram Abnormal Coordination Abnormal Difficulty In Walking Dystonia Erectile Dysfunction Hemiparesis Hyperreflexia Nuclear Magnetic Resonance Imaging Abnormal Paraesthesia Precerebral Artery Occlusion Vasculitis | Professional | | | | |

Date:08/15/00ISR Number: 3551923-7Report Type:Direct Company Report #
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------|-------------------|------|--------------|-------|
| Dose Required | | Blood Creatine | Health | Ritalin 20 Mg Tid | PS | | ORAL |
| 20 MG TID PO 5 YR Intervention to Prevent Permanent Impairment/Damage | | Phosphokinase Increased Liver Function Test Abnormal | Professional | | | | |

Date:08/16/00ISR Number: 3551473-8Report Type:Expedited (15-DaCompany Report #MPI-2000-04567 (1)
 Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|---------|------|--------------|-------|
| Dose Other | | Abnormal Behaviour | Literature | Ritalin | | | |

| | | | | |
|--|--|---------------------|---------------------------------|----|
| Required Intervention to AGE 5 - AGE 8 Prevent Permanent Impairment/Damage | Aggression Anxiety Condition Aggravated Depression Disturbance In Attention Drug Withdrawal Syndrome Feeling Abnormal Irritability Medication Error Paranoia Psychomotor Hyperactivity Speech Disorder Suicidal Ideation | Health Professional | (Methylphenidate Hydrochloride) | PS |
|--|--|---------------------|---------------------------------|----|

Date:08/22/00ISR Number: 3555733-6Report Type:Expedited (15-DaCompany Report #MPI-2000-04709(0)
 Age: Gender:Unknown I/FU:I

| | | | | | | | |
|---------|----------|--------------------|------------------------|-------------|------|----------------------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Psychotic Disorder | Company Representative | Metadate Er | PS | Medeva Pharmaceuticals Inc | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/24/00ISR Number: 3566371-3Report Type:Direct
Age:14 YR Gender:Male I/FU:I

Company Report #

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|--|---------------|-----------|------|--------------|-------|
| 600 MG PO BID | | Blood Thyroid Stimulating Hormone Increased | Health | Lithium | PS | | ORAL |
| 200 MG PO QID | | Condition Aggravated | Professional | Thorazine | SS | | ORAL |
| 500 MG PO BID | | Hypercholesterolaemia | | Depakote | SS | | ORAL |
| 200 MG PO BID | | Hypertriglyceridaemia | | Seroquel | SS | | ORAL |
| 250-750 MG PO | | | | Depakote | SS | | ORAL |
| 5MG PO HS | | | | Zyprexa | SS | | ORAL |
| 20 MG PO TID | | | | Ritalin | SS | | |
| | | | | Tenex | C | | |

Date:08/28/00ISR Number: 3560361-2Report Type:Expedited (15-DaCompany Report #PHFR2000GB00618
Age:15 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---------------------|-------------------|-------------------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged 10 MG/DAY | | Amnesia Overdose | Foreign Health | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| ORAL | | Photopsia | Professional | | | | |
| | | Respiratory Arrest | Other | Alcohol (Ethanol) | C | | |

Date:08/31/00ISR Number: 3565752-1Report Type:Expedited (15-DaCompany Report #PHFR1999GB00655
Age:14 YR Gender:Male I/FU:F

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|---|-------------------|---------|------|----------------------------------|-------|
| Other DIVIDED | | Blood Alkaline Phosphatase Increased | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| DOSES: | | Blood Bilirubin Increased | Professional | | | | |

15,15,10MG ,
ORAL
Cholestasis
Decreased Appetite
Jaundice
Weight Decreased
Other

Date:09/05/00ISR Number: 3565478-4Report Type:Direct Company Report #
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Health Professional | Methylphenidate | PS | | |

Date:09/07/00ISR Number: 3567587-2Report Type:Expedited (15-DaCompany Report #MPI-2000-04731(0)
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------------|------------------------|-------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Supraventricular Tachycardia | Company Representative | Metadate Er | PS | Medeva Pharmaceuticals Inc | |

10 MG

Date:09/12/00ISR Number: 3570553-4Report Type:Expedited (15-DaCompany Report #PHEH2000US08076
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT |
|---------|----------|---|
| Other | | Aggression Anger Drug Abuser Murder Mydriasis |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|---------------------|----------|--|---------------|---|------------------|--------------|-------|
| Dose | Duration | Overdose Panic Attack Psychomotor Hyperactivity | Report Source | Product | Role | Manufacturer | Route |
| 10 MG, TID, ORAL | | Psychotic Disorder Suicidal Ideation Toxicologic Test Abnormal | Consumer | Ritalin Tab Prozac (Fluoxetine Hydrochloride) Klonopin | PS C C | | ORAL |

Date:09/12/00ISR Number: 3570772-7Report Type:Expedited (15-DaCompany Report #MPI-2000-04709(1)
Age:9 YR Gender:Male I/FU:F

| | | | | | | | |
|--|----------|-------------------------------------|---|--|--------------|-------------------------------|------------------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged 30 MG TWICE A DAY PO | | Hallucination Psychotic Disorder | Health Professional Company Representative | Metadate Er Efexor Xr (Venlafaxine Hydrochloride) | PS SS | Medeva Pharmaceuticals Inc | ORAL ORAL |
| 75 MG EVERY DAY PO | | | | | | | |

Date:09/18/00ISR Number: 3574574-7Report Type:Expedited (15-DaCompany Report #PHNU2000DE01585
Age:16 YR Gender:Male I/FU:I

| | | | | | | | |
|---|----------|---|--|-------------|------|----------------------------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged 20 MG, QD, ORAL | | Condition Aggravated Epistaxis Von Willebrand'S Disease | Foreign Health Professional Other | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:09/18/00ISR Number: 3575224-6Report Type:Expedited (15-DaCompany Report #MPI-2000-04756 (0)
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------------------|---------------|--------------------------------------|------|--------------------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Drug Abuser | Other | Methylphenidate Hcl | PS | Md Pharmaceutical Inc | |
| SEE IMAGE | | | | | | | |
| | | Murder Psychotic Disorder | | Prozac (Fluoxetine Hydrochloride) | SS | | ORAL |
| SEE IMAGE | | | | | | | |
| | | Suicidal Ideation | | Klonopin (Clonazepam) | SS | | ORAL |
| SEE IMAGE | | | | | | | |

Date:09/25/00ISR Number: 3579682-2Report Type:Expedited (15-DaCompany Report #PHEH2000US08181
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|------------------------------------|------------------------|-----------------------------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | | Coombs Direct Test Positive | Health Professional | Ritalin-Sr | PS | Novartis Pharmaceuticals Corp | ORAL |
| 30 MG, QD, ORAL | | Haemolytic Anaemia Macrocytosis | | Nutropin Aq (Somatropin) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/27/00ISR Number: 3581989-XReport Type:Periodic Company Report #AR - 1398
 Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|--------------------|--|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Decreased Appetite Weight Decreased | Consumer Health | Methylphenidate 5mg Schein | PS | Schein | |
| 1/2 TABLET | | | Professional | | | | |
| BID | | | | Albutenol Nebulizer Motrin Ped. Susp. | C C | | |

Date:09/27/00ISR Number: 3581991-8Report Type:Periodic Company Report #AR - 1396
 Age:5.6 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | Consumer | Methylphenidate Hcl | PS | Schein | ORAL |
| 5 MG PO AM, 2.5 PM; 7 1/2 MG PO AM, 5 PM | | Aggression Condition Aggravated Drug Effect Decreased | Health Professional | | | | |

Date:10/02/00ISR Number: 3585710-0Report Type:Expedited (15-DaCompany Report #PHFR2000GB01403
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|--|--|---------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Blood Pressure Increased Cyanosis Drug Abuser Hyperhidrosis Respiratory Arrest | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | |

Date:10/04/00ISR Number: 3586658-8Report Type:Direct Company Report #
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|--------------------------|---------------|-----------------|------|--------------|-------|
| Other | 10MG 2 BID, 1 | Anxiety | | Generic Ritalin | PS | | |
| HS | | Disturbance In Attention | | | | | |
| | | Drug Ineffective | | | | | |
| | | Sleep Disorder | | | | | |

Date:10/13/00ISR Number: 3594981-6Report Type:Expedited (15-DaCompany Report #PHBS2000JP09715
 Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|------------|--------------------------------|-----------------------|-------------|------|----------------------------------|-------|
| Other | 10 MG/DAY, | Abnormal Behaviour Delusion | Foreign Literature | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| ORAL | | Depression | Health | | | | |
| 5 MG/DAY, | | Excitability | Professional | Ritaline | SS | | ORAL |
| ORAL | | Psychotic Disorder | Other | | | | |
| | | Schizophrenia | | | | | |
| | | Thought Blocking | | | | | |

Date:10/13/00ISR Number: 3595481-XReport Type:Expedited (15-DaCompany Report #PHFR2000GB01403
 Age:15 YR Gender:Female I/FU:F

| Outcome | PT |
|---|--|
| Life-Threatening Hospitalization - Initial or Prolonged | Asthenia Blood Pressure Increased Circulatory Collapse |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|--------------------------------|----------|--|--|---------|------|----------------------------------|-------|
| Dose | Duration | Cyanosis Drug Abuser Feeling Hot | Report Source | Product | Role | Manufacturer | Route |
| 10 MG, ONCE/SINGLE, ORAL | | Hyperhidrosis Respiratory Arrest Skin Discolouration Visual Disturbance | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:10/23/00ISR Number: 3599865-5Report Type:Direct Company Report #

Age: Gender:Female I/FU:I

| | | | | | | | |
|-----------------------------|----------|------------------|---------------|---------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Medication Error | | Ritalin Sr 20 | PS | | ORAL |
| 20 MG EVERY MORNING ORAL | | | | | | | |

Date:10/24/00ISR Number: 3601316-9Report Type:Expedited (15-DaCompany Report #MPI-2000-04731 (1)

Age:14 YR Gender:Male I/FU:F

| | | | | | | | |
|---------|----------|--|---------------------------|-------------|------|-------------------------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Chest Pain Dizziness | Health Professional | Metadate Er | PS | Medeva Pharmaceuticals Inc | |
| 10 MG | | Supraventricular Tachycardia Tachycardia | Company Representative | Prozac | C | | |

Date:10/26/00ISR Number: 3602257-3Report Type:Expedited (15-DaCompany Report #PHNU2000DE01916

Age:7 YR Gender:Male I/FU:I

| | | | | | | | |
|-------------------|----------|-----------|---------------|---------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Hospitalization - | | Hypotonia | Foreign | Ritalin | PS | Novartis | |

| | | | | |
|----------------------|-----------------------|--------------|----------------------|------|
| Initial or Prolonged | Loss Of Consciousness | Health | Pharmaceuticals Corp | ORAL |
| 1.25 DF, QD, | | | | |
| | Sedation | Professional | | |
| ORAL | | Other | | |

Date:10/31/00ISR Number: 3609836-8Report Type:Periodic Company Report #MPI-2000-04729 (0)
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------------------|---------------------------|-------------|------|-------------------------------|-------|
| Dose | | Abdominal Pain Hypersensitivity | Health Professional | Metadate Er | PS | Medeva Pharmaceuticals Inc | |
| 10 MG | | Vomiting | Company Representative | | | | |

Date:10/31/00ISR Number: 3609842-3Report Type:Periodic Company Report #MPI-2000-04633 (0)
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------------------------|------------------------|-------------|------|-------------------------------|-------|
| Dose | | Abdominal Pain Emotional Disorder | Health Professional | Metadate Er | PS | Medeva Pharmaceuticals Inc | ORAL |
| 10 MG, ONCE A | | | | | | | |
| DAY, PO | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/31/00ISR Number: 3609845-9Report Type:Periodic Company Report #MPI-2000-04763(0)
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------|------------------------|-------------|------|----------------------------|-------|
| Dose | | Tachycardia | Health Professional | Metadate Er | PS | Medeva Pharmaceuticals Inc | |
| 10 MG | | | Company Representative | | | | |

Date:11/01/00ISR Number: 3604026-7Report Type:Expedited (15-DaCompany Report #B0090064A
 Age:82 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|--------------|---------------------|---------------|------------|------|----------------|-------|
| Death | | Chronic Obstructive | | Salmeterol | PS | Glaxo Wellcome | |
| RESPIRATORY | | Airways Disease | | | | | |
| Hospitalization - (INHALATION) | 100MCG TWICE | Exacerbated | | Singulair | C | | |
| Initial or Prolonged | | | | Atrovent | C | Glaxo Wellcome | |
| PER DAY | 484 DAY | | | | | | |
| 2PUFF TWICE | | | | Clonazepam | C | | |
| PER DAY | | | | | | | |
| .5MG AS | | | | | | | |
| REQUIRED | | | | Respolin | C | Glaxo Wellcome | |
| | | | | Pulmicort | C | | |
| 800MCG TWICE | | | | | | | |
| PER DAY | | | | | | | |

Date:11/01/00ISR Number: 3604027-9Report Type:Expedited (15-DaCompany Report #B0090065A
 Age:75 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Death Cardiac Disorder Salmeterol PS Glaxo Wellcome
RESPIRATORY
Hospitalization -
(INHALATION) 50MCG TWICE
Initial or Prolonged
PER DAY 907 DAY

Date:11/01/00ISR Number: 3604028-0Report Type:Expedited (15-DaCompany Report #B0090066A
Age:57 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-------|---------------|------------|------|----------------|-------|
| Death | Death | | Salmeterol | PS | Glaxo Wellcome | |

Dose Duration
RESPIRATORY
Life-Threatening
(INHALATION) 50MCG TWICE
Hospitalization -
PER DAY 124 DAY
Initial or Prolonged

Date:11/01/00ISR Number: 3604029-2Report Type:Expedited (15-DaCompany Report #B0090068A
Age:65 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------------|---------------|------------|------|----------------|-------|
| Death | Chronic Obstructive | | Salmeterol | PS | Glaxo Wellcome | |

Dose Duration
RESPIRATORY
Life-Threatening Airways Disease
(INHALATION) 50MCG TWICE
Hospitalization - Exacerbated
PER DAY 810 DAY
Initial or Prolonged Myocardial Infarction

Date:11/01/00ISR Number: 3604030-9Report Type:Expedited (15-DaCompany Report #B0090069A
Age:87 YR Gender:Male I/FU:I

Outcome
Death
Life-Threatening

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hospitalization -
Initial or Prolonged

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|------------------------|-----------|---------------|------------|------|----------------|-------|
| RESPIRATORY (INHALATION) | 50MCG TWICE PER DAY | Pneumonia | | Salmeterol | PS | Glaxo Wellcome | |

Date:11/06/00ISR Number: 3608057-2Report Type:Expedited (15-DaCompany Report #PHEH2000US09739
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|--|---------------|---|------|----------------------------------|-------|
| Other 15 MG, BID, ORAL | | Abdominal Pain Abdominal Pain Upper | Consumer | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 30 MG, QD, ORAL | | Aggression Anger Anxiety Depression Drug Dependence Drug Withdrawal Syndrome | | Ritalin-Sr(Methylphe nidate Hydrochloride) Slow Release Tablet | SS | | ORAL |
| | | Fatigue Headache Hostility Insomnia Mental Disorder Murder Physical Assault Suicidal Ideation Weight Decreased | | Cocaine | SS | | |

Date:11/06/00ISR Number: 3608162-0Report Type:Expedited (15-DaCompany Report #PHFR2000GB00671
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | | |
|------------|----------------------|--------------|---------|----|----------------------|------|
| Other | Fundoscopy Abnormal | Foreign | Ritalin | PS | Novartis | |
| 25 MG/DAY, | Optic Disc Disorder | Health | | | Pharmaceuticals Corp | ORAL |
| ORAL | Retinal Pigmentation | Professional | | | | |
| | | Other | | | | |

Date:11/09/00ISR Number: 3609604-7Report Type:Direct Company Report #
 Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|----------------------|---------------|---------------------|------|--------------|-------|
| Life-Threatening | | Grand Mal Convulsion | | Concerta 18mg | PS | | ORAL |
| 1 QD ORAL | | Insomnia | | Wellbutrin Sr 100mg | SS | | ORAL |
| 2 BID ORAL | | Medication Error | | | | | |

Date:11/09/00ISR Number: 3610165-7Report Type:Expedited (15-DaCompany Report #CIP00000967
 Age:65 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------------|----------------|-------------------|------|---------------------|-------|
| Other | | Chills | Health | Actonel | PS | Procter And Gamble | |
| | | Choking | Professional | | | Pharmaceuticals Inc | |
| | | Drug Interaction | Company | | | Sub Procter And | |
| 5 MG DAILY, | | Dyspnoea | Representative | | | Gambl | ORAL |
| ORAL | | Hypersensitivity | | | | | |
| ORAL | | Palpitations | | Buspar (Buspirone | | | |
| | | Pharyngeal Oedema | | Hydrochloride) | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|------|--|--|--|---|----|--|------|
| ORAL | | | | Serzone (Nefazodone Hydrochloride) | SS | | ORAL |
| ORAL | | | | Synthroid (Levothyroxine Sodium) | SS | | ORAL |
| ORAL | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |

Date:11/13/00ISR Number: 3613368-0Report Type:Periodic Company Report #FLUV00299001834
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------------|---------------|---|------|---------------------------|-------|
| Dose Other | | Hostility Muscle Twitching | Consumer | Luvox | PS | Solvay Pharmaceuticals | ORAL |
| 50 MG DAILY | | | | | | | |
| PO; 75 MG | | | | | | | |
| DAILY PO | | | | | | | |
| | | | | Ritalin - Slow Release (Methylphenidate Hydrochloride) | SS | | ORAL |
| 10 MG DAILY | | | | | | | |
| PO | | | | | | | |

Date:11/20/00ISR Number: 3614618-7Report Type:Expedited (15-DaCompany Report #FLUV00300005819
 Age:71 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------------------|-------------------|---------|------|---------------------------|-------|
| Dose Other | | Depressed Level Of Consciousness | Foreign Health | Luvox | PS | Solvay Pharmaceuticals | ORAL |
| 25 MG DAILY | | | | | | | |
| PO,50 MG | | Depression | Professional | | | | |

| | | | | |
|---------------|--------------------------|-------|--|---------|
| DAILY PO, 75 | Haemoglobin Decreased | Other | | |
| MG DAILY PO, | Leukopenia | | | |
| 25 MG DAILY | Muscular Weakness | | | |
| 0.8 MG DAILY | Pancytopenia | | Constan (Alprazolam) | SS ORAL |
| PO | Platelet Count Decreased | | | |
| 1 MG DAILY PO | Splenomegaly | | Depas (Etizolam) | SS ORAL |
| | | | Besacolin (Bethanechol Chloride) | SS ORAL |
| 50 MG DAILY | | | | |
| PO | | | Lendormin (Brotizolam) | SS ORAL |
| 0.5 MG DIALY | | | | |
| PO | | | Magnesium Oxide (Magnesium Oxide) | SS ORAL |
| 1.59 G DAILY | | | | |
| PO | | | Methylphenidate Hydrochloride (Methylphenidate Hydrochloride) | SS ORAL |
| 10 MG DAILY | | | | |
| PO | | | Tsukushi Miya Bm | C C |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/24/00ISR Number: 3616770-6Report Type:Expedited (15-DaCompany Report #PHBS2000US08065
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|--------------------------------------|---------|------|----------------------------------|-------|
| Death | | Coronary Artery Disease Myocardial Infarction Sudden Death | Literature Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | |

Date:11/27/00ISR Number: 3617254-1Report Type:Expedited (15-DaCompany Report #PHNU2000DE02170
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|--|---------|------|----------------------------------|-------|
| Other | | Cerebrovascular Disorder Facial Palsy | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:12/01/00ISR Number: 3624878-4Report Type:Periodic Company Report #6980
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------------------------------|------------------------------|---------------|----------|------|--------------|-------|
| Other | 18 MG - 36 MG 1 X / 1 DAY | Anorexia Drug Ineffective | Consumer | Concerta | PS | Alza Corp | ORAL |

Date:12/01/00ISR Number: 3624879-6Report Type:Periodic Company Report #6984
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------------------|---------------------------------|------------------------|----------|------|--------------|-------|
| Other | 18 MG 1 X /1DAY, ORAL | Agitation Emotional Disorder | Health Professional | Concerta | PS | Alza Corp | ORAL |

Insomnia

Company
Representative

Imipramine
Zyprexa

C
C

Date:12/01/00ISR Number: 3624880-2Report Type:Periodic Company Report #6985
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | Consumer | Concerta | PS | Alza Corp | |
| 18 MG - 36MG | | Drug Ineffective | | | | | |
| 1 X /1 DAY | | Mania | | | | | |

Date:12/01/00ISR Number: 3624881-4Report Type:Periodic Company Report #6993
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Muscle Twitching | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | Professional | | | | |
| ORAL | | | Company Representative | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/01/00ISR Number: 3624882-6Report Type:Periodic Company Report #6994
 Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1DAY, | | | | | | | |
| ORAL | | | | | | | |
| | | | | Wellbutrin Sr | C | | |

Date:12/01/00ISR Number: 3624883-8Report Type:Periodic Company Report #6999
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | | | | | |
| ORAL | | | | | | | |
| | | | | Tegretol | C | | |
| | | | | Neurontin | C | | |
| | | | | Luvox | C | | |

Date:12/01/00ISR Number: 3624884-XReport Type:Periodic Company Report #7633
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyspepsia | | Concerta | PS | Alza Corp | |

Date:12/01/00ISR Number: 3624885-1Report Type:Periodic Company Report #7641
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Mydriasis | Health | Concerta | PS | Alza Corp | ORAL |
| ORAL, | | | | | | | |
| | | | Professional | | | | |
| DOSE/FREQ UNK | | | Company | | | | |

Representative

Date:12/01/00ISR Number: 3624886-3Report Type:Periodic Company Report #7642
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|--|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Diarrhoea | Health Professional Company Representative | Concerta | PS | Alza Corp | |

Date:12/01/00ISR Number: 3624887-5Report Type:Periodic Company Report #7665
Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated | Consumer | Concerta | PS | Alza Corp | ORAL |

1X/1DAY,ORAL;

18MG 2 TABS 1

X /DAY;18MG

1X/DAY,ORAL

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C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/01/00ISR Number: 3624888-7Report Type:Periodic Company Report #6899
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Health | Concerta | PS | Alza Corp | ORAL |
| 36M | | | | | | | |
| | | Hallucination | Professional | | | | |
| 1X/1DAY,ORAL | | | | | | | |
| | | Nausea | | Paxil | C | | |
| | | Vomiting | | Buspar | C | | |

Date:12/01/00ISR Number: 3624889-9Report Type:Periodic Company Report #6951
 Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Arrhythmia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 75MG | | | | | | | |
| | | Chest Pain | Health | | | | |
| 1X/1DAY,ORAL | | | | | | | |
| | | Condition Aggravated | Professional | Depakote | C | | |
| | | Hyperhidrosis | | | | | |
| | | Insomnia | | | | | |
| | | Overdose | | | | | |
| | | Palpitations | | | | | |

Date:12/01/00ISR Number: 3624890-5Report Type:Periodic Company Report #6952
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-------------|------------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pollakiuria | Health | Concerta | PS | Alza Corp | ORAL |
| DOSE | | | | | | | |
| | | | Professional | | | | |
| UNKN-ORAL | | | Company Representative | | | | |

Date:12/01/00ISR Number: 3624891-7Report Type:Periodic Company Report #6954
 Age:14 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG | | Dizziness | | | | | |
| 1X/1DAY,ORAL | | | | Depakote | SS | | |
| 250MG QAM & | | | | | | | |
| 500MG QHS | | | | | | | |

Date:12/01/00ISR Number: 3624892-9Report Type:Periodic Company Report #6957
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Hostility | Health | | | | |
| ORAL | | | Professional | Prozac | SS | | |
| 15MG 1X/1DAY | | | | Zoloft | SS | | ORAL |
| 25MG | | | | | | | |
| 1X/1DAY,PO | | | | | | | |

Date:12/01/00ISR Number: 3624893-0Report Type:Periodic Company Report #6961
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG | | | | | | | |
| 1X/1DAY,PO | | | | Celexa | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/01/00ISR Number: 3624896-6Report Type:Periodic Company Report #6969
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Emotional Disorder | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Rhinitis | | | | | |
| ORAL | | | | | | | |

Date:12/01/00ISR Number: 3624897-8Report Type:Periodic Company Report #6976
 Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dizziness | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG | | Pallor | Professional | | | | |
| 1X/1DAY, ORAL | | | | | | | |

Date:12/01/00ISR Number: 3624898-XReport Type:Periodic Company Report #6978
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hyperhidrosis | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG | | | | Prozac | C | | |
| 1X/1DAY, ORAL | | | | | | | |

Date:12/01/00ISR Number: 3624900-5Report Type:Periodic Company Report #6979
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|---|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pruritus | Health | Concerta | PS | Alza Corp | ORAL |
| ORAL | | Urticaria | Professional Company Representative | | | | |

Date:12/01/00ISR Number: 3625300-4Report Type:Periodic Company Report #7669
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Health | Concerta | PS | Alza Corp | ORAL |
| 54 MG 1X/ 1 | | | Professional | | | | |
| DAY, ORAL | | | | | | | |

Date:12/01/00ISR Number: 3625301-6Report Type:Periodic Company Report #7671
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------------|------------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depersonalisation | Health | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1 X / | | Headache | Professional | | | | |
| DAY ORAL | | Nausea | Company Representative | | | | |

Date:12/01/00ISR Number: 3625302-8Report Type:Periodic Company Report #7672
Age:40 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|--------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haemorrhage | Consumer | Concerta | PS | Alza Corp | |
| 54 MG > TO 72 | | | | | | | |
| MG 1X / 1 | | | | | | | |
| DAY, | | | | Ritalin | C | | |
| | | | | Methotrexate | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | |
|------------|---|
| Wellbutrin | C |
| Celexa | C |
| Vioxx | C |
| Allegra | C |
| Diovan | C |
| Pepcid | C |
| Flonase | C |
| Niacin | C |

Date:12/01/00ISR Number: 3625304-1Report Type:Periodic Company Report #7684
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|--------------------|------------------------|----------|------|--------------|-------|
| Other | 18 MG - 36 PO | Hallucination | Health | Concerta | PS | Alza Corp | |
| | 1X/ 1 DAY | Headache | Professional | | | | |
| | | Visual Disturbance | Company Representative | Zyrtec | C | | |

Date:12/01/00ISR Number: 3625305-3Report Type:Periodic Company Report #7686
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-------------|------------|---------------|----------|------|--------------|-------|
| Other | 36 MG 1X/ 1 | Dermatitis | Health | Concerta | PS | Alza Corp | ORAL |
| | DAY, ORAL | | Professional | | | | |

Date:12/01/00ISR Number: 3625306-5Report Type:Periodic Company Report #7706
 Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|----------------------|---------------|------------|------|--------------|-------|
| Other | 54 MG 1 X / 1 | Condition Aggravated | Consumer | Concerta | PS | Alza Corp | ORAL |
| | DAY, ORAL | Confusional State | | | | | |
| | | Insomnia | | Wellbutrin | C | | |

Speech Disorder

Date:12/01/00ISR Number: 3625307-7Report Type:Periodic Company Report #7707
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54 MG 1 X / 1 | | Drug Ineffective | | | | | |
| DAY , ORAL | | | | | | | |

Date:12/01/00ISR Number: 3625309-0Report Type:Periodic Company Report #7710
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|------------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Urticaria | Health | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1 X / 1 | | | Professional | | | | |
| DAY , PO | | | Company Representative | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/01/00ISR Number: 3625311-9Report Type:Periodic Company Report #7711
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------|----------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated | Health | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1 X/ 1 | | Laryngeal Oedema | Professional | | | | |
| DAY, ORAL | | Palpitations | Company | | | | |
| | | Pruritus | Representative | | | | |

Date:12/01/00ISR Number: 3625312-0Report Type:Periodic Company Report #7712
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|----------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Urticaria | Health | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X/ 1 | | | Professional | | | | |
| DAY , ORAL | | | Company | | | | |
| | | | Representative | | | | |

Date:12/01/00ISR Number: 3625314-4Report Type:Periodic Company Report #7719
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1 X/ 1 | | Insomnia | | | | | |
| DAY, ORAL | | Muscle Twitching | | | | | |
| | | Nervousness | | | | | |
| | | Pain | | | | | |

Date:12/01/00ISR Number: 3625315-6Report Type:Periodic Company Report #7727
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Insomnia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X/ 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:12/05/00ISR Number: 3622696-4Report Type:Expedited (15-DaCompany Report #PHNU2000DE02259
 Age:44 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------|---------------------|---------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged | | Cardiomegaly Dyspnoea | Foreign Consumer | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 2 DF, TID, | | | | | | | |
| ORAL | | | | | | | |
| | | Heart Rate Increased | Other | | | | |
| | | Hyperhidrosis | | | | | |

Date:12/11/00ISR Number: 3626760-5Report Type:Expedited (15-DaCompany Report #MPI-2000-04574(1)
 Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Pressure Increased Emotional Distress Heart Rate Increased | Literature | Ritalin (Methylphenidate Hydrochloride) | PS | | |
| 100MG/DAY (IN | | | | | | | |
| THREE DOSES) | | | | | | | |
| | | Intermittent Claudication | | | | | |
| | | Myocardial Ischaemia | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/13/00ISR Number: 3629216-9Report Type:Expedited (15-DaCompany Report #7835
Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|----------|------|--------------|-------|
| Hospitalization - 36MG 1X/DAY, Initial or Prolonged ORAL | | Arthralgia | Consumer | Concerta | PS | Alza Corp | ORAL |
| | | Myalgia | | | | | |
| | | Red Blood Cell Sedimentation Rate Increased White Blood Cell Count Increased | | | | | |

Date:12/13/00ISR Number: 3629507-1Report Type:Expedited (15-DaCompany Report #PHFR2000GB02022
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------|------------------------------|------|----------------------------------|-------|
| Other ORAL | | Circulatory Collapse Hyperventilation | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| | | | Professional Other | Klaricid (Clarithromycin) | C | | |

Date:12/14/00ISR Number: 3630240-0Report Type:Expedited (15-DaCompany Report #PHNU2000DE02170
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------|---------|------|----------------------------------|-------|
| Other ORAL | | Facial Palsy Herpes Virus Infection | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| | | | Professional Other | | | | |

Date:12/15/00ISR Number: 3631713-7Report Type:Expedited (15-DaCompany Report #PHRM2000FR01504
Age:45 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|----------------|---------|------|-------------------------------|-------|
| Death | | Intentional Misuse | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 500 MG, | | | Professional | | | | |
| ONCE/SINGLE, | | | | | | | |
| ORAL | | | | | | | |

Date:12/18/00ISR Number: 3633261-7Report Type:Expedited (15-DaCompany Report #PHFR2000GB02126
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------|----------------|---------|------|-------------------------------|-------|
| Other | | Oculogyration | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 30 MG DAY | | | Professional | | | | |
| ORAL | | | Other | | | | |

Date:12/19/00ISR Number: 3633742-6Report Type:Direct Company Report #
 Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-------------------------|------|--------------|-------|
| | | Drug Ineffective | | Generic Methylphenidate | PS | | |

| | | | | | | |
|---------------------|-----------------------|---------------------------|----------|----|-----------|------|
| Other 18 MG 1X/1 | Dizziness | Health | Concerta | PS | Alza Corp | ORAL |
| DAY, ORAL | Fall | Professional | | | | |
| | Loss Of Consciousness | Company Representative | | | | |

Date:12/26/00ISR Number: 3638133-XReport Type:Expedited (15-DaCompany Report #PHEH2000US11194
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------|----------|-----------------------|------------------------|--------------------------------------|------|----------------------------------|-------|
| Dose Other | | Hallucination, Visual | Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 10 MG, BID, ORAL | | | | Antihistaminics (Antihistaminics) | C | | |

Date:01/03/01ISR Number: 3641648-1Report Type:Expedited (15-DaCompany Report #001-0945-M0000196
Age:40 YR Gender:Female I/FU:F

| | |
|----------------------|---------------------------|
| Outcome | PT |
| Hospitalization - | Arthralgia |
| Initial or Prolonged | Asthenia |
| Other | Blood Potassium Decreased |
| | Carpal Tunnel Syndrome |
| | Cholelithiasis |
| | Cholestasis |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Adverse Event | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|--------------------------------|----------|------------------------------------|-------|
| | | Decreased Activity Dental Caries Depression | | | | | |
| 900 MG(300 MG TID):2400MG(8 00MG TID):2100MG(7 00MG | | Difficulty In Walking Dry Mouth | Consumer | Neurontin | PS | Parke Davis Pharmaceuticals Ltd | ORAL |
| | | Fall | | | | | |
| | | Fatigue | | | | | |
| | | Gallbladder Disorder | | | | | |
| | | Gallbladder Pain | | | | | |
| 80 MG PER ORAL | | Headache | | Baclofen | SS | | ORAL |
| | | Hypoaesthesia | | | | | |
| 1600 MG | | Hypothyroidism | | Ms Contin | SS | | |
| 2500 MG | | Joint Dislocation Lethargy | | Propulsid Methadone | SS SS | | |
| 1 OR 2 (Q 4 H PRN) | | Liver Function Test Abnormal | | Percocet | SS | | |
| 80 MG | | Lymphadenopathy | | Valium | SS | | |
| 8 MG PER ORAL | | Malnutrition | | Zanaflex | SS | | ORAL |
| 200 MG PER ORAL | | Movement Disorder | | Zoloft | SS | | ORAL |
| | | Nervous System Disorder | | | | | |
| 100 MG PER ORAL | | Oedema Peripheral | | Hydrochlorothiazide | SS | | ORAL |
| | | Osteoporosis | | | | | |
| 2000 MG PER ORAL | | Ovarian Cyst | | Veetids | SS | | ORAL |
| | 1 WK | Pain In Extremity | | | | | |
| | | Pruritus Skin Discolouration | | Synthroid Oxy Ir (Oxycodone | SS | | |

| | | | |
|------------|------------------|------------------|----|
| 8-10 DAILY | Skin Ulcer | Hydrochloride) | SS |
| 80 MG | Tendon Disorder | Lasix | SS |
| 80 MG | Vomiting | Ritalin | SS |
| 20 MCG | Weight Decreased | K-Dur | SS |
| | Weight Increased | Seroquel | SS |
| | | Ketamine | SS |
| | | Klonopin | SS |
| | | Corgard | SS |
| | | Relafen | SS |
| | | Celebrex | SS |
| 800 MG | | | |
| 4 MG | | Carafate | SS |
| 200 MG | | Dextromethorphan | SS |
| | | Nadolol | SS |
| | | Tegaderm | SS |

Date:01/10/01ISR Number: 3645534-2Report Type:Direct Company Report #
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|----------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper | | Ritalin (10mg) | PS | | ORAL |
| 1T PO TID | | | | | | | |

Date:01/10/01ISR Number: 3645551-2Report Type:Expedited (15-DaCompany Report #CIP00000967
Age:65 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------|----------------|---------------------|------|---------------------|-------|
| Dose | | | | | | | |
| Other | | Chills | Health | Actonel | PS | Procter And Gamble | |
| | | Choking | Professional | | | Pharmaceuticals Inc | |
| | | Drug Hypersensitivity | Company | | | Sub Procter And | |
| | | Drug Interaction | Representative | | | Gambl | ORAL |
| 5 MG TWICE | | | | | | | |
| DAILY, ORAL | | Dyspnoea | | | | | |
| | | Palpitations | | Buspar (Buspirone | | | |
| | | Pharyngeal Oedema | | Hydrochloride) | SS | | |
| | | Throat Tightness | | Serzone (Nefazodone | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | |
|---|---|----|------|
| 300 MG IN THE EVENING, ORAL / 150 MG AM & 300 MG PM, ORAL | Hydrochloride) | SS | ORAL |
| 0.75 MG DAILY, ORAL | Synthroid (Levothyroxine Sodium) | SS | ORAL |
| ORAL | Ritalin (Methylphenidate Hydrochloride) | SS | ORAL |

Date:01/10/01ISR Number: 3645583-4Report Type:Direct
Age:12 YR Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|-----------------------|---------------|--------------------|------|--------------|-------|
| Dose Other 72MG Q AM | | Dizziness Vomiting | | Concerta 72mg Q Am | PS | | |

Date:01/16/01ISR Number: 3648759-5Report Type:Expedited (15-DaCompany Report #PHBS2000AU08649
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|------------------|--|---------|------|----------------------------------|-------|
| Dose Other ORAL | | Aplastic Anaemia | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:01/17/01ISR Number: 3649160-0Report Type:Expedited (15-DaCompany Report #MPI-2000-04709 (2)

Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|-------------------------------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Hallucinations, Mixed Psychotic Disorder | Health Professional Company | Metadate Er | PS | Medeva Pharmaceuticals Ca Inc | |
| TWICE A DAY | | | Representative | Efexor Xr(Venlafaxine Hydrochloride) | SS | | |
| 75 , EVERY DAY | | | | | | | |

Date:01/17/01ISR Number: 3649326-XReport Type:Expedited (15-DaCompany Report #PHEH2001US00560

Age:79 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|----------------------------------|---------------|-----------------------------------|--------|----------------------------------|-------|
| Other | | Abnormal Behaviour Aggression | Consumer | Ritalin | PS | Novartis Pharmaceuticals Corp | |
| 5 MG, QD; 5 MG, BID | | Dementia Alzheimer'S Type | | | | | |
| | | Dermatitis Pruritus | | Zyprexa (Olanzapine) Oxycodone | C C | | |

Date:01/17/01ISR Number: 3649689-5Report Type:Expedited (15-DaCompany Report #PHRM2000FR01504

Age:45 YR Gender:Female I/FU:F

| Outcome | PT | Report Source |
|---------|--------------------|-------------------|
| Death | Intentional Misuse | Foreign Health |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Professional
Other

| Dose | Duration | Product | Role | Manufacturer | Route |
|---------------------------------|----------|--------------|------|----------------------------------|-------|
| 500 MG, ONCE/SINGLE, ORAL | | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| | | Meprobamate | SS | | |
| | | Amisulpride | SS | | |
| | | Codeine | C | | |
| | | Lorazepam | C | | |
| | | Acepromazine | C | | |
| | | Paracetamol | C | | |
| | | Propranolol | C | | |

Date:01/19/01ISR Number: 3651598-2Report Type:Expedited (15-DaCompany Report #PHNU2001DE00478
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|------------------------|-----------------------|---------|------|----------------------------------|-------|
| Dose Other ORAL | | Pulmonary Hypertension | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| | | | Professional Other | | | | |

Date:01/22/01ISR Number: 3652960-4Report Type:Expedited (15-DaCompany Report #PHEH2001US00655
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------|------------------------|---------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged | | Asthenia Paraesthesia | Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | |

Date:01/22/01ISR Number: 3652961-6Report Type:Expedited (15-DaCompany Report #PHEH2001US00654
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------|------------------------|---------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged | | Asthenia Paraesthesia | Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | |

Date:01/29/01ISR Number: 3657246-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP00910
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|---------------|---|-----------------------------------|-----------------------|--------|----------------------------------|-------|
| Other | | Complications Of Maternal Exposure To Therapeutic Drugs | Foreign Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | Anafranil | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | Convulsion Neonatal | | Wintermin Serenace | C C | | |

Date:02/02/01ISR Number: 3663605-1Report Type:Periodic Company Report #HQ6586830MAY2000
 Age:27 YR Gender:Female I/FU:I

| Outcome | PT |
|---|-------------------------------|
| Hospitalization - Initial or Prolonged | Abdominal Pain Amenorrhoea |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Application Site Reaction

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|--------------|--------------|---------------|---|------|--------------|-------|
| | | Consumer | Norplant System (Levonorgestrel, Implant) | PS | | |
| SUBCUTANEOUS | SUBCUTANEOUS | | Fluoxetine | C | | |
| | | | Diazepam | C | | |
| | | | Methylphenidate | I | | |

Date:02/05/01ISR Number: 3662759-0Report Type:Periodic Company Report #A015134
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hostility | Health | Zyrtec Tablets | PS | | ORAL |
| 10.00 MG | | | Professional | | | | |
| TOTAL:DAILY:0 | | | | | | | |
| RAL | | | | Ritalin | SS | | |
| | | | | Valium | SS | | |
| DAILY | | | | | | | |

Date:02/05/01ISR Number: 3663486-6Report Type:Periodic Company Report #PHEH1999US17294
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------|---------------|-------------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Health | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| 10 MG, BID, | | | Professional | | | | |
| ORAL | | | Other | | | | |

Date:02/05/01ISR Number: 3663487-8Report Type:Periodic Company Report #PHEH2000US03611
 Age:5 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------|----------|---------------------------------|---------------|---|--------|-------------------------------|-------|
| Hospitalization - Initial or Prolonged | | | Condition Aggravated Dyskinesia | Other | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| | | | | | Risperidone (Risperidone) Solution, 1.2mg | SS | | ORAL |
| | | | | | Tegretal (Carbamazepine) Depakote | C C | | |

Date:02/05/01ISR Number: 3663488-XReport Type:Periodic Company Report #PHEH2000US04072
 Age:8 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------|----------|--------------------|---------------|--|------|-------------------------------|-------|
| Hospitalization - Initial or Prolonged | | | Tardive Dyskinesia | Other | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| | | 6 MON | | | Risperidone (Risperidone) Tablet | SS | | |
| | | | | | Paxil (Paroxetine Hydrochloride) Tablet, 20 Mg | SS | | ORAL |
| | | | | | Depakote | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/05/01ISR Number: 3663489-1Report Type:Periodic Company Report #PHEH2000US07991
 Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------|---------------------|--------------------------|------|-------------------------------|-------|
| Life-Threatening Hospitalization - 1) 40 MG, QD, Initial or Prolonged ORAL; 2) 20 MG QD, ORAL | | Convulsion | Health Professional | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| | | | | Tegretol (Carbamazepine) | C | | |

Date:02/05/01ISR Number: 3663490-8Report Type:Periodic Company Report #PHEH2000US09745
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------------|---------------------|--|------|-------------------------------|-------|
| Other ORAL | 1460 DAY | Arrhythmia Hypertension | Health Professional | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| Other ORAL | 1460 DAY | | | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | SS | | ORAL |

Date:02/06/01ISR Number: 3661388-2Report Type:Expedited (15-DaCompany Report #10130
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|-------------------|------------------------|----------|------|--------------|-------|
| Death 36MG 1X/1DAY, ORAL | | Completed Suicide | Health Professional | Concerta | PS | Alza Corp | ORAL |
| | | | Company Representative | Zoloft | C | | |

Date:02/07/01ISR Number: 3660812-9Report Type:Expedited (15-DaCompany Report #A0138544A
Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|---------------|------------------|---------------|-----------------|------|----------------|-------|
| Hospitalization - | 450MG Per day | 1 YR | Convulsion | Wellbutrin | PS | Glaxo Wellcome | ORAL |
| Initial or Prolonged | TOPICAL | Drug Interaction | | Doxycycline | C | | |
| | | | | Acne Medication | C | | |
| | | | | Methylphenidate | I | | |
| | 18MG Per day | | | | | | |

Date:02/08/01ISR Number: 3662243-4Report Type:Direct Company Report #
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------------------------------|------|--------------|-------|
| | 15MG BID | Drug Ineffective | | Ritalin 15mg (10+5mg) Generic | PS | | |
| | -MOUTH | | | Ritalin 15mg (10+5mg) | SS | | |
| | 15MG BID | | | | | | |
| | -MOUTH | | | | | | |

Date:02/08/01ISR Number: 3662872-8Report Type:Expedited (15-DaCompany Report #A0138544A
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------------|------------------|---------------|---------------|------|--------------------|-------|
| Hospitalization - | 450 MG/PER | 1 YR | Convulsion | Wellbutrin Sr | PS | Glaxo Wellcome Inc | ORAL |
| Initial or Prolonged | DAY/ORAL | Drug Interaction | Professional | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

18 MG/PER DAY

| | | |
|--|---|----|
| | Methylphenidate (Formulation Unknown) | SS |
| | Doxycyline | C |
| | Acne Medication | C |

Date:02/09/01ISR Number: 3665904-6Report Type:Periodic Company Report #00-10-0117
Age:54 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Constipation Dry Mouth Sedation | Consumer | Thalomid (Thalidomide 50 Mg) Capsules | PS | Celgene Corp | ORAL |
| 100 MG QD | | Thinking Abnormal | | | | | |
| ORAL | | Tremor | | Ritalin Tablets | SS | | ORAL |
| ORAL | | | | Estrace | C | | |
| | | | | Vitamin Nos | C | | |
| | | | | Herbal Preparation | C | | |

Date:02/12/01ISR Number: 3663416-7Report Type:Expedited (15-DaCompany Report #254260
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Accutane Capsules | PS | Roche | |
| 366 DAY | | Depression Panic Attack Sleep Disorder | | Ritalin | SS | | |

Date:02/12/01ISR Number: 3663813-XReport Type:Direct Company Report #
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Metadate Er 10mg | | | |

10 MG QD

Tabs PS
Methadone 10 Mg Tabs SS

Date:02/13/01ISR Number: 3665029-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP00910
Age:3 DY Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------|---------------|---------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Clonic Convulsion | Foreign | Ritalin Tab | PS | | |
| | | Complications Of Maternal | Health | Anafranil(Clomiprami | | | |
| | | Exposure To Therapeutic | Professional | ne Hydrochloride) | | | |
| | | Drugs | Other | Tablet | SS | | |
| | | Convulsion Neonatal | | Wintermin(Chlorproma | | | |
| | | Dyskinesia | | zine Hydrochloride) | SS | | |
| TRANSPLACENTAL | TRANSPLACENTA | | | | | | |
| | | Jaundice Neonatal | | | | | |
| L | | | | | | | |
| | | Neonatal Disorder | | Serenace(Haloperidol | | | |
| | | | |) | SS | | |
| | | | | Contomin(Chlorpromaz | | | |
| | | | | ine Hydrochloride) | SS | | |
| TRANSPLACENTAL | TRANSPLACENTA | | | | | | |
| L | | | | | | | |
| | | | | Artane(Trihexyphenid | | | |
| | | | | yl Hydrochloride) | SS | | |
| TRANSPLACENTAL | TRANSPLACENTA | | | | | | |
| L | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/01ISR Number: 3665357-8Report Type:Expedited (15-DaCompany Report #254260
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|----------------|---------------|-------------------------------------|------|----------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | Consumer | Accutane | PS | Hlr Technology | ORAL |
| 2 PER DAY | | Depression | | | | | |
| ORAL | | Panic Attack | | Ritalin | | | |
| | | Sleep Disorder | | (Methylphenidated Hydrochloride) | SS | | ORAL |
| ORAL | | | | | | | |

Date:02/15/01ISR Number: 3666633-5Report Type:Expedited (15-DaCompany Report #PHBS2001NL01558
Age:35 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-------|--|--|------|---|-------|
| Dose | | | | | | | |
| Life-Threatening | | Shock | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) | PS | Novartis Pharmaceuticals Corp. Clinical Safety And Epidemiology | ORAL |
| 2 DF, QID, | | | | | | | |
| ORAL | | | | Morphine Hydrochloride Ampoule | SS | | |
| 5 MG/DAY | | | | Amitriptyline Tablet | C | | |
| | | | | Zoplicon Tablet | C | | |
| | | | | Seroxat Tablet | C | | |

Date:02/15/01ISR Number: 3666634-7Report Type:Expedited (15-DaCompany Report #PHNU2001DE00642
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haematoma | Foreign | Ritalin-Sr(Methylphe | | | |

Thrombocytopenia

Health
Professional
Other

nidate
Hydrochloride) Slow
Release Tablet

PS

Novartis
Pharmaceuticals
Corp.

ORAL

20 MG, QD,

ORAL

Zyrtec (Cetirizine
Hydrochloride)

C

Date:02/16/01ISR Number: 3667396-XReport Type:Expedited (15-DaCompany Report #PHEH2001US01470
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------------------|---------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Suicidal Ideation Weight Increased | Consumer | Ritalin (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Risperdal (Risperidone) | SS | | ORAL |
| | | | | Ddavn (Desmopressin) | C | | |
| | | | | Zoloft (Sertraline Hydrochloride) | C | | |
| | | | | Buspar (Buspirone) | | | |

ORAL

1) 0.5 MG,

TID, ORAL;

2) 2.5 MG,

QD, ORAL

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Freedom Of Information (FOI) Report

Hydrochloride) C

Date:02/16/01ISR Number: 3667530-1Report Type:Expedited (15-DaCompany Report #PHBS2001JP00910

Age:3 DY Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|---------------|--|--|---|------|--------------|-------|
| Dose Other | | Clonic Convulsion Complications Of Maternal Exposure To Therapeutic Drugs | Foreign Health Professional Other | Anafranil(Clomiprami ne Hydrochloride) Tablet | PS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |
| | | Convulsion Neonatal Crying Dyskinesia Neonatal | | Ritaline(Methylpheni date Hydrochloride) Tablet | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | Jaundice Neonatal | | | | | |
| | | | | Wintermin(Chlorproma zine Hydrochloride) | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |
| | | | | Serenace(Haloperidol) | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |
| | | | | Contomin(Chlorpromaz ine Hydrcochloride) | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |
| | | | | Artane(Trihexyphenid yl Hydrochloride) | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |

Date:02/22/01ISR Number: 3669407-4Report Type:Expedited (15-DaCompany Report #MPI-2001-00073(0)

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------|---|---------------------|------|--------------------------|-------|
| Hospitalization - Initial or Prolonged | | Depression | Foreign Literature Health Professional | Methylphenidate Hcl | PS | Md Pharmaceutical Inc | |

Date:02/22/01ISR Number: 3669935-1Report Type:Expedited (15-DaCompany Report #PHFR2001GB00735
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--|---------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged ORAL | | Eosinophilia Hepatosplenomegaly Pericardial Effusion Pleural Effusion | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:02/26/01ISR Number: 3670035-5Report Type:Direct Company Report #
 Age:35 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|-----------|---------------|-------------------------------|------|--------------|-------|
| Disability 36MG PO QD | | Hepatitis | | Concerta (36mg) Alza Pharm | PS | Alza Pharm | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/26/01ISR Number: 3670732-1Report Type:Expedited (15-DaCompany Report #PHNU2001DE00652
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------|----------------|---------|------|-------------------------------|-------|
| Dose | | | | | | | |
| Other | | Dyskinesia | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 10 MG, BID, | | Dysphagia | | | | | |
| ORAL | | Paresis | Professional | | | | |
| | | Speech Disorder | Other | | | | |

Date:02/26/01ISR Number: 3670874-0Report Type:Expedited (15-DaCompany Report #PHNU2001DE00694
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------------------------|----------------|-------------|------|-------------------------------|-------|
| Dose | | | | | | | |
| Other | | Ventricular Extrasystoles | Foreign Health | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| 1.5 - 0.5, | | | | | | | |
| ORAL | 730 DAY | | Professional | | | | |
| | | | Other | | | | |

Date:02/28/01ISR Number: 3681336-9Report Type:Periodic Company Report #A010258
 Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Surgery | Health | Zoloft | PS | Pfizer Pharmaceuticals Inc | |
| 50.00 MG | | Tremor | Professional | | | | |
| TOTAL | | | | Ritalin | SS | | ORAL |
| 110.00 MG | | | | | | | |
| TOTAL:TID:ORA | | | | | | | |

L

Imitrex Nasal Spray C
 Clonidine C

Date:02/28/01ISR Number: 3683192-1Report Type:Periodic Company Report #A016005
Age:8 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|----------------|---------|------|---------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Interaction | Health | Zoloft | PS | Pfizer | |
| 50.00 MG | | Mania | Professional | | | Pharmaceuticals Inc | |
| TOTAL:DAILY | | | Company | | | | |
| 30.00 MG | | | Representative | Ritalin | SS | | |
| TOTAL:DAILY | | | | | | | |

Date:02/28/01ISR Number: 3683193-3Report Type:Periodic Company Report #A016011
Age:10 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|----------------|---------|------|---------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Interaction | Health | Zoloft | PS | Pfizer | |
| 50.00 MG | | Mania | Professional | | | Pharmaceuticals Inc | |
| TOTAL:DAILY | | | Company | | | | |
| 30.00 MG | | | Representative | Ritalin | SS | | |
| TOTAL:DAILY | | | | | | | |

Date:02/28/01ISR Number: 3683204-5Report Type:Periodic Company Report #A015780
Age:14 YR Gender:Male I/FU:I

| | |
|---------|-----------|
| Outcome | PT |
| Other | Agitation |
| | Attention |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | |
|---------------|----------|---|---------------------|---------|------|----------------------------|
| | | Deficit/Hyperactivity Disorder Mania | | | | |
| Dose | Duration | | Report Source | Product | Role | Manufacturer |
| | | | Health Professional | Zoloft | PS | Pfizer Pharmaceuticals Inc |
| 50.00 MG | | | | | | ORAL |
| TOTAL:DAILY:0 | | | | | | |
| | | | | Ritalin | SS | |
| 30.00 MG | | | | | | |
| TOTAL:DAILY | | | | | | |

Date:02/28/01ISR Number: 3683205-7Report Type:Periodic Company Report #A015783
 Age: Gender: I/FU:I

| | | | | | | | |
|---------------|----------|-------|------------------------|---------|------|----------------------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Mania | Health Professional | Zoloft | PS | Pfizer Pharmaceuticals Inc | ORAL |
| Other | | | Company Representative | | | | |
| 50.00 MG | | | | Ritalin | SS | | |
| TOTAL:DAILY:0 | | | | | | | |
| | | | | | | | |
| 30.00 MG | | | | | | | |
| TOTAL:DAILY | | | | | | | |

Date:03/02/01ISR Number: 3673506-0Report Type:Expedited (15-DaCompany Report #PHFR2000GB02126
 Age:8 YR Gender:Male I/FU:F

| | | | | | | | |
|-------------|----------|-----------------------|-----------------------------|---------|------|-------------------------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Dyskinesia | Foreign Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| Other | | Eye Movement Disorder | | | | | |
| 15 MG, BID, | | Myopia | | | | | |
| ORAL | | | | | | | |

Oculogyration
Tic
Vision Blurred

Date:03/05/01ISR Number: 3674153-7Report Type:Expedited (15-DaCompany Report #PHFR1999GB00655
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|---|-------------------|-------------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Alkaline Phosphatase Increased | Foreign Health | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| DIVIDED | | | | | | | |
| DOSES: 15, | | | | | | | |
| 15, 10MG, | | | | | | | |
| ORAL | | | | | | | |
| Blood Bilirubin Increased | | | | | | | |
| Cholestasis | | | | | | | |
| Decreased Appetite | | | | | | | |
| Gilbert'S Syndrome | | | | | | | |
| Jaundice | | | | | | | |
| Weight Decreased | | | | | | | |

Date:03/05/01ISR Number: 3674484-0Report Type:Expedited (15-DaCompany Report #PHBS2000JP09475
Age:24 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------------------|-----------------------|---------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Decreased Appetite Drug Dependence | Foreign Literature | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 10 | | | | | | | |
| TABLETS/DAY, | | | | | | | |
| ORAL | | | | | | | |
| Drug Withdrawal Syndrome | | | | | | | |
| Fatigue | | | | | | | |
| Malaise | | | | | | | |
| Overdose | | | | | | | |
| Tryptanol (Amitriptyline Hydrochloride) | | | | | | | |
| Dogmatyl (Sulpiride) | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | |
|---|---|
| Horizon | C |
| Rohypnol (Flunitrazepam) | C |
| Doral (Quazepam) | C |
| Contomin (Chlorpromazine Hydrochloride) | C |
| Pyrethia | C |

Date:03/05/01ISR Number: 3679185-0Report Type:Periodic Company Report #10116
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Alkaline | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1 | | Phosphatase Increased | | | | | |
| DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3679186-2Report Type:Periodic Company Report #10117
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Muscle Twitching | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1X/1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3679187-4Report Type:Periodic Company Report #10118
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG (2-18MG) | | Sedation | | | | | |
| 1X1/DAY, PO | | | | Concerta (Methylphenidate | | | |

18MG 1X/1 Hcl) SS ORAL

DAY, PO

Date:03/05/01ISR Number: 3679188-6Report Type:Periodic Company Report #10119
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X/1 | | Tremor | | | | | |
| DAY, ORAL | | | | Clonidine | C | | |

Date:03/05/01ISR Number: 3679189-8Report Type:Periodic Company Report #10120
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|--|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Health Professional Company Representative | Concerta | PS | Alza Corp | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3679190-4Report Type:Periodic Company Report #10123
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------|------------------------|--------------------------------------|------|--------------|-------|
| Dose Other 36MG 1X/1DAY, ORAL | | Drug Ineffective | Health Professional | Concerta | PS | Alza Corp | ORAL |
| 36MG (2-18MG TABLETS QD). | | | | Concerta (Methylphenidate Hcl) | SS | | |
| 18MG 1X/1DAY, ORAL | | | | Concerta (Methylphenidate Hcl) | SS | | ORAL |

Date:03/05/01ISR Number: 3679191-6Report Type:Periodic Company Report #10124
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|------------------|------------------------|--------------------------------------|------|--------------|-------|
| Dose Other 36MG 1X/1DAY | | Drug Ineffective | Health Professional | Concerta | PS | Alza Corp | |
| 36MG (2-18MG TABLETS QD) | | | | Concerta (Methylphenidate Hcl) | SS | | |
| 18MG 1X/1DAY, ORAL | | | | Concerta (Methylphenidate Hcl) | SS | | ORAL |

Date:03/05/01ISR Number: 3679192-8Report Type:Periodic Company Report #10145
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3679193-XReport Type:Periodic Company Report #10149
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------|---------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Muscle Twitching | Consumer | Concerta | PS | Alza Corp | |
| 72MG (2-36MG) 1X / 1 DAY 54MG (18MG&36MG 1X/1DAY) | | | | | | | |
| | | | | Concerta (Methylphenidate Hcl) | SS | | |
| | | | | Claritin | C | | |

Date:03/05/01ISR Number: 3679194-1Report Type:Periodic Company Report #10222
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|------------------------|---------------------|---------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Company Representative | Concerta Miralax | PS C | Alza Corp | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3679479-9Report Type:Periodic Company Report #7997
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dysphagia | Health | Concerta | PS | Alza Corp | ORAL |
| 18 MG | | | Professional | | | | |
| 1X/1DAY, PO | | | | Depakote | C | | |
| | | | | Clonidine | C | | |
| | | | | Stimulants (Nos) | C | | |

Date:03/05/01ISR Number: 3679480-5Report Type:Periodic Company Report #7738
 Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|----------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Health | Concerta | PS | Alza Corp | ORAL |
| 18 MG | | | Professional | | | | |
| 1X/1DAY, ORAL | | Anaphylactic Reaction | | | | | |
| | | Chest Pain | Company | | | | |
| | | Dyspnoea | Representative | | | | |

Date:03/05/01ISR Number: 3679481-7Report Type:Periodic Company Report #7739
 Age:42 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Diarrhoea | Consumer | Concerta | PS | Alza Corp | |
| 18 MG-9 MG | | | | | | | |
| 1X/1 DAY | | Headache | | | | | |
| | | Tachycardia | | | | | |
| | | Vomiting | | | | | |

Date:03/05/01ISR Number: 3679482-9Report Type:Periodic Company Report #7740
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Skin Atrophy | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1X/1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| | | | | Wellbutrin Sr | C | | |

Date:03/05/01ISR Number: 3679483-0Report Type:Periodic Company Report #7748
 Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated | Health | Concerta | PS | Alza Corp | |
| 18-36 MG PO | | | | | | | |
| 1X/1 DAY | | | | | | | |
| | | Gait Disturbance | Professional | | | | |
| | | Tremor | | | | | |

Date:03/05/01ISR Number: 3679484-2Report Type:Periodic Company Report #7749
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alopecia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X/ 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| DOSE/FREQUENC | | | | Adderall | SS | | |
| Y | | | | Prozac | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3679485-4Report Type:Periodic Company Report #7750
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X/1 | | Dyspnoea | Health | | | | |
| DAY, ORAL | | Nervousness | Professional | | | | |
| | | Vasodilatation | | | | | |

Date:03/05/01ISR Number: 3679486-6Report Type:Periodic Company Report #7751
 Age:6 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Vision Blurred | Consumer | Concerta | PS | Alza Corp | |
| 18-36 MG PO | | | | | | | |
| 1X/1 DAY | | | | | | | |

Date:03/05/01ISR Number: 3679487-8Report Type:Periodic Company Report #7752
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X/1 | | Anorexia | Health | | | | |
| DAY, ORAL | | Chest Pain | Professional | | | | |
| | | Headache | | | | | |

Date:03/05/01ISR Number: 3679488-XReport Type:Periodic Company Report #7766
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1 | | | | | | | |

| | | | | | | | |
|---|-------------|----------------------|---------------|-----------|------|--------------|-------|
| DAY, ORAL | | Hostility | | | | | |
| | | Nervousness | | Remeron | | C | |
| Date:03/05/01ISR Number: 3679489-1Report Type:Periodic Company Report #7770 | | | | | | | |
| Age:46 YR | Gender:Male | I/FU:I | | | | | |
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Back Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/DAY | | | | | | | |
| | | Hypertonia | | | | | |
| ORAL | | | | | | | |
| Date:03/05/01ISR Number: 3679490-8Report Type:Periodic Company Report #7771 | | | | | | | |
| Age:11 YR | Gender:Male | I/FU:I | | | | | |
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Anorexia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | | | | | |
| | | Condition Aggravated | | | | | |
| ORAL | | | | | | | |
| | | Headache | | Calcium | | C | |
| | | Insomnia | | Vitamin D | | C | |
| Date:03/05/01ISR Number: 3679491-XReport Type:Periodic Company Report #7772 | | | | | | | |
| Age:21 YR | Gender:Male | I/FU:I | | | | | |
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Rectal Haemorrhage | Health | Concerta | PS | Alza Corp | ORAL |
| 18 - 54 MG PO | | | | | | | |
| | | | Professional | | | | |
| QD | | | | | | | |
| | | | | Aerobid | | C | |
| 18-Aug-2005 11:49 AM | | | | | | | |
| Page: 135 | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Serevent Inhaler C
 Maxair C

Date:03/05/01ISR Number: 3679492-1Report Type:Periodic Company Report #7773
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Muscle Twitching | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY | | | Health | | | | |
| ORAL | | | Professional | Singulair | C | | |
| | | | | Claritin | C | | |
| | | | | Proventil Inhaler | C | | |

Date:03/05/01ISR Number: 3679493-3Report Type:Periodic Company Report #7787
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Micturition Urgency | Health | Concerta | PS | Alza Corp | ORAL |
| 10 MG 1X/1DAY | | | Professional | | | | |
| ORAL | | Pollakiuria | | | | | |
| | | Urinary Incontinence | | | | | |

Date:03/05/01ISR Number: 3679494-5Report Type:Periodic Company Report #7788
 Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY | | | Health | | | | |
| ORAL | | Dyspepsia | | | | | |
| | | Flatulence | Professional | | | | |

Date:03/05/01ISR Number: 3679495-7Report Type:Periodic Company Report #7789
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Arrhythmia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG | | Hypertonia | | | | | |
| 1X/1DAY/ORAL | | Pharyngitis | | Paxil | C | | |

Date:03/05/01ISR Number: 3679496-9Report Type:Periodic Company Report #7790
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | |
| 54 MG QD > 72 | | | | | | | |
| MG QD | | | | | | | |

Date:03/05/01ISR Number: 3679497-0Report Type:Periodic Company Report #7791
Age:49 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X/1DAY | | | | | | | |
| ORAL | | | Health | | | | |
| | | | Professional | Celebrex | C | | |
| | | | | Glucophage | C | | |
| | | | | Actos | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3679498-2Report Type:Periodic Company Report #7792
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------|------------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyskinesia | Health | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1X/1 | | | Professional | | | | |
| DAY ORAL | | | Company Representative | | | | |

Date:03/05/01ISR Number: 3679499-4Report Type:Periodic Company Report #7793
 Age:14 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Emotional Disorder | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | Professional | | | | |
| ORAL | | Nervousness | | | | | |

Date:03/05/01ISR Number: 3679500-8Report Type:Periodic Company Report #7801
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | Health | | | | |
| ORAL | | Thinking Abnormal | Professional | Concerta (Oros Methylphenidate Hydrochloride) | SS | | |
| 1/2 18MG TAB | | | | | | | |
| 1X/1DAY | | | | | | | |

Date:03/05/01ISR Number: 3679501-XReport Type:Periodic Company Report #7802
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pruritus | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Skin Odour Abnormal | | | | | |
| ORAL | | | | Paxil | C | | |

Date:03/05/01ISR Number: 3679502-1Report Type:Periodic Company Report #7814
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cough | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Gastrointestinal Disorder | Health | | | | |
| ORAL | | Vomiting | Professional | | | | |

Date:03/05/01ISR Number: 3679503-3Report Type:Periodic Company Report #7815
 Age:34 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Respiratory Disorder | Consumer | Concerta | PS | Alza Corp | |
| DOSE AND | | | | | | | |
| FREQUENCY UNK | | | | Wellburtin | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3679504-5Report Type:Periodic Company Report #7819
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|---------------|--------------------|---------------|----------|------|--------------|-------|
| Other | 18MG-36MG-54M | Emotional Disorder | Consumer | Concerta | PS | Alza Corp | |
| G 1X/1DAY | | Headache | | | | | |

Date:03/05/01ISR Number: 3679505-7Report Type:Periodic Company Report #7823
 Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|----------|------|--------------|-------|
| Other | 36 MG | Convulsion | Consumer | Concerta | PS | Alza Corp | ORAL |
| 1X/1DAY, ORAL | | Headache | Health | | | | |
| | | | Professional | | | | |

Date:03/05/01ISR Number: 3679506-9Report Type:Periodic Company Report #7833
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|--------------|--------------|---------------|----------|------|--------------|-------|
| Other | 36MG/QD>36MG | Headache | Consumer | Concerta | PS | Alza Corp | |
| QAM & | | Hypertension | | | | | |
| 18MG@2PM | | | | Catapres | C | | |
| | | | | Tegretol | C | | |

Date:03/05/01ISR Number: 3679507-0Report Type:Periodic Company Report #7834
 Age:37 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | | |
|---------------|----------------|----------|----------|----|-----------|------|
| Other 72MG | Overdose | Consumer | Concerta | PS | Alza Corp | ORAL |
| 1X/1DAY,ORAL | Vision Blurred | | | | | |
| 20MG 4X/1DAY, | | | Ritalin | SS | | ORAL |
| PO | | | Creon 10 | C | | |
| | | | Librax | C | | |

Date:03/05/01ISR Number: 3679508-2Report Type:Periodic Company Report #7840
Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|-----------|------|--------------|-------|
| Other | | Abnormal Dreams | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Hallucination | Professional | | | | |
| ORAL | | | | Clonidine | C | | |

Date:03/05/01ISR Number: 3679509-4Report Type:Periodic Company Report #7843
Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------|---------------|-----------|------|--------------|-------|
| Other | | Headache | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG @ 7AM | | | | | | | |
| PO 5X/WK M-F | | | | Insulin | C | | |
| | | | | Rhinocort | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3679510-0Report Type:Periodic Company Report #7844
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Insomnia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1 X / 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3679511-2Report Type:Periodic Company Report #7909
 Age:48 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Coordination Abnormal | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X / | | | | | | | |
| 1D, ORAL | | | | | | | |
| Dizziness | | | | | | | |
| Thinking Abnormal | | | | | | | |

Date:03/05/01ISR Number: 3679512-4Report Type:Periodic Company Report #7911
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Face Oedema | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X / 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| Pruritus | | | | | | | |
| Tongue Oedema | | | | | | | |
| Urticaria | | | | | | | |
| 2 TO 3 18 MG | | | | | | | |
| TABS 1X / 1 | | | | | | | |
| DAY | | | | | | | |
| Concerta (Oros Methylphenidate Hydrochloride) | | | | | | | |
| SS | | | | | | | |
| 18 MG 1X / 1 | | | | | | | |
| Concerta (Oros Methylphenidate Hydrochloride) | | | | | | | |
| SS | | | | | | | |
| ORAL | | | | | | | |

DAY, PO

Nortriptyline

C

Date:03/05/01ISR Number: 3679513-6Report Type:Periodic Company Report #7912
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | |

Date:03/05/01ISR Number: 3679514-8Report Type:Periodic Company Report #7916
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------|----------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1X / 1 | | Chest Pain | Company | | | | |
| DAY, ORAL | | Ear Pain | Representative | | | | |
| | | Tinnitus | | | | | |
| | | Vertigo | | | | | |

Date:03/05/01ISR Number: 3679515-XReport Type:Periodic Company Report #7917
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1XC/ 1 | | Cough | | | | | |
| DAY, ORAL | | Headache | | | | | |
| | | Pharyngitis | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3679516-1Report Type:Periodic Company Report #7928
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Muscle Twitching | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1X / 1 | | | Health | | | | |
| DAY, PO | | | Professional | | | | |

Date:03/05/01ISR Number: 3679517-3Report Type:Periodic Company Report #7929
 Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1X / | | Anorexia | | | | | |
| 1DAY, PO | | Diarrhoea | | Concerta (Oros | | | |
| | | Flatulence | | Methylphenidate | | | |
| | | Headache | | Hydrochloride) | SS | | ORAL |
| 36 MG 1X / | | Weight Decreased | | | | | |
| 1DAY, ORAL | | | | Paxil | C | | |

Date:03/05/01ISR Number: 3679518-5Report Type:Periodic Company Report #7939
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X /1 | | Hypersensitivity | | | | | |
| DAY, PO | | Osteoarthritis | | Concerta (Oros | | | |
| | | | | Methylphenidate | | | |
| | | | | Hydrochloride) | SS | | ORAL |
| 18 MG 1X/ 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3679813-XReport Type:Periodic Company Report #10237
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------------|------------------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Epistaxis Headache Hypertension | Health Professional | Concerta (Methylphenidate Hcl) | PS | Alza Corp | |

Date:03/05/01ISR Number: 3679815-3Report Type:Periodic Company Report #7671
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - 1/2 TAB PO Initial or Prolonged X1/DAY Other | | Depersonalisation Headache Nausea | Health Professional Company Representative | Concerta | PS | Alza Corp | |

Date:03/05/01ISR Number: 3679817-7Report Type:Periodic Company Report #7684
 Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---|------------------------|-------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination Migraine Visual Disturbance | Health Professional Company Representative | Concerta Zyrtec | PS C | Alza Corp | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3679820-7Report Type:Periodic Company Report #7706
 Age:18 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54MG 1X/1DAY | | Confusional State | Health | | | | |
| , ORAL | | Insomnia | Professional | Wellbutrin | C | | |
| | | Speech Disorder | | | | | |

Date:03/05/01ISR Number: 3679823-2Report Type:Periodic Company Report #7711
 Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------------|----------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X /1 | | Face Oedema | Professional | | | | |
| DAY ORAL | | Headache | Company | | | | |
| | | Laryngeal Oedema | Representative | | | | |
| | | Palpitations | | | | | |
| | | Pruritus | | | | | |
| | | Urticaria | | | | | |

Date:03/05/01ISR Number: 3680459-8Report Type:Periodic Company Report #10024
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia | Consumer | Concerta | PS | Alza Corp | |
| 18MG-72MG PO | | Asthenia | | | | | |
| 1X/1 DAY | | Insomnia | | | | | |

Date:03/05/01ISR Number: 3680460-4Report Type:Periodic Company Report #10036
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Paraesthesia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54 MG 1X/1 | | | Health | | | | |
| DAY, ORAL | | | Professional | Concerta (Oros Methylphenidate Hydrochloride) | SS | | |
| 18 MG TO 36 | | | | | | | |
| MG 1X/1DAY | | | | | | | |

Date:03/05/01ISR Number: 3680461-6Report Type:Periodic Company Report #10039
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Headache | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X/1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3680466-5Report Type:Periodic Company Report #10045
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1X/1DAY | | Face Oedema | Health | | | | |
| , ORAL | | | Professional | Allergy Shots (Nos) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3680471-9Report Type:Periodic Company Report #10046
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|-------------|----------------|---------------|----------|------|--------------|-------|
| Other | 18 MG 1X/ 1 | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3680472-0Report Type:Periodic Company Report #10047
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|------------|------------------|---------------|---|------|--------------|-------|
| Other | 36 MG 1X/1 | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | ORAL |
| DAY, ORAL | | | | | | | |
| | | | | Concerta (Oros Methylphenidate Hydrochloride) | SS | | ORAL |
| 18 MG, 1X/1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3680473-2Report Type:Periodic Company Report #10049
 Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|------------|----------------------|---------------|----------|------|--------------|-------|
| Other | 18 MG 1X/1 | Personality Disorder | Consumer | Concerta | PS | Alza Corp | ORAL |
| DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3680474-4Report Type:Periodic Company Report #10104
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| | | | | | | | |

| | | | | | | |
|---------------------|--------------------------|--------------|-----------|----|-----------|------|
| Other 36 MG 1X/1 | Angioneurotic Oedema | Health | Concerta | PS | Alza Corp | ORAL |
| DAY, ORAL | Dermatitis | Professional | | | | |
| | Face Oedema Urticaria | | Clonidine | C | | |

Date:03/05/01ISR Number: 3680475-6Report Type:Periodic Company Report #10105
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|--------------|---------------|-----------|------|--------------|-------|
| Dose Other 18 MG | | Agitation | Consumer | Concerta | PS | Alza Corp | ORAL |
| 1X/1DAY, ORAL | | Anxiety | | | | | |
| | | Eye Disorder | | Singulair | C | | |

Date:03/05/01ISR Number: 3680476-8Report Type:Periodic Company Report #10115
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose Other 36 MG 1X/1 | | Vomiting | Consumer | Concerta | PS | Alza Corp | ORAL |
| DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3681337-0Report Type:Periodic Company Report #7942
 Age:17 YR Gender:Female I/FU:I

| | |
|------------------|---|
| Outcome Other | PT Chills Face Oedema Pruritus |
|------------------|---|

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Urticaria

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------------|----------|------|--------------|-------|
| 35 MG 1X/1 | | Consumer | Concerta | PS | Alza Corp | ORAL |
| DAY, ORAL | | | Tylenol | C | | |

Date:03/05/01ISR Number: 3681338-2Report Type:Periodic Company Report #7975
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | Consumer | Concerta | PS | Alza Corp | ORAL |
| Other | | Drug Ineffective | | | | | |
| 18 MG | | Insomnia | | | | | |
| 1X/1DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3681339-4Report Type:Periodic Company Report #7979
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------------|---|------|--------------|-------|
| Dose | | | Health Professional | Concerta (Oros Methylphenidate Hydrochloride) | PS | | ORAL |
| Other | | Headache | | | | | |
| 36 MG | | | | | | | |
| 1X/1DAY, ORAL | | | | | | | |

Date:03/05/01ISR Number: 3681340-0Report Type:Periodic Company Report #7985
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | Consumer | Concerta | PS | Alza Corp | ORAL |
| Other | | Dizziness | | | | | |
| 36 MG 1X/DAY, | | Headache | | | | | |
| ORAL | | | | | | | |

Vomiting

Paxil

C

Date:03/05/01ISR Number: 3681341-2Report Type:Periodic
Age:15 YR Gender:Not SpecifiI/FU:I

Company Report #7986

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | Consumer | Concerta | PS | Alza Corp | |
| 1-18 MG TAB | | Anxiety | | | | | |
| 1X/DAY | | Hyperhidrosis | | Concerta (Oros | | | |
| | | Nervousness | | Methylphenidate | | | |
| 18 MG | | | | Hydrochloride) | SS | | ORAL |
| 1X/1DAY, PO | | | | Zoloft | C | | |

Date:03/05/01ISR Number: 3681342-4Report Type:Periodic
Age:7 YR Gender:Male I/FU:I

Company Report #7987

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | Consumer | Concerta | PS | Alza Corp | |
| 18 MG TAB | | Anxiety | | | | | |
| 1X/1DAY | | Hostility | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3681343-6Report Type:Periodic Company Report #7989
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG | | Arrhythmia | | | | | |
| 1X/1DAY, ORAL | | Constipation | | | | | |
| | | Dyspnoea | | | | | |

Date:03/05/01ISR Number: 3681344-8Report Type:Periodic Company Report #7990
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Nausea | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 - 36 MG PO | | Overdose | | | | | |
| 1X/1DAY | | Tachycardia | | Serevent | C | | |
| | | Vasodilatation | | Singulair | C | | |
| | | | | Proventil | C | | |

Date:03/05/01ISR Number: 3681345-XReport Type:Periodic Company Report #7991
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Paraesthesia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54 MG 1X/DAY, | | Pruritus | | | | | |
| ORAL | | | | | | | |

Date:03/05/01ISR Number: 3681346-1Report Type:Periodic Company Report #7992
 Age:34 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | | |
|-------------------------|-------------------------------------|----------|---|----|-----------|------|
| Other 36MG TAB-1 | Constipation | Consumer | Concerta | PS | Alza Corp | |
| 1/21X/1DAY | Drug Ineffective | | | | | |
| | Gastrointestinal Disorder Tremor | | Concerta (Oros Methylphenidate Hydrochloride) | SS | | ORAL |
| 36MG 1X/1DAY, PO | | | | | | |

Date:03/05/01ISR Number: 3681358-8Report Type:Periodic Company Report #7996
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|----------|----------------|------------------------|----------|------|--------------|-------|
| Other 36MG 1X/1 DAY, ORAL | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| | | | Health Professional | Allegra | C | | |

Date:03/05/01ISR Number: 3681359-XReport Type:Periodic Company Report #7998
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|--|---------------|----------|------|--------------|-------|
| Other 1TAB1X/1DAY-2 TAB1X/1DAY | | Abdominal Pain Anorexia Depression Insomnia Weight Decreased | Consumer | Concerta | PS | Alza Corp | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3681360-6Report Type:Periodic Company Report #7999
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|----------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anaphylactic Reaction | Health | Concerta | PS | Alza Corp | ORAL |
| 36 MG | | Dermatitis | Professional | | | | |
| 1X/1DAY, PO | | Dyspnoea | Company | Concerta (Oros | | | |
| | | Face Oedema | Representative | Methylphenidate | | | |
| | | | | Hydrochloride) | SS | | ORAL |
| 18MG 1X/1DAY, | | | | | | | |
| ORAL | | | | | | | |

Date:03/05/01ISR Number: 3681361-8Report Type:Periodic Company Report #10001
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Halitosis | Consumer | Concerta | PS | Alza Corp | |
| 18MG - 72 MG | | Stomatitis | | | | | |
| 1X/1DAY | | | | | | | |

Date:03/05/01ISR Number: 3681362-XReport Type:Periodic Company Report #10002
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG - 54MG | | Hostility | | | | | |
| PO 1X/1 DAY | | | | | | | |

Date:03/05/01ISR Number: 3681363-1Report Type:Periodic Company Report #10014
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|--------------|-------------------|----------|----------|----|-----------|
| Other | Anorexia | Consumer | Concerta | PS | Alza Corp |
| 36MG TO 18MG | | | | | |
| | Insomnia | | | | |
| 1X/1 DAY | | | | | |
| | Pain In Extremity | | | | |
| | Sedation | | | | |

Date:03/05/01ISR Number: 3681364-3Report Type:Periodic Company Report #10015
 Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis | Consumer | Concerta | PS | Alza Corp | |
| 18MG - 36 MG | | | | | | | |
| | | Headache | | | | | |
| QD | | | | | | | |
| | | Muscle Twitching | | Benzamycin | C | | |
| | | Skin Discolouration | | | | | |

Date:03/05/01ISR Number: 3681365-5Report Type:Periodic Company Report #10016
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cough | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54MG 1X/1DAY, | | | | | | | |
| ORAL | | Sinusitis | | | | | |
| | | Upper Respiratory Tract | | | | | |
| | | Infection | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/01ISR Number: 3681366-7Report Type:Periodic Company Report #10017
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|-----------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | 72MG TO 36 MG | Anorexia | Consumer | Concerta | PS | Alza Corp | ORAL |
| | PO 1X/1DAY | Dyspepsia | | | | | |
| | | | | Imipramine | C | | |
| | | | | Clonidine | C | | |

Date:03/05/01ISR Number: 3681367-9Report Type:Periodic Company Report #10023
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | 18MG 1X/1DAY, | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| | ORAL | Anorexia | | | | | |
| | | Emotional Disorder | | | | | |

Date:03/12/01ISR Number: 3681651-9Report Type:Expedited (15-DaCompany Report #PHBS2001AR02330
 Age:15 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------------|---|---------------------------------|---------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | 10 MG ONCE | Blood Pressure Increased Body Temperature Increased | Foreign Literature Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| | ORAL | Circulatory Collapse Cyanosis Hallucination, Visual Heart Rate Decreased Medication Error Respiratory Depression | Professional Other | | | | |

Date:03/14/01ISR Number: 3680933-4Report Type:Expedited (15-DaCompany Report #PHEH2001US02106
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---------------------------------------|---------------|--------------------------------------|------|----------------------------------|-------|
| Death | | Abnormal Behaviour Anxiety | Consumer | Ritalin | PS | Novartis Pharmaceuticals Corp | |
| 2555 DAY | | Completed Suicide Depression | | Prozac (Fluoxetine Hydrochloride) | SS | | |
| 2555 DAY | | Drug Dependence Personality Change | | | | | |

Date:03/14/01ISR Number: 3680974-7Report Type:Expedited (15-DaCompany Report #PHEH2001US02103
Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--------------------------------|--|------------------------|-------------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged | 55 MG QAM, 15 MG Q PM, ORAL | Headache Hypoaesthesia Loss Of Consciousness | Health Professional | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:03/14/01ISR Number: 3681714-8Report Type:Expedited (15-DaCompany Report #PHNU2001DE00642
Age:9 YR Gender:Female I/FU:F

| Outcome | PT |
|--|---|
| Hospitalization - Initial or Prolonged Other | Drug Ineffective Haematoma Idiopathic |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Thrombocytopenic Purpura

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-----------------------------|--|------|-------------------------------|-------|
| 20MG/DAY, ORAL | | Foreign Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 20 MG, QD, ORAL | | Other | Ritalin-Sr(Methylphenidate Hydrochloride)Slow Release Tablet, 20mg | SS | | ORAL |
| | | | Zyrtec (Cetirizine Hydrochloride) | C | | |

Date:03/19/01ISR Number: 3683421-4Report Type:Direct Company Report #USP 53796
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|-------------------------------------|----------|--------------|-------|
| Dose Other | | Medication Error | | Metadate Er Methadone Hydrochloride | PS SS | Medava | |

Date:03/20/01ISR Number: 3685655-1Report Type:Expedited (15-DaCompany Report #10405
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------|---------------------|------------------------|--------|--------------|-------|
| Hospitalization - 18 MG 1X/1 Initial or Prolonged DAY, ORAL | | Convulsion | Health Professional | Concerta | PS | Alza Corp | ORAL |
| 450 MG 1X/1 DAY, PO | | Drug Interaction | Other | Wellbutrin | SS | | ORAL |
| | | | | Doxycycline Acne Cream | C C | | |

Date:03/20/01ISR Number: 3685775-1Report Type:Expedited (15-DaCompany Report #001-0073-M0100130
Age:20 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|--|----------------------|--------------------------------------|-------|
| Hospitalization - Initial or Prolonged PER ORAL | | Blood Albumin Decreased Convulsion | Consumer | Dilantin | PS | Parke Davis Div Warner Lambert Co | ORAL |
| Other | | Drug Interaction Drug Level Below Therapeutic Hypoventilation Pneumonia Sinusitis Status Epilepticus Urinary Tract Infection | | Methylphenidate (Methylphenidate) Hydrocortisone (Hydrocortisone) Testosterone (Testosterone) Levothyroxine (Levothyroxine) | SS SS SS SS | | |

Date:03/27/01ISR Number: 3690489-8Report Type:Expedited (15-DaCompany Report #10397
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|----------|-------------------------|---------------|--------------------------------------|------|--------------|-------|
| Other 36MG 1X/1 DAY, ORAL | | Hallucination, Auditory | Consumer | Concerta | PS | Alza Corp | ORAL |
| | | | | Concerta (Methylphenidate Hcl) | SS | | ORAL |

18MG 1X/1DAY,

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

ORAL

Date:03/27/01ISR Number: 3690491-6Report Type:Expedited (15-DaCompany Report #10438
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | Health | Concerta | PS | Alza Corp | |
| 54 (>THAN 10 PILLS) | | | Professional | | | | |

Date:03/27/01ISR Number: 3690649-6Report Type:Direct Company Report #
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression Anger Anxiety | | Methylphenidate | PS | | |

Date:03/28/01ISR Number: 3691922-8Report Type:Expedited (15-DaCompany Report #10451
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|------------------------|--|------------------------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - 36 MG QAM + Initial or Prolonged 18 MG Q NOON | | Aggression Agitation Irritability | Health Professional | Concerta Risperdal Clonidine Albuterol Dexedrine | PS C C C C | Alza Corp | |

Date:03/28/01ISR Number: 3691925-3Report Type:Expedited (15-DaCompany Report #10449
Age:15 YR Gender:Male I/FU:I

| | | | | | | | |
|----------------------|--------------|--------------------|---------------|-------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Hospitalization - | 54 MG 1 | Abnormal Behaviour | Health | Concerta | PS | Alza Corp | ORAL |
| Initial or Prolonged | X/1DAY, ORAL | Aggression | Professional | Zyprexa | C | | |
| | | | | Depakote Er | C | | |

Date:03/29/01ISR Number: 3692637-2Report Type:Expedited (15-DaCompany Report #10456
Age:9 YR Gender:Male I/FU:I

| | | | | | | | |
|----------------------|-------------|--------------------|---------------|------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Hospitalization - | 108 MG 1X 1 | Abnormal Behaviour | Health | Concerta | PS | Alza Corp | |
| Initial or Prolonged | DAY | Anxiety | Professional | | | | |
| | | Dysarthria | | Wellbutrin | C | | |
| | | Grunting | | Dexedrine | C | | |
| | | Lethargy | | Desyrel | C | | |
| | | Respiratory Rate | | Methylin | C | | |
| | | Increased | | | | | |

Date:04/02/01ISR Number: 3694653-3Report Type:Expedited (15-DaCompany Report #PHFR2001GB01061
Age:12 YR Gender:Male I/FU:I

| | | |
|----------------------|------------------------|---------------|
| Outcome | PT | Report Source |
| Hospitalization - | Allergic Granulomatous | Foreign |
| Initial or Prolonged | Angiitis | Health |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Professional
Other

| Dose | Duration | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|--------|-------------------------------|-------|
| 25 MG/D, ORAL | | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| | | Beclometasone Ventolin | C C | | |

Date:04/02/01ISR Number: 3694683-1Report Type:Expedited (15-DaCompany Report #PHNU2001DE004778
Age:7 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|-------------|--|--------------------------------|---------|------|-------------------------------|-------|
| Life-Threatening | 1-0.5, ORAL | Cardiomegaly Pulmonary Hypertension | Foreign Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:04/03/01ISR Number: 3695478-5Report Type:Expedited (15-DaCompany Report #10502
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|----------|------------------------|----------|------|--------------|-------|
| Death | 1X/1DAY, ORAL | Overdose | Health Professional | Concerta | PS | Alza Corp | ORAL |

Date:04/05/01ISR Number: 3698250-5Report Type:Expedited (15-DaCompany Report #10503
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------------------------|---|---------------|----------|------|--------------|-------|
| Other | 36-54MG 1 X / 1 DAY | Abdominal Pain Upper Blood Bilirubin Increased Diarrhoea Hepatitis B Surface | Consumer | Concerta | PS | Alza Corp | |

Antigen Positive
Jaundice
Ph Urine Increased
Vomiting
White Blood Cells Urine
Positive

Date:04/06/01ISR Number: 3700272-2Report Type:Expedited (15-DaCompany Report #MPU-2001-00156 (0)
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------------------------|---------------|---|------------------|--------------------------|-------|
| Hospitalization - Initial or Prolonged 25MG DAILY | | Allergic Granulomatous Angiitis | Foreign | Methylphenidate Hcl Beclomethasone Dipropionate Ventolin (Salbutamol) | PS C C | Md Pharmaceutical Inc | |

Date:04/12/01ISR Number: 3704071-7Report Type:Expedited (15-DaCompany Report #10449
Age:15 YR Gender:Male I/FU:F

| Outcome | PT |
|---|---|
| Hospitalization - Initial or Prolonged | Abnormal Behaviour Aggression Agitation |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Irritability

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|------------------------|-------------|------|--------------|-------|
| 54MG 1X/1DAY, ORAL | | Health Professional | Concerta | PS | Alza Corp | ORAL |
| | | | Zyprexa | C | | |
| | | | Depakote Er | C | | |

Date:04/12/01ISR Number: 3704072-9Report Type:Expedited (15-DaCompany Report #10451
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|-------------|------|--------------|-------|
| Hospitalization - 36 MG GAM + Initial or Prolonged 18MG Q NOON | | Aggression Agitation Irritability | Health Professional | Concerta | PS | Alza Corp | |
| | | | | Risperdal | C | | |
| | | | | Clonidine | C | | |
| | | | | Albuterol | C | | |
| | | | | Dexedrine | C | | |
| | | | | Theophyl-Sr | C | | |

Date:04/13/01ISR Number: 3704415-6Report Type:Direct Company Report #
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|--|----------|--------------|-------|
| Life-Threatening 5 MG & X3 Hospitalization - 0.25MQ0.10 Initial or Prolonged X1X1 Disability Required Intervention to Prevent Permanent Impairment/Damage | | Aggression Catatonia Depression Dry Mouth Growth Retardation Headache Keratoconjunctivitis Sicca Mania | | Ritalin 5 Mg&10 Mg Clonidine 0.5 Mg | PS SS | | |

Mood Swings
 Palpitations
 Psychomotor Hyperactivity
 Pyrexia
 Sleep Disorder
 Vision Blurred
 Weight Gain Poor

Date:04/13/01ISR Number: 3705111-1Report Type:Expedited (15-DaCompany Report #10597
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|----------|------|--------------|-------|
| Hospitalization - 54MG (36MG + Initial or Prolonged 18MG) 1X/DAY | | Abnormal Behaviour Aggression Anxiety | Health Professional | Concerta | PS | Alza Corp | |

Date:04/16/01ISR Number: 3705953-2Report Type:Expedited (15-DaCompany Report #PHFR2001GB01248
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------|--|---------|------|----------------------------------|-------|
| Dose Other | | Papilloedema | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/16/01ISR Number: 3706159-3Report Type:Expedited (15-DaCompany Report #PHBS2001JP00910

Age:3 DY Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|---------------|---|-----------------------------------|---|------|----------------------------------|-------|
| Dose Other | | Complications Of Maternal Exposure To Therapeutic Drugs | Foreign Health Professional | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |
| | | Convulsion Neonatal Dyskinesia Jaundice Neonatal | Other | Anafranil(Clomiprami ne Hydrochloride) Tablet | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |
| | | | | Wintermin(Chlorproma zine Hydrochloride) | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |
| | | | | Serenace(Haloperidol) | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |
| | | | | Contomin(Chlorpromaz ine | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |
| | | | | Artane (Trihexyphenidyl Hydrochloride) | SS | | |
| TRANSPLACENTAL L | TRANSPLACENTA | | | | | | |

Date:04/17/01ISR Number: 3707365-4Report Type:Expedited (15-DaCompany Report #10600

Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose Other | | Dyssomnia | Consumer | Concerta | PS | Alza Corp | |
| 36 MG 1X/1DAY | | | | | | | |

18 MG

Concerta
(Methylphenidate
Hcl)

SS

ORAL

1X/1DAY, ORAL

Prozac

C

Date:04/19/01ISR Number: 3708275-9Report Type:Expedited (15-DaCompany Report #10585

Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | |
| Other | | Agitation | | | | | |
| | | Arthralgia | | | | | |
| | | Decreased Appetite | | | | | |
| | | Dysarthria | | | | | |
| | | Dyskinesia | | | | | |
| | | Headache | | | | | |
| | | Heart Rate Increased | | | | | |
| | | Hyperhidrosis | | | | | |
| | | Muscle Twitching | | | | | |
| | | Nervousness | | | | | |
| | | Palpitations | | | | | |
| | | Pruritus | | | | | |
| | | Pulse Pressure Increased | | | | | |
| | | Tremor | | | | | |
| | | Vision Blurred | | | | | |
| | | Visual Disturbance | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/19/01ISR Number: 3708276-0Report Type:Expedited (15-DaCompany Report #10502
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|---------------------------------|---------------|----------|------|--------------|-------|
| Death | | Abnormal Behaviour | Health | Concerta | PS | Alza Corp | ORAL |
| 54MG 1X/1DAY, ORAL | | Cardiac Disorder | Professional | | | | |
| | | Coma | | | | | |
| | | Drug Level Above Therapeutic | | | | | |
| | | Hepatic Steatosis | | | | | |
| | | Overdose | | | | | |
| | | Pulmonary Congestion | | | | | |
| | | Pulmonary Oedema | | | | | |

Date:04/20/01ISR Number: 3708677-0Report Type:Expedited (15-DaCompany Report #10598
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------------|---------------|--------------|------|--------------|-------|
| Other | | Anger | Health | Concerta | PS | Alza Corp | ORAL |
| 18 MG | | Bipolar Disorder | Professional | | | | |
| 1X/1DAY, ORAL | | Condition Aggravated | | Multivitamin | C | | |
| | | Depressed Mood | | | | | |
| | | Depression | | | | | |
| | | Disturbance In Attention | | | | | |
| | | Educational Problem | | | | | |
| | | Feeling Abnormal | | | | | |
| | | Insomnia | | | | | |
| | | Nightmare | | | | | |
| | | Suicidal Ideation | | | | | |
| | | Thinking Abnormal | | | | | |

Date:04/24/01ISR Number: 3710572-8Report Type:Expedited (15-DaCompany Report #PHFR2001GB01262
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-----------------|---------------|---------|------|--------------|-------|
| Life-Threatening | | Medulloblastoma | Foreign | Ritalin | PS | Novartis | |

ORAL

Health

Pharmaceuticals Corp ORAL

Professional

Other

Date:04/30/01ISR Number: 3715284-2Report Type:Expedited (15-DaCompany Report #PHNU2000DE02259

Age:44 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|---|-------------------|---------|------|----------------------------------|-------|
| Life-Threatening | | Cardiomegaly Cerebral Ischaemia | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 2 DF, TID, | | Coma | Professional | | | | |
| ORAL | | Congestive Cardiomyopathy Dyspnoea Heart Rate Increased Hyperhidrosis Hypoxia Ventricular Fibrillation | Other | | | | |

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| | | | | | |
|---|----------------------------------|------------------------|--|--------|--------------------------|
| Hospitalization - Initial or Prolonged 90MG DAILY | Obsessive-Compulsive Disorder | Foreign Literature | Methylphenidate Hcl | PS | Md Pharmaceutical Inc |
| | Theft | Health Professional | Sertraline (Sertraline) Clonidine (Clonidine) | C C | |

Date:05/03/01ISR Number: 3717120-7Report Type:Expedited (15-DaCompany Report #PHNU2000DE01232
Age: Gender:Male I/FU:F

| Outcome Dose Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------------------------|--|-------------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged ORAL | Chest Pain Cyanosis | Foreign Health Professional Other | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:05/03/01ISR Number: 3717369-3Report Type:Expedited (15-DaCompany Report #10502
Age:13 YR Gender:Male I/FU:F

| | |
|------------------|---|
| Outcome Death | PT Bicuspid Aortic Valve Cardiomegaly Coma Drug Toxicity Hepatic Steatosis |
|------------------|---|

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|-----------------------|----------|--|------------------------|------------------------|---------|--------------|-------|
| Dose | Duration | Overdose Pulmonary Congestion Pulmonary Oedema | Report Source | Product | Role | Manufacturer | Route |
| 54MG 1X/1DAY, ORAL | | | Health Professional | Concerta Wellbutrin | PS C | Alza Corp | ORAL |

Date:05/07/01ISR Number: 3718237-3Report Type:Expedited (15-DaCompany Report #MPI-2001-05047 (0)
Age:15 YR Gender:Female I/FU:I

| | | | | | | | |
|--|----------|--|---|---------------------|------|--------------------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Hospitalization - Initial or Prolonged 10 MG ONCE Required Intervention to Prevent Permanent Impairment/Damage | | Blood Pressure Increased Body Temperature Increased Circulatory Collapse Cyanosis Hallucination, Visual Pulse Absent Respiratory Arrest | Foreign Literature Health Professional | Methylphenidate Hcl | PS | Md Pharmaceutical Inc | |

Date:05/07/01ISR Number: 3718639-5Report Type:Expedited (15-DaCompany Report #10723
Age:10 YR Gender:Male I/FU:I

| | | | | | | | |
|--|----------|---|------------------------|---------------------------------|--------------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Hospitalization - 18 MG 1X/1DAY Initial or Prolonged ORAL | | Headache Lethargy Pyrexia Sinusitis Tachycardia | Health Professional | Concerta Zoloft Clonidine | PS C C | Alza Corp | ORAL |

Date:05/08/01ISR Number: 3718338-XReport Type:Expedited (15-DaCompany Report #259738
Age:44 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Anaemia | | Trimethoprim | PS | Roche | |
| 8 | DAY | | | | | | |
| | | Leukopenia | | Ritalin | SS | | |
| 11 | DAY | | | | | | |
| | | Purpura | | Lansoprazole | C | | |
| | | Thrombocytopenia | | Lorazepam | C | | |
| 18 | DAY | | | Citalopram | C | | |
| | | | | Dexamethasone | C | | |
| DOSE | | | | | | | |
| VARIABLE. | | | | | | | |
| | | | | Co-Danthramer | C | | |
| 8 | DAY | | | | | | |
| | | | | Atenolol | C | | |
| 7 | DAY | | | | | | |
| | | | | Diamorphine | C | | |
| VARIABLE | | | | | | | |
| DOSE. | 36 | DAY | | | | | |
| | | | | Metoclopramide | C | | |
| 29 | DAY | | | | | | |
| | | | | Haloperidol | C | | |
| 67 | DAY | | | | | | |
| | | | | Magnesium | C | | |
| 67 | DAY | | | | | | |

Date:05/08/01ISR Number: 3718816-3Report Type:Direct Company Report #
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Claritin Reditab | PS | | ORAL |
| 1 PO X 1 ONLY | | | | | | | |
| | | Muscle Twitching | | Ritalin | SS | | |
| 7MG BID | | | | | | | |
| | | Psychotic Disorder | | | | | |
| | | Self Mutilation | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/08/01ISR Number: 3719318-0Report Type:Expedited (15-DaCompany Report #PHBS2000AU08649
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------|--|-------------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged 10 MG/DAY, ORAL | | Aplastic Anaemia | Foreign Health Professional Other | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:05/08/01ISR Number: 3719700-1Report Type:Expedited (15-DaCompany Report #10503
 Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|--|--|----------|------|--------------|-------|
| Other 36-54MG 1X/1DAY | | Abdominal Pain Upper Blood Bilirubin Increased Diarrhoea Hepatitis B Surface Antigen Positive Jaundice Nausea Ph Urine Increased Urine Analysis Abnormal Vomiting | Consumer Health Professional | Concerta | PS | Alza Corp | |

Date:05/09/01ISR Number: 3720421-XReport Type:Expedited (15-DaCompany Report #10739
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|--|----------|------|--------------|-------|
| Other 72 MG (1-36 MG+2-18 MG)/DAY | | Condition Aggravated Nephrolithiasis | Literature Health Professional | Concerta | PS | Alza Corp | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|--------------|---|------------------|---|------|--------------------------|-------|
| Life-Threatening | 200 MG 2 PER | Anaemia Folate Deficiency | Foreign Other | Trimpex | PS | Hoffmann La Roche Inc | ORAL |
| | DAY ORAL | Leukopenia | | | | | |
| | 15 MG 2 PER | Purpura Serum Ferritin Increased Thrombocytopenia | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |
| | DAY ORAL | Vitamin B12 Increased | | | | | |
| | | | | Lansoprazole (Lansoprazole) | C | | |
| | | | | Lorazepam (Lorazepam) | C | | |
| | | | | Citalopram (Citalopram) | C | | |
| | | | | Dexamethasone (Dexamethasone) | C | | |
| | | | | Co-Danthramer (Danthopron/Poloxamer) | C | | |
| | | | | Atenolol (Atenolol) | C | | |
| | | | | Diamorphine (Diacetylmorphine) | C | | |
| | | | | Metoclopramide (Metoclopramide) | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hydrochloride) C
 Haloperidol
 (Haloperidol) C
 Magnesium (Magnesium
 Nos) C

Date:05/10/01ISR Number: 3720724-9Report Type:Expedited (15-DaCompany Report #PHEH2001US02103
 Age:17 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|------------------------|---|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged 15 MG Q PM, ORAL | | Headache Hypoaesthesia Loss Of Consciousness Visual Disturbance | Health Professional | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |
| 40 MG, QD | | | | Methylphenidate (Methylphenidate Hydrochloride) Slow Release Tablet | SS | | |

Date:05/11/01ISR Number: 3722364-4Report Type:Direct Company Report #
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---|---------------|---------------------------|------|--------------|-------|
| Other CONCERTA PO | | Aggression Condition Aggravated | | Concerta 18/36 Mg Alza | PS | Alza | ORAL |
| ADDERRAL PO | | Hallucination, Visual Psychotic Disorder | | Adderral 2.5/5 Mg | SS | | ORAL |

Date:05/11/01ISR Number: 3722418-2Report Type:Expedited (15-DaCompany Report #PHNU1996DE00281
 Age:14 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--------------------------------|-------------------|---------|------|----------------------------------|-------|
| Life-Threatening ORAL | | Aplastic Anaemia Leukopenia | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |

Thrombocytopenia

Professional

Other

Date:05/14/01ISR Number: 3724080-1Report Type:Expedited (15-DaCompany Report #PHNU2000DE02259

Age:44 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|-------------------|---------|------|----------------------------------|-------|
| Life-Threatening | | Cardiomegaly Cerebral Ischaemia | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 90 MG/DAY, ORAL | | Coma | Professional | | | | |
| | | Congestive Cardiomyopathy Dyspnoea Heart Rate Increased Hyperhidrosis Hypoxia Ventricular Fibrillation | Other | | | | |

Date:05/14/01ISR Number: 3724103-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP04522

Age:28 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|-------------|-------------------|---------|------|----------------------------------|-------|
| Other | | Drug Abuser | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | NASAL |
| MORE THAN 100 MG, NASAL | | | Professional | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Lexotan (Bromazepam) C
 Serenace C
 Restas
 (Flutoprazepam) C

Date:05/24/01ISR Number: 3728689-0Report Type:Expedited (15-DaCompany Report #PHNU2001DE01271
 Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|-------------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged 0.75 DF, 5QD, ORAL | | Back Pain Benign Intracranial Hypertension Brain Oedema Diplopia | Foreign Health Professional Other | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:05/25/01ISR Number: 3729295-4Report Type:Expedited (15-DaCompany Report #PHFR2001GB01248
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------|--|---------|------|----------------------------------|-------|
| Other ORAL | | Papilloedema | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:05/25/01ISR Number: 3730539-3Report Type:Expedited (15-DaCompany Report #PHNU2001DE01271
 Age:11 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|--------------------------|-------------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged 0.75 DF, 5QD, ORAL | | Back Pain Benign Intracranial Hypertension Brain Oedema Diplopia | Foreign Health Professional Other | Ritalin Jodthyrox | PS C | Novartis Pharmaceuticals Corp | ORAL |

Hormone Level Abnormal

Date:05/29/01ISR Number: 3730093-6Report Type:Expedited (15-DaCompany Report #MPI-2001-05385(0)
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|------------------------|-------------|------|---------------------------------|-------|
| Hospitalization - Initial or Prolonged 90 MG, OVER 12 HRS, PO | | Adjustment Disorder With Depressed Mood Delirium Dysarthria Eye Rolling Malaise | Health Professional | Metadate Er | PS | Celltech Pharmaceuticals Inc | ORAL |

Date:05/29/01ISR Number: 3731055-5Report Type:Periodic Company Report #PHEH2000US09485
Age:41 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|---|-------------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged 20 MG, QD, ORAL | | Blood Alkaline Phosphatase Increased Blood Bilirubin Increased Liver Function Test Abnormal | Health Professional | Ritalin-Sr Claritin (Loratadine) St. John;S Wort | PS C | Novartis Pharmaceuticals Corp | ORAL |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Hypericum
Perforatum) C
Kava "Ratiopharm"
(Kava-Kava Rhizoma) C

Date:05/29/01ISR Number: 3731058-0Report Type:Periodic Company Report #PHEH2000US09742
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------------|----------|----------------------------------|------------------------|----------------------|--------|----------------------------------|-------|
| Dose Other 30 MG, QD, ORAL | | Arthralgia Convulsion Fall | Health Professional | Methylphenidate Hcl | PS | Novartis Pharmaceuticals Corp | ORAL |
| 20 MG, QD, ORAL | | Gaze Palsy Headache | | Methylphenidate Hcl | SS | | ORAL |
| | | Myalgia | | Minocycline Aleve | C C | | |

Date:05/30/01ISR Number: 3730744-6Report Type:Expedited (15-DaCompany Report #MPU-2001-00181 (0)
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|-----------------------------------|---------------------|------|--------------------------|-------|
| Disability 10 MG (MORNING & MIDDAY), 5 MG (TEATIME), 2.5 MG | | Cyanosis Erythema Feeling Cold Skin Disorder | Foreign Health Professional | Methylphenidate Hcl | PS | Md Pharmaceutical Inc | |

Date:05/31/01ISR Number: 3731134-2Report Type:Expedited (15-DaCompany Report #261128
Age:17 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------|----------|--|---------------|-------------------------------|----------|--------------|-------|
| Other | | | Attention Deficit/Hyperactivity Disorder | | Accutane Capsules Concerta | PS SS | Roche | |
| 34 | DAY | | Leukopenia Thrombocytopenia | | | | | |

Date:06/01/01ISR Number: 3732249-5Report Type:Expedited (15-DaCompany Report #PHBS1999N008474
 Age:15 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------|----------|-----------------------------------|--------------------|--------------------------------|------|-------------------------------|-------|
| Other | | | Arterial Disorder Eye Disorder | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| ORAL | | | Migraine Papilloedema | Professional Other | Selo-Zok (Metoprolol Tartrate) | C | | |

Date:06/01/01ISR Number: 3732259-8Report Type:Expedited (15-DaCompany Report #PHNU2000DE02274
 Age:11 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|------|----------|--------------------------------|----------------|---------|------|-------------------------------|-------|
| Other | | | Electrocardiogram Qt Prolonged | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 10MG/DAY, | | | | Professional | | | | |
| ORAL | | | | Other | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3732278-1Report Type:Expedited (15-DaCompany Report #261128
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|------------------------------|--|------|----------------|-------|
| Dose | | | | | | | |
| Other | | Attention | Consumer | Accutane | PS | Hlr Technology | ORAL |
| ORAL | | Deficit/Hyperactivity Disorder Leukopenia | Health Professional Other | Concerta (Methylphenidate Hydrochloride) | SS | | ORAL |
| 36 MG DAILY | | Thrombocytopenia | | | | | |
| ORAL | | Viral Infection | | | | | |

Date:06/01/01ISR Number: 3733519-7Report Type:Periodic Company Report #7802
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------------------|---------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pruritus Skin Odour Abnormal | Consumer Health Professional | Concerta (Oros Methylphenidate Hydrochloride) | PS | Alza Corp | ORAL |
| 18MG 1X / | | | | | | | |
| 1DAY, ORAL | | | | Paxil | C | | ORAL |
| 10MG 1X / 1 | | | | | | | |
| DAY, PO | | | | | | | |

Date:06/01/01ISR Number: 3733521-5Report Type:Periodic Company Report #7987
Age:7 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------------------------|--------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation Anxiety Confusional State | Consumer Health Professional | Concerta (Methylphenidate Hcl) | PS | Alza Corp | |
| 54 MG (3-18MG | | Hostility | | | | | |
| TAB) 1X/1D | | | | | | | |

Date:06/01/01ISR Number: 3733523-9Report Type:Periodic Company Report #7990
 Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Accidental Overdose | Consumer | Concerta (Oros | | | |
| | | Asthenia | Health | Methylphenidate | | | |
| | | Headache | Professional | Hydrochloride) | PS | Alza Corp | |
| 72 MG X 1 | | Nausea | | | | | |
| DOSE | | Tachycardia | | Serevent | C | | |
| 2X / 1 DAY | | Vasodilatation | | | | | |
| PRESENT | | | | Singulair | C | | |
| 1 X / 1 DAY | | | | | | | |
| PRESENT | | | | Proventil | C | | |
| PRN PRESENT | | | | | | | |

Date:06/01/01ISR Number: 3733528-8Report Type:Periodic Company Report #7992
 Age:34 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Constipation | Consumer | Concerta (Oros | | | |
| | | Drug Ineffective | Health | Methylphenidate | | | |
| | | Gastrointestinal Disorder | Professional | Hydrochloride) | PS | Alza Corp | |
| 36MG TAB-1 | | Tremor | | | | | |
| 1/2 1X/ 1 DAY | | | | Concerta (Oros | | | |
| | | | | Methylphenidate | | | |
| | | | | Hydrochloride) | SS | | ORAL |
| 36MG 1X / 1 | | | | | | | |
| DAY, PO | | | | | | | |

| | | | | | | |
|-------------|--------------------------------------|------------------------------------|---|----|-----------|------|
| Other | Agitation Anxiety Eye Disorder | Consumer Health Professional | Concerta (Oros Methylphenidate Hydrochloride) | PS | Alza Corp | ORAL |
| 18MG 1X / 1 | | | | | | |
| DAY, ORAL | | | Singulair | C | | |
| PRN PRESENT | | | | | | |

Date:06/01/01ISR Number: 3733538-0Report Type:Periodic Company Report #10237
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------------------------|------------------------|--------------------------------------|------|--------------|-------|
| Other | | Epistaxis Headache Hypertension | Health Professional | Concerta (Methylphenidate Hcl) | PS | Alza Corp | |
| 36MG 1X / 1 | | | | | | | |
| DAY | | | | | | | |

Date:06/01/01ISR Number: 3733541-0Report Type:Periodic Company Report #10449
 Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------------------|------------------------|--------------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Condition Aggravated Hostility | Health Professional | Concerta (Methylphenidate Hcl) | PS | Alza Corp | ORAL |
| 54MG 1X / 1 | | | | | | | |
| DAY, ORAL | | | | Zyprexa | C | | |
| 500MG 1X / 1 | | | | | | | |
| DAY PRESENT | | | | Depakote | C | | |
| ER 500MG 1X / | | | | | | | |
| 1 DAY PRESENT | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3733543-4Report Type:Periodic Company Report #10451
 Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|--------------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Agitation Condition Aggravated Hostility | Health Professional | Concerta (Methylphenidate Hcl) | PS | Alza Corp | |
| 36 MG QAM + 18 MG Q NOON 1MG 2X / 1 DAY, PO PRESENT | | | | Risperdal | C | | ORAL |
| 0.1MG 1X / 1 DAY, PO PRESENT | | | | Clonidine | C | | ORAL |
| 2 PUFFS BID PRN PRESENT PRESENT | | | | Albuterol | C | | |
| 200 MG PRESENT | | | | Dexedrine | C | | |
| | | | | Theophyl-Sr | C | | |

Date:06/01/01ISR Number: 3733545-8Report Type:Periodic Company Report #10502
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------|----------|--------------------|------------------------|----------------------------------|------|--------------|-------|
| Death | | Intentional Misuse | Health Professional | Concerta (Methlphenidate Hcl) | PS | Alza Corp | ORAL |
| 54G 1X / 1 DAY, ORAL | | | | Wellbutrin | C | | |

Date:06/01/01ISR Number: 3733547-1Report Type:Periodic Company Report #10503
Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|------------------------------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Diarrhoea Jaundice | Consumer Health Professional | Concerta (Methylphenidate Hcl) | PS | Alza Corp | |
| 54MG 1X / 1 | | | | | | | |
| DAY | | Nausea Vomiting | | | | | |

Date:06/01/01ISR Number: 3733550-1Report Type:Periodic Company Report #10597
Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|---|-----------------------------------|------------------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | Hospitalization - Initial or Prolonged | Condition Aggravated Hostility | Health Professional | Concerta (Methylphenidate Hcl) | PS | Alza Corp | |
| 54MG (36MG + 18MG) 1X / 1 | | | | | | | |
| DAY | | | | | | | |

Date:06/01/01ISR Number: 3734201-2Report Type:Periodic Company Report #10274
Age:3 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|-----------------------|---------------|------------------------|---------------------------|----------|--------------|-------|
| Dose | | | | | | | |
| Other | 18MG 1X/1DAY, ORAL | Hallucination | Health Professional | Concerta Clonidine | PS SS | Alza Corp | ORAL |
| .1MG (2TAB QHS) - .1MG (QHS) | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Claritin C

Date:06/01/01ISR Number: 3734202-4Report Type:Periodic Company Report #10281
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Skin Discolouration | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54MG (3-18MG | | | Health | | | | |
| TABS) / DAY | | | Professional | | | | |

Date:06/01/01ISR Number: 3734203-6Report Type:Periodic Company Report #10282
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------|---|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Emotional Disorder Hostility | Health Professional Company Representative | Concerta | PS | Alza Corp | |

Date:06/01/01ISR Number: 3734204-8Report Type:Periodic Company Report #10290
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|---------------------|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alopecia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1DAY, | | | | | | | |
| ORAL | | | | Clonidine Zyrtec | C C | | |

Date:06/01/01ISR Number: 3734205-XReport Type:Periodic Company Report #10297
 Age:3 YR Gender:Female I/FU:I

| | | | | | | | |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Other | | Condition Aggravated | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Personality Disorder | | | | | |
| ORAL | | | | | | | |

Date:06/01/01ISR Number: 3734206-1Report Type:Periodic Company Report #10300
 Age:5 YR Gender:Male I/FU:I

| | | | | | | | |
|------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Other | | Anorexia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/ | | Nystagmus | | | | | |
| 1DAY, ORAL | | Tic | | | | | |
| | | Vision Blurred | | | | | |
| | | Visual Disturbance | | | | | |

Date:06/01/01ISR Number: 3734207-3Report Type:Periodic Company Report #10351
 Age:11 YR Gender:Male I/FU:I

| | | | | | | | |
|------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Other | | Dizziness | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/ | | Visual Disturbance | Health | | | | |
| 1DAY, ORAL | | | Professional | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734208-5Report Type:Periodic Company Report #10352
 Age:15 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------------|-------------------|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Confusional State | Consumer | Concerta | PS | Alza Corp | |
| 18MG 1X/ 1DAY | | Insomnia | Health Professional | Tylenol Motrin | C C | | |

Date:06/01/01ISR Number: 3734209-7Report Type:Periodic Company Report #10353
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|-----------------------------------|---------------|--|------------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Insomnia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/ 1DAY, ORAL | | Muscle Twitching | | | | | |
| | | Upper Respiratory Tract Infection | | Rynatan Mvi Acidophilos Vitamin C | C C C C | | |

Date:06/01/01ISR Number: 3734210-3Report Type:Periodic Company Report #10363
 Age:38 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|-----------|------------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Diarrhoea | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/ 1DAY, ORAL | | | Company Representative | | | | |

Date:06/01/01ISR Number: 3734211-5Report Type:Periodic Company Report #10367
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|---------------|----------------------|----------|----------|----|-----------|
| Other | Aggression | Consumer | Concerta | PS | Alza Corp |
| 54 MG | | | | | |
| (3-18,G)1X/1D | Condition Aggravated | | | | |
| AY | Drug Ineffective | | Prozac | C | |

Date:06/01/01ISR Number: 3734212-7Report Type:Periodic Company Report #10369
 Age:12 YR Gender:Male I/FU:I

| | | | | | | | |
|-----------|----------|------------------|---------------|----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Dermatitis | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1 | | Drug Ineffective | Health | | | | |
| DAY, ORAL | | | Professional | Ritalin | C | | |

Date:06/01/01ISR Number: 3734213-9Report Type:Periodic Company Report #10371
 Age:10 YR Gender:Male I/FU:I

| | | | | | | | |
|-----------|----------|----------|---------------|-----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Insomnia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1 | | | | | | | |
| DAY, ORAL | | | | Clonidine | C | | |
| | | | | Claritin | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734214-0Report Type:Periodic Company Report #10376
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Muscle Twitching | Consumer | Concerta | PS | Alza Corp | |
| ADHD | | | Health Professional | Zoloft | C | | |
| | | | | Claritin | C | | |
| | | | | Zyrtec | C | | |

Date:06/01/01ISR Number: 3734215-2Report Type:Periodic Company Report #10379
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | |
| 72 MG (2-36MG | | | | | | | |
| TABS) /DAY | | Chest Pain | Health | | | | |
| | | Headache | Professional | | | | |

Date:06/01/01ISR Number: 3734216-4Report Type:Periodic Company Report #10383
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Face Oedema | Consumer | Concerta | PS | Alza Corp | |
| 36MG TO 18MG | | | | | | | |
| | | Muscle Twitching | Health | | | | |
| 1X/1DAY | | Pain | Professional | | | | |

Date:06/01/01ISR Number: 3734217-6Report Type:Periodic Company Report #10389
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | Health | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1DAY, | | | | | | | |

ORAL
 Anxiety Professional
 Irritability Melatonin C

Date:06/01/01ISR Number: 3734218-8Report Type:Periodic Company Report #10396
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hostility | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG (2-18MG) | | Nervousness | Health | | | | |
| /DAY PO | | | Professional | Tegretol | C | | |

Date:06/01/01ISR Number: 3734219-XReport Type:Periodic Company Report #10398
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18 MG | | | | | | | |
| 1X/1DAY, ORAL | | | | | | | |

Date:06/01/01ISR Number: 3734220-6Report Type:Periodic Company Report #10407
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG-54MG | | Hyperhidrosis | | | | | |
| 1X/1DAY, PO | | Sedation | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734221-8Report Type:Periodic Company Report #10414
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Insomnia | Consumer | Concerta | PS | Alza Corp | |
| 36MG | | | | | | | |
| (2-18MG)/DAY | | | | | | | |

Claritin C

Date:06/01/01ISR Number: 3734222-XReport Type:Periodic Company Report #10415
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Health | Concerta | PS | Alza Corp | ORAL |
| 54MG(18MG+36M | | | | | | | |
| G)/DAY PO | | | | | | | |

Professional
 Company Representative

Date:06/01/01ISR Number: 3734223-1Report Type:Periodic Company Report #10419
 Age:60 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hostility | Health | Concerta | PS | Alza Corp | ORAL |
| 18 MG 1X 1DAY | | | | | | | |
| ORAL | | | | | | | |

Professional

Date:06/01/01ISR Number: 3734224-3Report Type:Periodic Company Report #10420
 Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | | | | | |

Professional

PO

Concerta
(Methylphenidate
Hcl0

SS

ORAL

18 MG 1X/DAY,

ORAL

Date:06/01/01ISR Number: 3734225-5Report Type:Periodic Company Report #10421
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pruritus | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAT | | Rash Maculo-Papular | Professional | | | | |

ORAL

Date:06/01/01ISR Number: 3734226-7Report Type:Periodic Company Report #10434
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/DAY | | | | | | | |

ORAL

Prozac

C

Date:06/01/01ISR Number: 3734227-9Report Type:Periodic Company Report #10435
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hostility | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG-36MG | | | Professional | | | | |

1X/1DAY, PO

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734228-0Report Type:Periodic Company Report #10439
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Muscle Twitching | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 MG | | | | | | | |
| 1X/1DAY, ORAL | | | | | | | |

Date:06/01/01ISR Number: 3734229-2Report Type:Periodic Company Report #10442
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dysphonia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY | | | | | | | |
| ORAL | | | | | | | |

Date:06/01/01ISR Number: 3734230-9Report Type:Periodic Company Report #10446
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1DAY, | | | | | | | |
| PO | | | | | | | |
| Asthenia | | | | | | | |
| Dizziness | | | | | | | |
| Insomnia | | | | | | | |
| Nausea | | | | | | | |

Date:06/01/01ISR Number: 3734231-0Report Type:Periodic Company Report #10447
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Central Nervous System | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | | | | | |

| | | | | | | | |
|--|---------------|----------------------|---------------|-----------------|------|--------------|-------|
| ORAL | | Stimulation | | Health | | | |
| | | Insomnia | | Professional | | | |
| Date:06/01/01ISR Number: 3734232-2Report Type:Periodic Company Report #10450 | | | | | | | |
| Age:8 YR | Gender:Male | I/FU:I | | | | | |
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Other | | Condition Aggravated | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54MG/ | | Insomnia | Health | | | | |
| 1X/1DAY, ORAL | | | Professional | Ddavp | C | | |
| Date:06/01/01ISR Number: 3734233-4Report Type:Periodic Company Report #10452 | | | | | | | |
| Age:50 YR | Gender:Female | I/FU:I | | | | | |
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Other | | Asthenia | Health | Concerta | PS | Alza Corp | ORAL |
| 72MG 1X/1DAY, | | Dizziness | Professional | | | | |
| PO | | | | Methlyphenidate | C | | |
| Date:06/01/01ISR Number: 3734234-6Report Type:Periodic Company Report #10453 | | | | | | | |
| Age:6 YR | Gender:Male | I/FU:I | | | | | |
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Other | | Anorexia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Vomiting | | | | | |
| ORAL | | | | | | | |
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734235-8Report Type:Periodic Company Report #10454
 Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54MG 1X/1DAY, | | | | | | | |
| ORAL | | | | | | | |
| Haldol | | | | | | | |
| C | | | | | | | |

Date:06/01/01ISR Number: 3734236-XReport Type:Periodic Company Report #10466
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|-------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Confusional State | Consumer | Concerta | PS | Alza Corp | ORAL |
| 72MG(4-18MG)/ | | | | | | | |
| DAY PO | | | | | | | |
| Depression | | | | | | | |
| Emotional Disorder | | | | | | | |
| Sedation | | | | | | | |
| Concerta (Methylphenidate Hcl) | | | | | | | |
| SS | | | | | | | |
| ORAL | | | | | | | |
| 72 MG (2-36 | | | | | | | |
| MG) DAY PO | | | | | | | |
| Clonidine | | | | | | | |
| C | | | | | | | |

Date:06/01/01ISR Number: 3734237-1Report Type:Periodic Company Report #10467
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------|----------|---------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pyrexia | Health | Concerta | PS | Alza Corp | ORAL |
| 54MG 1X/1DAY, | | | | | | | |
| ORAL | | | | | | | |
| Vasodilatation | | | | | | | |
| Professional | | | | | | | |
| Clonidine | | | | | | | |
| C | | | | | | | |

Date:06/01/01ISR Number: 3734238-3Report Type:Periodic Company Report #10475
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination | Health | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1DAY, | | | Professional | | | | |
| PO | | | | | | | |

Date:06/01/01ISR Number: 3734239-5Report Type:Periodic Company Report #10478
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyskinesia | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAT, | | Gait Disturbance | Professional | | | | |
| ORAL | | Muscle Twitching | | | | | |

Date:06/01/01ISR Number: 3734240-1Report Type:Periodic Company Report #10480
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54 MG | | | | Clonidine | C | | |
| 1X/1DAY, PO | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734241-3Report Type:Periodic Company Report #10481
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Accidental Overdose | Health | Concerta | PS | Alza Corp | ORAL |
| 72MG (54MG + | | Agitation | Professional | | | | |
| 18MG) 2X / | | | | | | | |
| DAY PO | | | | Growth Hormone | C | | |

Date:06/01/01ISR Number: 3734242-5Report Type:Periodic Company Report #10486
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis | Health | Concerta | PS | Alza Corp | ORAL |
| 54MG 1X/ | | | Professional | | | | |
| 1DAY, ORAL | | | | | | | |

Date:06/01/01ISR Number: 3734243-7Report Type:Periodic Company Report #10498
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG PO 5X/ 1 | | Headache | | | | | |
| WEEK | | Pallor | | | | | |
| | | Vomiting | | | | | |

Date:06/01/01ISR Number: 3734244-9Report Type:Periodic Company Report #10499
 Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Other Hostility Consumer Concerta PS Alza Corp
 36MG (2 -
 18MG TAB) 1X/
 1 DAY
 Clonidine C

Date:06/01/01ISR Number: 3734245-0Report Type:Periodic Company Report #10500
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1DAY, | | Anorexia | Health | | | | |
| ORAL | | | Professional | | | | |

Date:06/01/01ISR Number: 3734246-2Report Type:Periodic Company Report #10508
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Tremor | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/ | | | | | | | |
| 1DAY, ORAL | | | | Zoloft | C | | |

Date:06/01/01ISR Number: 3734247-4Report Type:Periodic Company Report #10514
 Age:13 YR Gender:Male I/FU:I

| Outcome | PT |
|---------|----------------|
| Other | Abdominal Pain |
| | Anorexia |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Headache

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|---------------|----------|------|--------------|-------|
| 36MG 1X/ 1DAY, ORAL | | Consumer | Concerta | PS | Alza Corp | ORAL |

Date:06/01/01ISR Number: 3734248-6Report Type:Periodic Company Report #10574
Age:15 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|------------------------------|---------------|--------------------------------------|------|--------------|-------|
| Dose Other 18MG 1X/ 1DAY | | Anxiety | Consumer | Concerta | PS | Alza Corp | |
| 36MG (2 - 18MG TABS) 1X/ 1 DAY | | Drug Ineffective Headache | | Concerta (Methylphenidate Hcl) | SS | Alza Corp | |

Date:06/01/01ISR Number: 3734249-8Report Type:Periodic Company Report #10577
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------|---------------|----------|------|--------------|-------|
| Dose Other 18MG 1X/ 1DAY, ORAL | | Bradycardia | Health | Concerta | PS | Alza Corp | ORAL |
| | | Headache | Professional | | | | |
| | | Hypotension | | | | | |

Date:06/01/01ISR Number: 3734250-4Report Type:Periodic Company Report #10578
Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | | |
|---------------------------------|--|----------|----------|----|-----------|------|
| Other 36MG 1X/ 1DAY, ORAL | Anxiety Dizziness Hypertonia Palpitations | Consumer | Concerta | PS | Alza Corp | ORAL |
|---------------------------------|--|----------|----------|----|-----------|------|

Date:06/01/01ISR Number: 3734251-6Report Type:Periodic Company Report #10579
 Age:21 YR Gender:Female I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|-----------------------|------------------------------------|-----------------------------|----------|--------------|-------|
| 18MG 1X/1DAY, ORAL | | Epistaxis Headache | Consumer Health Professional | Concerta Glucophage | PS SS | Alza Corp | ORAL |
| 500MG 2X/ 1DAY | | | | Birth Control Pill (Nos) | C | | |

Date:06/01/01ISR Number: 3734252-8Report Type:Periodic Company Report #10580
 Age:6 YR Gender:Male I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|-------------------------------|---------------|----------|------|--------------|-------|
| 18MG 1X/ 1DAY, ORAL | | Coagulation Time Prolonged | Consumer | Concerta | PS | Alza Corp | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734253-XReport Type:Periodic Company Report #10581
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|--------------|---------------|----------|------|--------------|-------|
| Dose | | | Health | Concerta | PS | Alza Corp | ORAL |
| Other | | Anxiety | | | | | |
| 18MG 1X/ 1DAY, ORAL | | Hypertension | Professional | | | | |
| | | Tachycardia | | | | | |

Date:06/01/01ISR Number: 3734254-1Report Type:Periodic Company Report #10588
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | Consumer | Concerta | PS | Alza Corp | ORAL |
| Other | | Halitosis | | | | | |
| 54MG 1X/ 1DAY, ORAL | | | Health | | | | |
| | | | Professional | | | | |

Date:06/01/01ISR Number: 3734255-3Report Type:Periodic Company Report #10589
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | Consumer | Concerta | PS | Alza Corp | ORAL |
| Other | | Abdominal Pain | | | | | |
| 18MG 1X/ 1DAY, ORAL | | Insomnia | | | | | |
| | | Rhinitis | | | | | |

Date:06/01/01ISR Number: 3734256-5Report Type:Periodic Company Report #10601
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | Consumer | Concerta | PS | Alza Corp | |
| Other | | Drug Ineffective | | | | | |
| 18 MG 1X/ | | | | | | | |

1DAY

Health

Professional

Date:06/01/01ISR Number: 3734257-7Report Type:Periodic Company Report #10602
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Attention | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/ | | Deficit/Hyperactivity | | | | | |
| 1DAY, ORAL | | Disorder | | | | | |
| | | Condition Aggravated | | | | | |

Date:06/01/01ISR Number: 3734258-9Report Type:Periodic Company Report #10610
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pruritus | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/ | | Urticaria | | | | | |
| 1DAY, ORAL | | | | | | | |

Date:06/01/01ISR Number: 3734259-0Report Type:Periodic Company Report #10611
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | Health | Concerta | PS | Alza Corp | ORAL |
| 36 MG 1X/ 1 | | | Professional | | | | |
| DAY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734260-7Report Type:Periodic Company Report #10612
 Age:4 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|---|------------------------|----------|------|--------------|-------|
| Dose | | | Health | Concerta | PS | Alza Corp | ORAL |
| Other | | Agitation | Professional | | | | |
| 18MG 1X/ 1DAY, ORAL | | Emotional Disorder | Company Representative | Depakote | C | | |
| | | Gait Disturbance Hallucination Insomnia | | | | | |

Date:06/01/01ISR Number: 3734261-9Report Type:Periodic Company Report #10617
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | Consumer | Concerta | PS | Alza Corp | ORAL |
| Other | | Condition Aggravated | | | | | |
| 18MG 1X/1DAY ORAL | | Eructation | | | | | |

Date:06/01/01ISR Number: 3734262-0Report Type:Periodic Company Report #10618
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--------------------|---------------|-----------|------|--------------|-------|
| Dose | | | Health | Concerta | PS | Alza Corp | ORAL |
| Other | | Emotional Disorder | Professional | | | | |
| 18 MG 1X/1DAY ORAL | | Insomnia | | Proventil | C | | |

Date:06/01/01ISR Number: 3734263-2Report Type:Periodic Company Report #10619
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | Health | Concerta | PS | Alza Corp | ORAL |
| Other | | Emotional Disorder | | | | | |
| 18MG 1X/1DAY | | | | | | | |

Professional

ORAL

Date:06/01/01ISR Number: 3734264-4Report Type:Periodic Company Report #10620
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Emotional Disorder | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY | | Hyperventilation | Professional | | | | |
| ORAL | | Tachycardia | | | | | |
| | | Tremor | | | | | |

Date:06/01/01ISR Number: 3734265-6Report Type:Periodic Company Report #10621
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG | | | Professional | | | | |
| 1X/1DAY/ORAL | | | | | | | |

Date:06/01/01ISR Number: 3734266-8Report Type:Periodic Company Report #10626
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 2X/2DAY, | | | | | | | |
| PO | | | | Metadate Er | C | | |
| | | | | Ritalin | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734267-XReport Type:Periodic Company Report #10627
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | Health | Concerta | PS | Alza Corp | ORAL |
| 36MG | | Dyspnoea | Professional | | | | |
| 1X/1DAY/ORAL | | | | | | | |

Date:06/01/01ISR Number: 3734268-1Report Type:Periodic Company Report #10628
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|-----------|------------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Back Pain | Health | Concerta | PS | Alza Corp | |
| UNKNOWN | DOSE/FREQUENC | | Professional | | | | |
| Y UNK | | | | | | | |
| | | | Company Representative | | | | |

Date:06/01/01ISR Number: 3734269-3Report Type:Periodic Company Report #10633
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|---------------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Laboratory Test Abnormal | Health | Concerta | PS | Alza Corp | |
| UNKNOWN | DOSAGE/FREQUE | | Professional | | | | |
| NCY UNKNOWN | | | | | | | |
| | | | | Zoloft | SS | | |
| 50MG | | | | | | | |

Date:06/01/01ISR Number: 3734270-XReport Type:Periodic Company Report #10634
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Weight Increased | Consumer | Concerta | PS | Alza Corp | |
| 72 MG 1X/1DAY | | | | | | | |

Date:06/01/01ISR Number: 3734271-1Report Type:Periodic Company Report #10637
Age:44 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Headache | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54MG | | | | | | | |
| (2-18+1-18MG) | | | | | | | |
| /DAY PO | | | | | | | |
| | | | | Imitrex | C | | |
| | | | | Amerge | C | | |

Date:06/01/01ISR Number: 3734272-3Report Type:Periodic Company Report #10638
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | |
| 18MG 1X/1DAY | | | | | | | |
| | | Drug Ineffective | | Concerta (Methylphenidate Hcl) | SS | | |
| 36MG 1X/1DAY | | | | | | | |

Date:06/01/01ISR Number: 3734273-5Report Type:Periodic Company Report #10645
Age:13 YR Gender:Female I/FU:I

| Outcome | PT |
|---------|--|
| Other | Dizziness Muscle Twitching Oedema Peripheral |

Freedom Of Information (FOI) Report

Skin Discolouration

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------------------------------|----------|------|--------------|-------|
| 36MG (2-18MG TAB) | | Consumer Health Professional | Concerta | PS | Alza Corp | |

Date:06/01/01ISR Number: 3734274-7Report Type:Periodic Company Report #10650
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------|---------------|--------------------------------------|----------|--------------|--------------|
| Dose Other 36MG ((2-18MG TAB) 1 DAY PO 18MG (1X-1DAY, ORAL) | | Headache Nausea Vomiting | Consumer | Concerta (Methylphenidate Hcl) | PS SS | Alza Corp | ORAL ORAL |

Date:06/01/01ISR Number: 3734275-9Report Type:Periodic Company Report #10660
Age:40 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|------------------------|---------------------------------------|--------------|--------------|-------|
| Dose Other 72MG (54MG+18MG1X/ X1DAY) | | Anxiety Back Pain Myalgia Pyrexia | Health Professional | Concerta Grifulvin Ventolin | PS C C | Alza Corp | |

Date:06/01/01ISR Number: 3734276-0Report Type:Periodic Company Report #10663
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Headache | Consumer | Concerta | PS | Alza Corp | ORAL |
| 54MG 1X/1DAY, | | Nausea | | | | | |
| ORAL | | Nervousness | | | | | |
| | | Sedation | | | | | |

Date:06/01/01ISR Number: 3734277-2Report Type:Periodic Company Report #10666
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------------|----------|---|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyspnoea | Health | Concerta | PS | Alza Corp | |
| UNKNOWN | DOSAGE-UNK | | Professional Company Representative | | | | |

Date:06/01/01ISR Number: 3734278-4Report Type:Periodic Company Report #10667
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyskinesia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Paranoia | | | | | |
| ORAL | | Sedation | | | | | |
| | | Speech Disorder | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734279-6Report Type:Periodic Company Report #10721
 Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------|--------------|---|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypertension | Health | Concerta | PS | Alza Corp | |
| UNKNOWN | DOSE UNKNOWN | | Professional Company Representative | | | | |

Date:06/01/01ISR Number: 3734280-2Report Type:Periodic Company Report #10727
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation | Health | Concerta | PS | Alza Corp | ORAL |
| 54MG | | Headache | Professional | | | | |
| (18+36MG)1X/1 | | Nausea | | | | | |
| DAY PO | | Vomiting | | | | | |

Date:06/01/01ISR Number: 3734281-4Report Type:Periodic Company Report #10728
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypertension | Health | Concerta | PS | Alza Corp | ORAL |
| 36MG(2-18MG) | | | Professional | | | | |
| 1X/1DAY PO | | | | Lisinopril | C | | |
| | | | | Amlodipine | C | | |

Date:06/01/01ISR Number: 3734282-6Report Type:Periodic Company Report #10730
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Other Leukocytosis Consumer Concerta PS Alza Corp ORAL
18MG 1X/1DAY,
Purpura
ORAL

Date:06/01/01ISR Number: 3734283-8Report Type:Periodic Company Report #10731
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1DAY, | | Face Oedema | | | | | |
| ORAL | | | | Topamax | C | | |

Date:06/01/01ISR Number: 3734284-XReport Type:Periodic Company Report #10732
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Hostility | Professional | | | | |
| ORAL | | Nervousness | | | | | |

Date:06/01/01ISR Number: 3734285-1Report Type:Periodic Company Report #10733
Age:12 YR Gender:Female I/FU:I

| Outcome | PT |
|---------|-------------------|
| Other | Confusional State |
| | Muscle Twitching |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|-------------|----------|---|---------------|----------|------|--------------|-------|
| | | Personality Disorder Thinking Abnormal | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36 1X/1DAY, | | | | | | | |
| PO | | | | | | | |

Date:06/01/01ISR Number: 3734286-3Report Type:Periodic Company Report #10734
Age:68 YR Gender:Male I/FU:I

| | | | | | | | |
|---------------|----------|-------------------|---------------|-------------------------|--------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | Consumer | Concerta | PS | Alza Corp | ORAL |
| Other | | Anxiety | | | | | |
| 36MG 1X/1DAY, | | Nervousness | | | | | |
| ORAL | | Thinking Abnormal | | Triamterene Atenolol | C C | | |

Date:06/01/01ISR Number: 3734287-5Report Type:Periodic Company Report #10743
Age:11 YR Gender:Male I/FU:I

| | | | | | | | |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | Consumer | Concerta | PS | Alza Corp | ORAL |
| Other | | Anxiety | | | | | |
| 18MG 1X/1DAY, | | Depression | | | | | |
| ORAL | 2 DAY | Muscle Twitching | | Paxil | C | | |

Date:06/01/01ISR Number: 3734288-7Report Type:Periodic Company Report #10747
Age:9 YR Gender:Male I/FU:I

| | | | | | | | |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | Consumer | Concerta | PS | Alza Corp | ORAL |
| Other | | Keratoconjunctivitis | | | | | |
| 36MG 1X/1DAY, | | Sicca | | | | | |
| ORAL | | | | | | | |

Muscle Twitching

Date:06/01/01ISR Number: 3734289-9Report Type:Periodic Company Report #10748
Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-----------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Attention | Consumer | Concerta | PS | Alza Corp | |
| 18MG TO 54MG | | Deficit/Hyperactivity | | | | | |
| 1X/1DAY | | Disorder | | Akne-Mycin Cream | C | | |
| | | Emotional Disorder | | | | | |
| | | Personality Disorder | | | | | |
| | | Thinking Abnormal | | | | | |

Date:06/01/01ISR Number: 3734290-5Report Type:Periodic Company Report #10781
Age: Gender:Not SpecifiI/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | Health | | | | |
| ORAL | | | Professional | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734462-XReport Type:Periodic Company Report #10639
 Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Leukopenia | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1DAY, | | Thrombocytopenia | Health | | | | |
| ORAL | | | Professional | Accutane | SS | | |

Date:06/01/01ISR Number: 3734463-1Report Type:Periodic Company Report #10214
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Diarrhoea | | | | | |
| ORAL | | Headache | | | | | |
| | | Vomiting | | | | | |

Date:06/01/01ISR Number: 3734464-3Report Type:Periodic Company Report #10221
 Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyskinesia | Consumer | Concerta | PS | Alza Corp | |
| 27MG | | | Health | | | | |
| (1.5-18MG | | | Professional | | | | |
| TAB) / 1DAY | | | | Ritalin | C | | |
| | | | | Proventil | C | | |
| | | | | Centrum Vitamins | C | | |
| | | | | Citracal Calcium | | | |
| | | | | Supplement | C | | |

Date:06/01/01ISR Number: 3734466-7Report Type:Periodic Company Report #10235
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Urticaria | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | Health | | | | |
| ORAL | | | Professional | | | | |

Date:06/01/01ISR Number: 3734467-9Report Type:Periodic Company Report #10239
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------|------------------------|--------------------------|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Dreams | Health | Concerta | PS | Alza Corp | ORAL |
| 18 MG | | Hallucination | Professional | | | | |
| 1X/1DAY, PO | | | Company Representative | Augmentin Guaifenesin | C C | | |

Date:06/01/01ISR Number: 3734468-0Report Type:Periodic Company Report #10241
Age:11 YR Gender:Male I/FU:I

| Outcome | PT |
|---------|---|
| Other | Chest Pain Dyspnoea Emotional Disorder Hostility Insomnia Nausea |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Vomiting

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------|----------|------|--------------|-------|
| 18-36MG | | Consumer | Concerta | PS | Alza Corp | ORAL |
| 1X/1DAY, PO | | Health Professional | | | | |

Date:06/01/01ISR Number: 3734470-9Report Type:Periodic Company Report #10242
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------|---------------|-------------|------|--------------|-------|
| Dose | | | Consumer | Concerta | PS | Alza Corp | |
| Other | | Condition Aggravated | | | | | |
| 72MG (4-18MG | | Personality Disorder | | | | | |
| TABS)/1DAY | | | | Clonidine | C | | |
| | | | | Catapressan | C | | |

Date:06/01/01ISR Number: 3734471-0Report Type:Periodic Company Report #10243
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | Consumer | Concerta | PS | Alza Corp | |
| Other | | Agitation | | | | | |
| 54MG | | Mydriasis | | | | | |
| (36MG+18MG) | | | | | | | |
| 1X/1DAY | | | | | | | |

Date:06/01/01ISR Number: 3734472-2Report Type:Periodic Company Report #10244
 Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------|---------------|----------|------|--------------|-------|
| Dose | | | Consumer | Concerta | PS | Alza Corp | ORAL |
| Other | | Amnesia | | | | | |
| 36 MG | | | | | | | |

1X/1DAY, ORAL
Skin Disorder
Tachycardia

Date:06/01/01ISR Number: 3734474-6Report Type:Periodic Company Report #10245
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | |
| 36 MG 1X/1DAY | | | Health Professional | | | | |

Date:06/01/01ISR Number: 3734476-XReport Type:Periodic Company Report #10246
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | Health | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | Paraesthesia | Professional | | | | |
| ORAL | | | | | | | |

Date:06/01/01ISR Number: 3734477-1Report Type:Periodic Company Report #10247
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | |
| 18MG-54MG | | | | | | | |
| 1X/1DAY | | | | Zyprexa | C | | |
| | | | | Mvi | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734479-5Report Type:Periodic Company Report #10248
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|---|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Psychomotor Hyperactivity | Health | Concerta | PS | Alza Corp | |
| DOSAGE- | | | Professional Company Representative | | | | |

Date:06/01/01ISR Number: 3734480-1Report Type:Periodic Company Report #10249
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|------------------|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Concerta | PS | Alza Corp | |
| 54MG (3-18MG) | | | | | | | |
| 1X/1 DAY | | | | Tenex Ritalin | C C | | |

Date:06/01/01ISR Number: 3734481-3Report Type:Periodic Company Report #10257
 Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Tremor | Consumer | Concerta | PS | Alza Corp | |
| 36MG (2-18MG) | | | Health | | | | |
| 1X/1DAY | | | Professional | | | | |

Date:06/01/01ISR Number: 3734483-7Report Type:Periodic Company Report #10258
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated | Consumer | Concerta | PS | Alza Corp | ORAL |
| 36MG 1X/1DAY, | | | | | | | |

Hostility

PO

Mvi

C

Date:06/01/01ISR Number: 3734484-9Report Type:Periodic Company Report #10259
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Headache | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | | | | | |
| ORAL | | | | | | | |

Penicillin

C

Date:06/01/01ISR Number: 3734486-2Report Type:Periodic Company Report #10271
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | ORAL |
| 18MG 1X/1DAY, | | | | | | | |
| ORAL | | | | | | | |
| Drug Ineffective | | | | | | | |

Date:06/01/01ISR Number: 3734487-4Report Type:Periodic Company Report #10272
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | |
| 36MG (2-18MG | | | | | | | |
| 1X/DAY) | | | | | | | |
| Anxiety | | | | | | | |
| Hyperacusis | | | | | | | |
| Health | | | | | | | |
| Professional | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/01/01ISR Number: 3734489-8Report Type:Periodic Company Report #10273
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|----------------|---------------|--------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Consumer | Concerta | PS | Alza Corp | |
| 72MG PO X | | | | | | | |
| 1/DAY | | | | | | | |
| | | | | Paxil | C | | |
| | | | | Risperdal | C | | |
| | | | | Allegra | C | | |
| | | | | Accolate | C | | |
| | | | | Ranitidine | C | | |
| | | | | Atrovent | C | | |
| | | | | Promethazine | C | | |
| | | | | Benadryl | C | | |
| | | | | Epipen Prn | C | | |

Date:06/04/01ISR Number: 3733536-7Report Type:Periodic Company Report #A107244
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------------|----------------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Sedation | Health Professional | Geodon | PS | Pfizer Central Research | |
| 20.00 MG | | | | | | | |
| TOTAL:DAILY | | | | | | | |
| | | | | Methyphenidate | SS | | |
| 5.00 MG TOTAL | | | | | | | |
| | | | | Clonidine | C | | |

Date:06/06/01ISR Number: 3736117-4Report Type:Periodic Company Report #MK200105-0085-1
 Age:38 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------------|-------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Health Professional | Methylin Er | PS | Mallinckrodt Inc | |
| 20 MG ER, TID | | | | | | | |

Date:06/11/01ISR Number: 3737167-4Report Type:Periodic Company Report #2000-10-1252
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|----------|------|----------------------|-------|
| Dose | | Drug Effect Decreased | Health | Claritin | PS | Schering Corp Sub | |
| ORAL | | Drug Interaction | Professional | | | Schering Plough Corp | ORAL |
| UNKNOWN | | | | Ritalin | SS | | |

Date:06/11/01ISR Number: 3737979-7Report Type:Expedited (15-DaCompany Report #PHBS2001JP05750
Age:49 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------------------|-------------------|---------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged 150 | | Intentional Misuse | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| TABLETS/D, | | | Professional | | | | |
| ORAL | | | Other | | | | |

Date:06/18/01ISR Number: 3741505-6Report Type:Expedited (15-DaCompany Report #MPI-2001-05755 (0)
Age:13 YR Gender:Male I/FU:I

| Outcome | PT |
|---------|-------------------------------|
| Death | Abdominal Pain |
| Other | Abdominal Pain Upper Anger |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--|-------------------|--|------------------|-------------------------------|-------|
| | | Anxiety Depression Emotional Disorder | Report Source | | | | |
| | | Fatigue Fear Headache Hostility Injury | Consumer Other | Methylphenidate Hcl Ritalin (Methylphenidate Hydrochloride) | PS SS | Celltech Manufacturing Inc | |
| 30MG PER DAY, UNK | | Insomnia Mental Disorder Murder Personality Disorder Suicidal Ideation Weight Decreased | | | | | |

Date:06/19/01ISR Number: 3742460-5Report Type:Expedited (15-DaCompany Report #10908
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|----------------------------|---------------------|--------|--------------|-------|
| Hospitalization - 18MG 1X/1 Initial or Prolonged DAY, ORAL | | Agitation Condition Aggravated | Health Professional | Concerta | PS | Alza Corp | ORAL |
| | | Dystonia Irritability Psychomotor Hyperactivity | | Delsym Ibuprofen | C C | | |

Date:06/20/01ISR Number: 3743570-9Report Type:Expedited (15-DaCompany Report #MPI-2001-05759(0)
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|------------------------|-------------|------|-------------------------------|-------|
| Other 40MG IN AM & 20MG AFTERNOON, PO | | Platelet Count Decreased Viral Infection | Health Professional | Metadate Er | PS | Celltech Manufacturing Inc | ORAL |

Date:06/21/01ISR Number: 3743750-2Report Type:Direct
Age:5 YR Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|------------|---------------|---------------------|------|--------------|-------|
| Dose Required | | Aggression | | Concerta Er 1mg Tab | | | |
| Intervention to | | | | Alza | PS | Tab A/Z | ORAL |
| 18MG 3X IN | | | | | | | |
| Prevent Permanent | | | | Buspar | C | | |
| THE AM ORAL | | | | Zyprexa | C | | |
| Impairment/Damage | | | | Topamax | C | | |
| | | | | Claritin | C | | |

Date:06/21/01ISR Number: 3743751-4Report Type:Direct
Age:4 YR Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|------------|---------------|---------------------|------|--------------|-------|
| Dose Required | | Aggression | | Methylphenidate 5mg | PS | | ORAL |
| 5MG 2X A DAY | | | | | | | |
| Intervention to | | | | | | | |
| ORAL | | | | | | | |
| Prevent Permanent | | | | Buspar | C | | |
| Impairment/Damage | | | | Zyprexa | C | | |
| | | | | Topomax | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/25/01ISR Number: 3747230-XReport Type:Expedited (15-DaCompany Report #MPI-2001-05776 (0)
 Age:3 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------------------|------------------------|-------------|------|---------------------------------|-------|
| Hospitalization - Initial or Prolonged 20 MG, ONCE | | Abnormal Behaviour | Health Professional | Metadate Cd | PS | Celltech Pharmaceuticals Inc | |

Date:06/29/01ISR Number: 3750829-8Report Type:Expedited (15-DaCompany Report #MPI-2001-05774(0)
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--|------------------------|---------------------|------|-------------------------------|-------|
| Other 40MG DAILY, | | Aggression Condition Aggravated | Foreign Literature | Methylphenidate Hcl | PS | Celltech Manufacturing Inc | |
| | | Drug Tolerance Decreased Feeling Abnormal Impulsive Behaviour Obsessive-Compulsive Disorder Tic | Health Professional | | | | |

Date:07/02/01ISR Number: 3751030-4Report Type:Expedited (15-DaCompany Report #PHEH2001US05251
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|------------------------|--|---------|----------------------------------|-------|
| Death | | Drug Interaction Psychotic Disorder | Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | |
| | | | | Provigil (Modafinil) Corticosteroids (No Ingredients/Substances) | SS C | | |

Date:07/02/01ISR Number: 3751453-3Report Type:Expedited (15-DaCompany Report #001-0981-M0104621
 Age:56 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | | |
|---|--|------------------------|--------------------------------------|----|------------|------|
| Hospitalization - 10 MG Initial or Prolonged (DAILY), PER Other ORAL | Alanine Aminotransferase Increased Aspartate | Health Professional | Lipitor | PS | Pfizer Inc | ORAL |
| 60 MG (TWICE DAY), PER ORAL | Aminotransferase Increased Blood Bilirubin Increased Clumsiness | | Fluoxetine (Fluoxetine) | SS | | ORAL |
| 40 MG (DAILY), PER ORAL | Electrocardiogram Abnormal Global Amnesia Weight Increased | | Omeprazole (Omeprazole) | SS | | ORAL |
| 30 MG (TWICE DAILY), PER ORAL | | | Methylphenidate (Methylphenidate) | SS | | ORAL |
| | | | Alprazolam (Alprazolam) | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/02/01ISR Number: 3751793-8Report Type:Expedited (15-DaCompany Report #PHBS2001JP06327
 Age:86 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-----------------------------------|-------------------|---|------|----------------------------------|-------|
| Dose Other | | Delirium Hallucination, Visual | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 40 MG/DAY, ORAL | | | Professional | | | | |
| | | | Other | Fluvoxamine Maleate (Fluvoxamine Maleate) | SS | | ORAL |
| 75 MG/DAY, ORAL | | | | | | | |
| | | | | Loramet (Lormetazepam) | SS | | ORAL |
| 2 MG/DAY, ORAL | | | | | | | |

Date:07/03/01ISR Number: 3752105-6Report Type:Expedited (15-DaCompany Report #MPU-2001-00179(0)
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------------------------|-------------------|---------------------|------|-------------------------------|-------|
| Dose Other | | Arrhythmia Electrocardiogram Qt | Foreign Health | Methylphenidate Hcl | PS | Celltech Manufacturing Inc | |
| 5MG ONCE DAILY, 10MG TWICE DAILY, AND 5 MG AT 4:00 PM | | Prolonged | Professional | | | | |

Date:07/05/01ISR Number: 3753020-4Report Type:Expedited (15-DaCompany Report #PHBS2001JP06554
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---------------|---------------------|--------------------------|------|-------------------------------|-------|
| Hospitalization - Initial or Prolonged | | Hallucination | Foreign Literature | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| ORAL | | | Health Professional | Anafranil (Clomipramine) | SS | | ORAL |
| | | | Other | Pemoline | C | | |

Date:07/09/01ISR Number: 3754852-9Report Type:Direct Company Report #
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------|---------------------|------|--------------|-------|
| Other | | Aggression | | Concerta 36 Mg Alza | PS | Alza | ORAL |
| 72 MG ONCE IN | | Hallucination | | | | | |
| AM ORAL | | Suicidal Ideation | | | | | |

Date:07/10/01ISR Number: 3755727-1Report Type:Expedited (15-DaCompany Report #2013273
Age:45 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|---------------------|--|------|--------------|-------|
| Death | | Drug Toxicity | Health Professional | Morphine Sulfate (Similar To Nda 19-516) | PS | | |
| | | Toxicologic Test Abnormal | Other | Alprazolam | SS | | |
| | | | | Methylphenidate Hcl | SS | | |
| | | | | Nordiazepam | SS | | |
| | | | | Chlordiazepoxide | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/10/01ISR Number: 3756640-6Report Type:Expedited (15-DaCompany Report #2013274
Age:45 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------|---------------------------|---|------|--------------|-------|
| Death | | Accidental Overdose | Health Professional Other | Morphine Sulfate (Similar To Andas 74-769 And 74-862) | PS | | |
| | | | | Alprazolam | SS | | |
| | | | | Methylphenidate Hcl | SS | | |
| | | | | Nordiazepam | SS | | |
| | | | | Chlordiazepoxide | SS | | |

Date:07/11/01ISR Number: 3756815-6Report Type:Expedited (15-DaCompany Report #PHFR2001IE01924
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----------------------|-----------------------------------|---------|------|-------------------------------|-------|
| Hospitalization - Initial or Prolonged | | Circulatory Collapse | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | |

Date:07/13/01ISR Number: 3758454-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP06554
Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------------|--------------------------|------|-------------------------------|-------|
| Hospitalization - Initial or Prolonged | | Hallucination, Tactile Hallucinations, Mixed | Foreign Literature | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| ORAL | | | Health Professional | Anafranil (Clomipramine) | SS | | ORAL |
| | | | Other | Pemoline | SS | | |

Date:07/16/01ISR Number: 3759030-5Report Type:Direct Company Report #
Age:35 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Drug Ineffective

Methylin 20mg

Mallinckrod

PS

Mallinckrod

2 TIMES

Date:07/16/01ISR Number: 3759488-1Report Type:Expedited (15-DaCompany Report #HQ3176612JUL2001

Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------|------------------------|-----------------------------------|------|---------------------------|-------|
| Death | | Death | Health Professional | Effexor Xr | PS | Wyeth Ayerst Laboratories | ORAL |
| ORAL | | | Company Representative | Methylphenidate (Methylphenidate) | SS | | |

Date:07/18/01ISR Number: 3760233-4Report Type:Direct Company Report #

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|------------------|---------------|---------|------|--------------|-------|
| | | Medication Error | | Ritalin | PS | Novartis | ORAL |
| 400 TABS | | | | Ritalin | SS | Novartis | ORAL |
| 270 TABS | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/18/01ISR Number: 3761064-1Report Type:Expedited (15-DaCompany Report #PERCODAN2001-00174
 Age:44 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------------|------------------|------|--------------------------|-------|
| Death | | Atherosclerosis | Health Professional | Percodan | PS | Endo Pharmaceuticals Inc | |
| | | Blood Alcohol Increased | | | | | |
| | | Coronary Artery Disease | | Alfentanil | SS | | |
| | | Ecchymosis | | Fentanyl | SS | | |
| | | Excoriation | | Sufentanil | SS | | |
| | | Haemangioma Of Liver | | Methyl-Phenidate | SS | | |
| | | Laceration | | | | | |
| | | Laryngeal Disorder | | | | | |
| | | Lung Disorder | | | | | |
| | | Overdose | | | | | |
| | | Pericardial Effusion | | | | | |
| | | Pleural Disorder | | | | | |
| | | Spleen Disorder | | | | | |
| | | Sputum Discoloured | | | | | |

Date:07/19/01ISR Number: 3762218-0Report Type:Expedited (15-DaCompany Report #PHBS2001JP00910
 Age:3 DY Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------|----------|-------------------------------|---------------------|--|------|-------------------------------|-------|
| Other | | Clonic Convulsion | Foreign Literature | Ritalin | PS | Novartis Pharmaceuticals Corp | |
| TRANSPLACENTAL | | Complications Of Maternal | | | | | |
| | | Exposure To Therapeutic Drugs | Health Professional | Anafranil (Clomipramine Hydrochloride) | | | |
| TRANSPLACENTAL | | Convulsion Neonatal | Other | Tablet | SS | | |
| | | Dyskinesia | | | | | |
| | | Jaundice Neonatal | | Wintermin (Chlorpromazine Hydrochloride) | SS | | |
| TRANSPLACENTAL | | Neonatal Disorder | | | | | |
| | | | | Serenace (Haloperidol) | SS | | |
| TRANSPLACENTAL | | | | | | | |
| | | | | Contomin (Chlorpromazine Hydrochloride) | SS | | |
| TRANSPLACENTAL | | | | | | | |
| | | | | Artane | | | |

(Trihexyphenidyl
Hydrochloride) SS

TRANSPLACENTAL

Date:07/20/01ISR Number: 3762329-XReport Type:Direct
Age:7 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|-----------------------------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Psychomotor Hyperactivity | | Concerta 18mg Alza Corporation | PS | Alza Corporation | ORAL |
| 18MG QAM ORAL | | | | Ritalin 10mg Ciba | SS | Ciba | ORAL |
| 10MG 11AM | | | | | | | |
| ORAL | | | | | | | |

Date:07/20/01ISR Number: 3762381-1Report Type:Direct
Age: Gender:Male I/FU:U

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| | | Dermatitis Hypersensitivity Psychomotor Hyperactivity | | Ritalin (5 Mg) | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/23/01ISR Number: 3763706-3Report Type:Expedited (15-DaCompany Report #PHFR2001GB02046
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------|---|-----------------------|---------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | 20-40 MG/DAY | Aggression Feeling Abnormal | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | |
| | | Obsessive-Compulsive Disorder Tic | Professional Other | | | | |

Date:07/23/01ISR Number: 3766038-2Report Type:Periodic Company Report #US008207
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---|--|----------------|--------------|-------|
| Dose | | | | | | | |
| Death | | Drug Interaction Psychotic Disorder | Health Professional Company Representative | Provigil Ritalin Corticosteroids | PS SS SS | Cephalon Inc | |

Date:07/26/01ISR Number: 3766406-9Report Type:Expedited (15-DaCompany Report #PHFR2001GB02070
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|-----------------------------------|---------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | | Dysphoria | Foreign Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | |

Date:07/27/01ISR Number: 3766931-0Report Type:Expedited (15-DaCompany Report #PHFR2001GB02086
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------------------|-----------------------------------|-----------------------------------|---------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | 5 0MG DAILY, ORAL | Electrocardiogram Qt Prolonged | Foreign Health Professional | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |

Date:07/27/01ISR Number: 3767108-5Report Type:Expedited (15-DaCompany Report #2001065051US
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------|---------------------------------|---|------------------|----------------------------|-------|
| Life-Threatening Hospitalization - Initial or Prolonged Disability Other Required Intervention to 15 MG, QD | 1203 DAY | Pituitary Tumour | Study Health Professional | Genotropin (Somatropin) Powder, Sterile Cortef (Hydrocortisone) Tablet | PS SS | Pharmacia And Upjohn Co | |
| Prevent Permanent Impairment/Damage 500 MG, QD | | | | Tegretol (Carbamazepine) | SS | | |
| 25 MG, QD | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/31/01ISR Number: 3768556-XReport Type:Expedited (15-DaCompany Report #MPI-2001-05047(1)
 Age:15 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------------------|---------------|---------------------|------|-------------------|-------|
| Dose | | Amnesia | Foreign | Methylphenidate Hcl | PS | Celltech | |
| 10 OR 20 MG | | Blood Pressure Increased | Literature | | | Manufacturing Inc | |
| ONCE; | | Circulatory Collapse | Health | | | | |
| | | Cyanosis | Professional | | | | |
| | | Pulse Absent | | | | | |
| | | Pyrexia | | | | | |
| | | Respiratory Arrest | | | | | |
| | | Visual Disturbance | | | | | |

Date:07/31/01ISR Number: 3769099-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP00910
 Age:4 DY Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------|---------------|---------------------------|---------------|-----------------|------|----------------------|-------|
| Dose | | Complications Of Maternal | Foreign | Ritalin Tab | PS | Novartis | |
| Other | | Exposure To Therapeutic | Literature | | | Pharmaceuticals Corp | |
| TRANSPLACENTAL | TRANSPLACENTA | Drugs | Health | | | | |
| L | | Convulsion Neonatal | Professional | Anafranil | | | |
| | | Drug Withdrawal Syndrome | Other | (Clomipramine | | | |
| TRANSPLACENTAL | TRANSPLACENTA | Neonatal | | Hydrochloride) | SS | | |
| L | | Dyskinesia | | | | | |
| | | Jaundice Neonatal | | Wintermin | | | |
| TRANSPLACENTAL | TRANSPLACENTA | | | (Chlorpromazine | SS | | |
| L | | | | Hydrochloride) | | | |
| | | | | Serenace | | | |
| TRANSPLACENTAL | TRANSPLACENTA | | | (Haloperidol) | SS | | |
| L | | | | | | | |
| | | | | Contomin | | | |
| | | | | (Chlorpromazine | | | |

TRANSPLACENTAL TRANSPLACENTA Hydrochloride) SS
 L
 Artane
 (Trihexyphenidyl
 Hydrochloride) SS
 TRANSPLACENTAL TRANSPLACENTA
 L

Date:08/01/01ISR Number: 3769511-6Report Type:Expedited (15-DaCompany Report #MPI-2001-05759(1)
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------------------|---------------------|-------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Platelet Count Decreased | Health Professional | Metadate Er | PS | Celltech Manufacturing Inc | ORAL |
| 30 MG, QAM, | | | | | | | |
| PO | | | | | | | |

Date:08/08/01ISR Number: 3773299-2Report Type:Expedited (15-DaCompany Report #PHFR2001GB02070
 Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------|-----------------------------------|--|------|-------------------------------|-------|
| Dose | | | | | | | |
| Other | | Dysphoria | Foreign Health Professional Other | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | Novartis Pharmaceuticals Corp | ORAL |
| 20 MG/DAY, | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/08/01ISR Number: 3773455-3Report Type:Expedited (15-DaCompany Report #PHBS2001US07798
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------|---------------|---------------------|------|----------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Interaction | Literature | Sandimmune | PS | Novartis | |
| 420 MG/D, | | Drug Level Above | Health | | | Pharmaceuticals Corp | ORAL |
| ORAL | 22 | Therapeutic | Professional | | | | |
| | | Drug Level Below | | Bupropion | | | |
| 75 MG, BID | 22 | Therapeutic | | (Amfebutamone) | SS | | |
| | | | | Methylphenidate | | | |
| 5 MG, BID | 22 | | | (Methylphenidate | | | |
| | | | | Hydrochloride) | SS | | |
| | | | | Azathioprine | | | |
| | | | | (Azathioprine) | C | | |
| | | | | Prednisone | C | | |
| | | | | Dipyridamole | | | |
| | | | | (Dipyridamole) | C | | |
| | | | | Nifedipine | C | | |
| | | | | Sulfamethoxazole | | | |
| | | | | W/Trimethoprim | | | |
| | | | | (Sulfamethoxazole) | C | | |
| | | | | Calcium Carbonate | C | | |
| | | | | Aluminium Hyrdoxide | | | |
| | | | | W/Magnesium | | | |
| | | | | Hydroxide | C | | |

Date:08/09/01ISR Number: 3775251-XReport Type:Expedited (15-DaCompany Report #PHFR2001GB02214
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------------------|---------------|---------|------|----------------------|-------|
| Dose | | | | | | | |
| Other | | Electrocardiogram Qt | Foreign | Ritalin | PS | Novartis | |
| 10 MG, TID, | | Prolonged | Health | | | Pharmaceuticals Corp | ORAL |
| ORAL | | | Professional | | | | |
| | | | Other | | | | |

Date:08/09/01ISR Number: 3775259-4Report Type:Expedited (15-DaCompany Report #PHFR2001IE01924
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------|--|---------|------|----------------------------------|-------|
| Hospitalization - Initial or Prolonged | | Circulatory Collapse | Foreign Health Professional Other | Ritalin | PS | Novartis Pharmaceuticals Corp | |

Date:08/13/01ISR Number: 3775962-6Report Type:Direct Company Report #
Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------------------------|----------------------------------|---------------|-----------------------------------|------|--------------|-------|
| Death | 25 MGS AM, 15 MGS NOON ORAL | Arrhythmia Headache Nausea | | Ritalin / 25&15 Mgs / Novartis | PS | Novartis | ORAL |

Date:08/13/01ISR Number: 3775981-XReport Type:Expedited (15-DaCompany Report #HQ3176612JUL2001
Age: Gender:Unknown I/FU:F

| Outcome | PT | Report Source |
|---------|------------------------|------------------------|
| Death | No Adverse Drug Effect | Health Professional |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Company Representative | Product | Role | Manufacturer | Route |
|------|----------|------------------------|------------------------------------|------|---------------------------|-------|
| ORAL | | | Effexor Xr | PS | Wyeth Ayerst Laboratories | ORAL |
| | | | Methylphenidate (Methylphenidate,) | SS | | |

Date:08/13/01
 Age: 16 YR
 Gender:Male
 I/FU:I

ISR Number: 3776024-4
 Report Type:Expedited (15-Da
 Company Report #PHEH2001US06527

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------|---------------|-----------------------------------|------|-------------------------------|-------|
| Dose | | | Consumer | Ritalin Tab | PS | Novartis Pharmaceuticals Corp | |
| Other | | Murder | | Prozac (Fluoxetine Hydrochloride) | SS | | |

Date:08/14/01
 Age:16 YR
 Gender:Female
 I/FU:I

ISR Number: 3777337-2
 Report Type:Expedited (15-Da
 Company Report #MPI-2001-05948 (0)

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|--------------------|---------------------|------|----------------------------|-------|
| Dose | | | Foreign Literature | Methylphenidate Hcl | PS | Celltech Manufacturing Inc | |
| Other | | Delusion Of Reference Depressed Mood | Health | | | | |
| 10MG DAY IN | | Depression | Professional | | | | |
| AM | | Persecutory Delusion Schizophreniform Disorder | | | | | |

Date:08/15/01
 Age: 16 YR
 Gender:Female
 I/FU:I

ISR Number: 3777453-5
 Report Type:Direct
 Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---|-----------------------------|------|--------------|-------|
| Dose | | | Drug Effect Decreased Medication Error | Concerta All Strengths Alza | PS | Alza | |

Date:08/16/01ISR Number: 3779010-3Report Type:Expedited (15-DaCompany Report #MPU-2001-00393 (0)
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|-----------------------------------|------------------|---------------------|------|-------------------------------|-------|
| Dose | | | | | | | |
| Other | | Electrocardiogram Qt Prolonged | Foreign Other | Methylphenidate Hcl | PS | Celltech Manufacturing Inc | |
| 10 MG THREE TIMES A DAY | | | | | | | |

Date:08/20/01ISR Number: 3779881-0Report Type:Direct Company Report #USP 081460
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------|---------------|------------------------|--------------|-------------------|-------|
| Dose | | | | | | | |
| TABLET, EXTENDED RELEASE TABLET | | Medication Error | | Concerta Ativan | PS SS | Alza Mylan | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/20/01ISR Number: 3780626-9Report Type:Expedited (15-DaCompany Report #PHBS2001CH08192
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-----------------------------------|-----------------------|---------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | | Platelet Aggregation Decreased | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 20 MG/DAY, ORAL | | | Professional Other | | | | |

Date:08/20/01ISR Number: 3780651-8Report Type:Expedited (15-DaCompany Report #PHFR2001GB02271
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--|-------------------|--------------------------|------|----------------------------------|-------|
| Dose | | | | | | | |
| Other | | Attention Deficit/Hyperactivity Disorder | Foreign Health | Ritalin | PS | Novartis Pharmaceuticals Corp | ORAL |
| 5 MG, BID, ORAL | | | Professional | | | | |
| ORAL | | Condition Aggravated Drug Interaction | Other | Clarityn (Loratadine) | SS | | ORAL |

Date:08/20/01ISR Number: 3780811-6Report Type:Expedited (15-DaCompany Report #2001-08-0812
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|-------------------|-----------------|------|---|-------|
| Dose | | | | | | | |
| Other | | Attention Deficit/Hyperactivity Disorder | Foreign Health | Claritin | PS | Schering Corp Sub Schering Plough Corp | ORAL |
| ORAL | | | Professional | Ritalin Tablets | SS | | ORAL |
| 5MG BID ORAL | | Condition Aggravated Drug Interaction Inhibition | Other | | | | |

Date:08/23/01ISR Number: 3782489-4Report Type:Direct
Age:41 YR Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|-------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation Cognitive Disorder | | Ritalin-Ciba-16 Sr 20mg Novartis | PS | Novartis | ORAL |
| SR 20MG/ONCE | | Decreased Appetite | | | | | |
| IN/ORAL | | Insomnia Motor Dysfunction Paranoia Speech Disorder | | | | | |

Date:08/27/01ISR Number: 3783487-7Report Type:Expedited (15-DaCompany Report #MPU-2001-00412(0)
Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|------------------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Face Oedema Tongue Oedema | Foreign | Equasym 5mg (Methylphenidate Hydrochloride Usp 5mg) | PS | | ORAL |
| 2.5 MG THREE | | | | | | | |
| TIMES DAILY, | | | | | | | |
| PO | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/27/01ISR Number: 3783538-XReport Type:Expedited (15-DaCompany Report #MPI-2001-05758 (0)

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------|---------------|---------------------|------|--------------|-------|
| Death | | Abnormal Behaviour | Consumer | Methylphenidate | | | |
| Disability | | Anxiety | Other | Tablets | | | |
| Other | | Completed Suicide | | (Unspecified) | | | |
| | | Depression | | (Methylpheniate | PS | | |
| | | Drug Dependence | | Metadate Er Tablets | | | |
| | | Injury | | (Strength | | | |
| | | Pain | | Unspecified) | | | |
| | | Personality Change | | (Methylphenidate | | | |
| | | | | Hydrochloride | SS | | |
| | | | | Ritalin | | | |
| | | | | (Methylphenidate | | | |
| | | | | Hydrochloride) | SS | | |
| | | | | Methylphenidate | | | |
| | | | | Sustained Release | SS | | |
| | | | | Methylin | SS | | |
| | | | | Methylin Er | SS | | |
| | | | | Prozac (Fluoxetine | | | |
| | | | | Hydrochloride) | SS | | |

Date:09/04/01ISR Number: 3787992-9Report Type:Direct

Age:43 YR Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Insomnia | | Concerta 18mg Alza | PS | Alza | |
| 18MG 4 AM | | | | Cephalexin 250 Mg | | | |
| | | | | Teva 1 Qid | SS | Teva | |
| 250 MG 1 QID | | | | Vicodin | C | | |

Date:09/04/01ISR Number: 3791056-8Report Type:Periodic

Age:20 YR Gender:Male I/FU:I

Company Report #10776

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Health Professional | Concerta | | | |
| | | | | (Methylphenidate | | | |

| | | | | | |
|----------------------|---------------|-----------------------|----------------------|-----------------------|--------------|
| 18MG | | Company | Hcl) | PS | ORAL |
| 1X/1DAY,ORAL | | Representative | | | |
| Date:09/04/01 | | ISR Number: 3791057-X | Report Type:Periodic | Company Report #10773 | |
| Age:14 YR | Gender:Female | I/FU:I | | | |
| Outcome | PT | Report Source | Product | Role | Manufacturer |
| Dose | Duration | | | | Route |
| Hospitalization - | Tachycardia | Consumer | Concerta | | |
| Initial or Prolonged | | | (Methylphenidate | | |
| | | | Hcl) | PS | ORAL |
| 54MG 1X/1DAY, | | | | | |
| ORAL | | | Celexa | C | |
| | | | Wellbutrin Sr | C | |

Date:09/04/01 ISR Number: 3791058-1 Report Type:Periodic Company Report #10777
Age:58 YR Gender:Female I/FU:I

Outcome PT
Hospitalization - Angina Pectoris
Initial or Prolonged Chest Pain

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--|---------------|--------------------------------------|------|--------------|-------|
| 18MG 1X/1DAY, ORAL | | Laryngospasm Malaise Pain Palpitations Ventricular Extrasystoles | Consumer | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| | | | | Premarin | C | | |
| | | | | Prilosec | C | | |
| | | | | Detrol | C | | |

Date:09/05/01ISR Number: 3788578-2Report Type:Expedited (15-DaCompany Report #PHFR2001GB02434
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|-----------------------------------|--|------|--------------|-------|
| Other ORAL | | Chest Pain | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

Date:09/05/01ISR Number: 3788583-6Report Type:Expedited (15-DaCompany Report #PHBS2001JP08737
Age:19 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Life-Threatening ORAL | | Blood Creatine Phosphokinase Increased Convulsion | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | Depressed Level Of Consciousness Hyperthermia Malignant Shock | Other | | | | |

Date:09/05/01ISR Number: 3788595-2Report Type:Expedited (15-DaCompany Report #PHNU2001DE01943
Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---|--|---|------|--------------|-------|
| Dose Other | | Blood Creatine Phosphokinase Increased | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, BID, ORAL | | | | Ritaline (Methylphenidate Hydrocholride) Slow Release Tablet | SS | | ORAL |
| 20 MG/DAY, ORAL | | | | | | | |

Date:09/06/01ISR Number: 3789771-5Report Type:Periodic Company Report #260601
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|------------------------|---|--------------|--------------|-------|
| Dose Other | | Anxiety Drug Interaction Hyperhidrosis Palpitations Tachycardia | Health Professional | Rocaltrol (Calcitriol) Concerta (Methylphenidate Hydrochloride) Adderall | PS SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Amphetamine
Aspartate/Amphetamin
e
Sulfate/Dextroamphet C
Calcium (Calcium
Nos) C

Date:09/07/01ISR Number: 3790162-1Report Type:Expedited (15-DaCompany Report #11308
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|---------------------------------|--------------------------------------|--------|--------------|-------|
| Dose Other | | Dysphagia | Health Professional Other | Concerta (Methylphenidate Hcl) | PS | | |
| 36MG 1X/1DAY | | | | | | | |
| ONE DOSE | | | | Wellbutrin Depakote | C C | | |

Date:09/07/01ISR Number: 3790184-0Report Type:Expedited (15-DaCompany Report #10908
Age:5 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------|------------------------|--------------------------------------|--------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Psychomotor Hyperactivity | Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 18MG 1X/1DAY, | | | | | | | |
| ORAL | | | | Delsym Ibuprofen | C C | | |

Date:09/12/01ISR Number: 3791865-5Report Type:Direct Company Report #
Age:43 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|----------------------|------|--------------|-------|
| Dose Other | | Insomnia | | Concerta 18 Mg, Alza | PS | Alza | |
| 5 AM | | | | | | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------|---------------|----------------------|------|--------------|-------|
| 1 QID | | | | Cephalexin 250 Mg | SS | Teva | |
| | | | | Teva | | | |
| | | | | Vicodin | C | | |
| Date:09/17/01ISR Number: 3793836-1Report Type:Direct Company Report # | | | | | | | |
| Age: Gender:Male I/FU:I | | | | | | | |
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Methylphenidate 5mg | PS | Geneva | |
| 1 TID 047 | | | | Geneva | | | |
| | | | | Methylphenidate 10mg | SS | Geneva | |
| 1 TID 047 | | | | Geneva | | | |
| | | | | Allegra | C | | |
| | | | | Advair | C | | |
| | | | | Flonase | C | | |
| Date:09/17/01ISR Number: 3794516-9Report Type:Expedited (15-DaCompany Report #PHBS2001JP09045 | | | | | | | |
| Age:80 YR Gender:Male I/FU:I | | | | | | | |
| Outcome | | PT | | | | | |
| Other | | Blood Creatine | | | | | |
| | | Phosphokinase Increased | | | | | |
| | | Depressed Level Of | | | | | |
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | |
|---------------|----------|---|--|--|-------------|--------------|
| | | Consciousness Pyrexia Urinary Tract Infection | | | | |
| Dose | Duration | | Report Source | Product | Role | Manufacturer |
| | | | Foreign Health Professional Other | Ritaline(Methylpheni datate Hydrochloride) Tablet | PS | |
| 10 MG/D, ORAL | | | | Bufferin (Aluminium Glycinate, Magnesium Carbonate) Mexitil (Mexdiletine Hydrochloride) Adalat Xl | C C C | |
| | | | | | | Route |
| | | | | | | ORAL |

Date:09/18/01ISR Number: 3795191-XReport Type:Expedited (15-DaCompany Report #2001065051US
Age:9 YR Gender:Male I/FU:F

| | | | | | | | |
|--|----------|------------------|---------------------------------|---|----------------------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Life-Threatening Hospitalization - Initial or Prolonged Disability Other Required 15 MG, QD, 1203 DAY Intervention to Prevent Permanent 500 M G, QD, Impairment/Damage | | Pituitary Tumour | Study Health Professional | Genotropin (Somatropin) Powder, Sterile Cortef (Hydrocortisone) Tablet Tegretol (Carbamazepine) Ritalin (Methylphenidate Hydrochloride) | PS SS SS SS | | |
| 25 MG, QD, | | | | | | | |

Date:09/19/01ISR Number: 3795135-0Report Type:Direct Company Report #
Age:9 YR Gender:Female I/FU:I

| | | | | | | | |
|--------------|----------|-------------|---------------|----------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| 36 MG + PO Q | | Face Oedema | | Concerta 36 Mg | PS | | ORAL |

DAY

Date:09/21/01ISR Number: 3797420-5Report Type:Expedited (15-DaCompany Report #HQ6112118SEP2001

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Clonic Convulsion Drug Interaction Loss Of Consciousness | Health Professional Company Representative | Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release) | PS | | ORAL |
| 150 MG 3X PER | | | | | | | |
| 1 DAY, ORAL | | | | | | | |
| SEE IMAGE | | | | Klonopin (Clonazepam) | SS | | ORAL |
| SEE IMAGE | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/24/01ISR Number: 3797912-9Report Type:Expedited (15-DaCompany Report #MPI-2001-05988(0)
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------------------|------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Laboratory Test Abnormal Syncope | Health Professional | Methylphenidate Tablets 10mg (Methylphenidate Hydrochloride 10mg) | PS | | |

10MG

Date:09/24/01ISR Number: 3798375-XReport Type:Expedited (15-DaCompany Report #PHFR2001GB02434
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|--|--|------|--------------------------------------|-------|
| Other | | Chest Pain Medication Error Stomach Discomfort | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | Novartis Pharmaceuticals Corp. | ORAL |

20 MG, BID,

ORAL

Date:09/28/01ISR Number: 3802102-7Report Type:Expedited (15-DaCompany Report #PHBS2001NZ09415
 Age:18 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|--|---|------|--------------|-------|
| Other | | Anaphylactoid Reaction | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Unknown | PS | | ORAL |

50 MG/DAY,

ORAL

Date:09/28/01ISR Number: 3802671-7Report Type:Periodic Company Report #2000UW03120
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------------|----------|----------|---------------|----------|------|--------------|-------|
| Hospitalization - 50 MG QAM PO | | Priapism | Health | Seroquel | PS | | ORAL |
| Initial or Prolonged 25 MG PO | | | Professional | Seroquel | SS | | ORAL |
| Required 75 MG HS PO | | | | Seroquel | SS | | ORAL |
| Intervention to 50 MG QAM PO | | | | Seroquel | SS | | ORAL |
| Prevent Permanent 10 MG QID | | | | Ritalin | SS | | |
| Impairment/Damage 30 MG BID | | | | Ritalin | SS | | |
| 20 MG BID | | | | Ritalin | SS | | |
| | | | | Lithium | C | | |

Date:10/01/01ISR Number: 3802601-8Report Type:Expedited (15-DaCompany Report #PHFR2001GB02623
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------|-------------------------------------|--|------|--------------|-------|
| Life-Threatening 25 MG, TID, ORAL | | Neutropenia | Health Professional Other | Ritaline (Methylpheni date Hydrochloride) | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/01ISR Number: 3802743-7Report Type:Expedited (15-DaCompany Report #FLUV00301003977
 Age:30 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|----------------------------------|---------------------|---|------|--------------|-------|
| Death | | Cerebral Infarction | Foreign | Luvox 25 | | | |
| Life-Threatening | | Depressed Level Of Consciousness | Health Professional | (Fluvoxamine Maleate) | PS | | ORAL |
| 50 MG DAILY | | | | | | | |
| PO | | Drug Toxicity | Other | | | | |
| | | Neuroleptic Malignant Syndrome | | Toledomin (Milnacipran) | SS | | ORAL |
| 150 MG DAILY | | | | | | | |
| PO | | Pupils Unequal | | | | | |
| | | Renal Failure Acute | | Amoxan (Amoxapine) | SS | | ORAL |
| 300 MG DAILY | | | | | | | |
| PO | | | | Paxil (Paroxetine Hydrochloride) | SS | | ORAL |
| 10 MG DAILY | | | | | | | |
| PO | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |
| 10 MG DAILY | | | | | | | |
| PO | | | | Rize (Clotiazepam) | C | | |
| | | | | Solanax (Alprazolam) | C | | |

Date:10/04/01ISR Number: 3806044-2Report Type:Expedited (15-DaCompany Report #11308
 Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------|---------------------|--------------------------------|------|--------------|-------|
| Other | | Dysphagia | Health Professional | Concerta (Methylphenidate Hcl) | PS | | |
| 36 MG 1X/DAY | | Foreign Body Trauma | Other | | | | |
| | | | | Wellbutrin | C | | |
| | | | | Depakote | C | | |

Date:10/05/01ISR Number: 3805407-9Report Type:Direct
Age: Gender: I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---|------|---------------------------|-------|
| Dose | | Medication Error | | Metadate Cd (Methylphenidate Hydrochloride) Capsule, Extended Release | PS | Celltech | |
| | | | | Metadate Er (Methylphenidate Hydrochloride) Extended Release | SS | Medeva Pharmaceuticals | |

Date:10/10/01ISR Number: 3807021-8Report Type:Expedited (15-DaCompany Report #PHFR2001GB02702
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------------------------|---------------|--------------------------|------|--------------|-------|
| Dose | | Condition Aggravated | Foreign | Ritaline | | | |
| Other | | Impulsive Behaviour | Health | (Methylphenidat | | | |
| | | Increased Appetite | Professional | 20+20+15 Mg/Day | PS | | ORAL |
| 20+20+15MG | | Psychomotor Hyperactivity | Other | | | | |
| /DAY,ORAL | | | | Clarityn (Loratadine) | SS | | ORAL |
| 10 MG/DAY, | | | | | | | |
| ORAL | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/10/01ISR Number: 3807028-0Report Type:Expedited (15-DaCompany Report #PHNU2001DE02264
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Aplastic Anaemia Neutrophil Count Decreased Platelet Count Decreased | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, DU, ORAL | | Skin Discolouration White Blood Cell Count Decreased | | | | | |

Date:10/11/01ISR Number: 3807714-2Report Type:Direct Company Report #
Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---|---------------|--|------|--------------|-------|
| 20MG -20MG -10 | | Aggression Educational Problem Impulse-Control Disorder | | Methylphenidate -(10 Mg) (Shein) | PS | Shein | |
| 20MG-20MG-10 | | | | Methylphenidate(10mg) (Mallinolsudt) | SS | Mallinolsudt | |

Date:10/12/01ISR Number: 3809379-2Report Type:Expedited (15-DaCompany Report #MPI-2001-05774 (1)
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|---|--|------|--------------|-------|
| Other 40MG, BID, PO | | Aggression Feeling Abnormal Obsessive-Compulsive Disorder | Foreign Literature Health Professional | Methylphenidate Tablets 20 Mg (Methylphenidate Hydrochloride 20 Mg) | PS | | ORAL |
| | | Tic | | Imipramine (Imipramine) | C | | |

Date:10/15/01ISR Number: 3809541-9Report Type:Expedited (15-DaCompany Report #11308
Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------------------|---------------------------------|---|------------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dysphagia Foreign Body Trauma | Health Professional Other | Concerta (Methylphenidate Hcl) | PS | | |
| 36MG 1X/1DAY | | | | Wellbutrin Depakote Clonidine Stimulants (Nos) | C C C C | | |

Date:10/16/01ISR Number: 3810291-3Report Type:Expedited (15-DaCompany Report #PHBS2001CA09991
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening Hospitalization - Initial or Prolonged Disability | | Compartment Syndrome Muscle Disorder | Foreign Consumer Other | Ritaline (Methylphenidate Hydrochloride) | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/16/01ISR Number: 3810623-6Report Type:Expedited (15-DaCompany Report #PHEH2001US08070
 Age:45 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------------------------|--|--|--------------|-------|
| Hospitalization - Initial or Prolonged | | Ammonia Increased Asthenia Blood Creatinine Increased | Study Health Professional | Ritalin(Methylphenidate Hydrochloride) Gleevec | PS SS | | ORAL |
| 100 MG, QD, ORAL | | Blood Urea Increased Coordination Abnormal Creatine Urine Increased Fatigue Gait Disturbance Lethargy Sedation | | Ambien(Zolpidem Tartrate) Ibuprofen (Ibuprofen) Morphine Sulfate(Morphine Sulfate) Oxycodone(Oxycodone) Bromfed (Brompheniramine Maleate) Centrum(Vitamin Nos) Chlorpromazine (Chlorpromazine) Spironolactone | SS SS SS SS C C C C | | |

Date:10/18/01ISR Number: 3811406-3Report Type:Expedited (15-DaCompany Report #PHNU2001DE02288
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|---|---|------|--------------|-------|
| Other | | Aggression Delusion Hallucination Obsessive-Compulsive Disorder | Foreign Health Professional Company Representative Other | Ritaline (Methylphenidate Hydrochloride) Sugar-Coated Tablet | PS | | ORAL |
| 25 MG/DAY, ORAL | | | | | | | |

Date:10/18/01ISR Number: 3811619-0Report Type:Expedited (15-DaCompany Report #PHEH2001US07958
 Age:48 YR Gender:Female I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--|------------------------|--|------|--------------|-------|
| | | Blood Pressure Increased Thyroid Neoplasm | Health Professional | Ritalin (Methylphenidat Hydrochloride) Tablet, 5 Mg | PS | | ORAL |
| 5 MG, QID, ORAL | | | | | | | |

Date:10/22/01ISR Number: 3813504-7Report Type:Expedited (15-DaCompany Report #HQ7290318OCT2001
Age: Gender:Unknown I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|---|--|--------------|--------------|-------|
| | | Drug Interaction Neuroleptic Malignant Syndrome | Health Professional Company Representative | Effexor Xr (Venlafaxine Hydrochloride, Capsule, Methylphenidate (Methylphenidate) | PS SS | | ORAL |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/23/01ISR Number: 3813651-XReport Type:Expedited (15-DaCompany Report #HQ7334618OCT2001

Age:16 YR Gender: I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|------|----------|--------------------------------------|---------------|---|------|--------------|-------|
| Death | | | Completed Suicide Intentional Misuse | Literature | Hydroxyzine Hcl (I.M.) (Hydroxyzine Hydrochloride, Injection) | PS | | |
| OVERDOSE | | | | | | | | |
| AMOUNT | | | | | | | | |
| UNKNOWN | | | | | | | | |
| OVERDOSE | | | | | Amitriptyline (Amitriptyline,) | SS | | ORAL |
| AMOUNT | | | | | | | | |
| UNKNOWN, ORAL | | | | | | | | |
| OVERDOSE | | | | | Methyphenidate Hydrochloride (Methyphenidate Hydrochloride,) | SS | | ORAL |
| AMOUNT | | | | | | | | |
| UNKNOWN, ORAL | | | | | | | | |

Date:10/31/01ISR Number: 3818201-XReport Type:Expedited (15-DaCompany Report #PHNU2001DE02290

Age:20 YR Gender:Female I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|------|----------|--|-----------------------------|---|------|--------------|-------|
| Other | | | Abortion Complications Of Maternal Exposure To Therapeutic | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 30-40MG/DAY, | | | | | | | | |
| ORAL | | | Drugs | Other | | | | |
| | | | Psoriasis | | | | | |

Date:10/31/01ISR Number: 3818202-1Report Type:Expedited (15-DaCompany Report #PHNU2001DE02288
Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|------------|---|------------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Acrophobia Delusion Hallucination | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Sugar-Coated Tablet | PS | | ORAL |
| 20 MG/DAY, ORAL | | Obsessive-Compulsive Disorder | Company Representative Other | | | | |
| ORAL | | | | Fenistil(Dimetindene Maleate) | SS | | ORAL |
| RESPIRATORY (INHALATION) | INHALATION | | | Cortisone(Cortisone) Spray | SS | | |

Date:10/31/01ISR Number: 3818754-1Report Type:Expedited (15-DaCompany Report #99CDN10751
Age:7 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening Hospitalization - Initial or Prolonged | | Compartment Syndrome Muscle Disorder | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 15 MG, BID, ORAL | | | | Ritalin-Sr (Metyhylphenidate Hydrochloride) Slow Release Tablet, 20 Mg | SS | | ORAL |
| 20 MG, QD, | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

ORAL

Date:11/01/01ISR Number: 3819864-5Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--------------|------------------|---------------|---------------------|------|--------------|-------|
| Life-Threatening | 5MG TID ORAL | Supraventricular | | Methylphenidate 5mg | PS | | ORAL |
| Hospitalization - Initial or Prolonged | | Tachycardia | | Celexa | C | | |

Date:11/01/01ISR Number: 3819895-5Report Type:Direct
 Age:15 YR Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|------------------|---------------|---------|------|--------------|-------|
| Other | 15 MG PO Q AM | Drug Ineffective | | Ritalin | PS | | ORAL |

Date:11/02/01ISR Number: 3820193-4Report Type:Expedited (15-DaCompany Report #PHNU2001DE02485
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-------------|---------------------------|-----------------------------------|---|------|--------------|-------|
| Other | 10 MG, QID, | Ventricular Extrasystoles | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

ORAL

Date:11/07/01ISR Number: 3822082-8Report Type:Expedited (15-DaCompany Report #A044-002-003326
 Age:72 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
|---------|----------|----|---------------|---------|------|--------------|-------|

| | | | | | |
|-----------------------------------|------------------|--------------|---|----|------|
| Hospitalization - SEE IMAGE | Drug Interaction | Foreign | Aricept (Donepezil) | PS | ORAL |
| Initial or Prolonged SEE IMAGE | Posture Abnormal | Health | Zyprexa (Olanzapine) | SS | ORAL |
| | | Professional | Ritalin (Methylphenidate Hydrochloride) | SS | ORAL |
| SEE IMAGE | | | Thrombran (Trazodone Hydrochloride) | C | |
| | | | Ass (Acetylsalicylic Acid) | C | |

Date:11/07/01ISR Number: 3824092-3Report Type:Expedited (15-DaCompany Report #2001-10-1935
Age:66 YR Gender:Male I/FU:I

| | |
|----------------------|-------------------------|
| Outcome | PT |
| Hospitalization - | Atelectasis |
| Initial or Prolonged | Decreased Appetite |
| | Demyelinating |
| | Polyneuropathy |
| | Difficulty In Walking |
| | Drug Interaction |
| | Dysphagia |
| | Faecal Incontinence |
| | Guillain-Barre Syndrome |
| | Haemoglobin Decreased |
| | Joint Stiffness |
| | Metabolic Acidosis |
| | Muscular Weakness |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------------------------|--|------|--------------|-------|
| | | Nervous System Disorder Neuropathy Peripheral Oral Candidiasis | | | | | |
| | | Oxygen Saturation Decreased Platelet Count Decreased | Study Health Professional | Intron A (Interferon Alfa-2b Recombinant) Injectable | PS | | |
| SUBCUTANEOUS | 10 MU | Pneumonia | Other | | | | |
| SUBCUTANEOUS; | | Renal Cyst | | | | | |
| 6 MU | | Urinary Incontinence | | | | | |
| SUBCUTANEOUS | | Weight Decreased | | Ritalin Blinded Study | SS | | ORAL |
| ORAL | | | | Lipitor (Atorvastatin) | C | | |
| | | | | Prilosec | C | | |
| | | | | Lasix | C | | |
| | | | | Glucophage | C | | |
| | | | | Micronase | C | | |
| | | | | K-Dur (Potassium Chloride) | C | | |
| | | | | Inderal | C | | |
| | | | | Zyloprim | C | | |
| | | | | Multivitamins | C | | |
| | | | | Tylenol | C | | |

Date:11/08/01ISR Number: 3822918-0Report Type:Expedited (15-DaCompany Report #PHBS2001CH10815
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Anxiety Chest Pain Confusional State Dyspnoea | Foreign Health Professional Other | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | PS | | ORAL |
| 10 TO 20 MG/DAY, ORAL | | Hallucination Hyperhidrosis Palpitations Psychotic Disorder | | | | | |

Syncope

Date:11/13/01ISR Number: 3824180-1Report Type:Direct
 Age:9 YR Gender:Female I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin Generic | PS | Generic | |
| 5MG 1 QD M-F | | Fatigue | | | | | |

Date:11/13/01ISR Number: 3824766-4Report Type:Expedited (15-DaCompany Report #PHBS2001US11161
 Age:39 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------------|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression Drug Dependence | Literature Consumer | Ritaline (Methylphenidate Hydrochloride) Oxycontin (Oxycodone Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | Percocet (Oxycodone Hydrochloride, Paracetamol) | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/13/01ISR Number: 3824839-6Report Type:Expedited (15-DaCompany Report #96USA13341
Age:20 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Overdose Schizophrenia, Paranoid Type Suicidal Ideation | Health Professional | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | PS | | ORAL |
| ORAL | | | | Paxil (Paroxetine Hydrochloride) Tablet | C | | |

Date:11/13/01ISR Number: 3825469-2Report Type:Expedited (15-DaCompany Report #96USA13562
Age:20 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------------------|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Intentional Misuse Suicide Attempt | Health Professional | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | 364 DAY | | | Paxil (Paroxetine Hydrochloride) | C | | |

Date:11/13/01ISR Number: 3826153-1Report Type:Expedited (15-DaCompany Report #PHNU2001DE02553
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Pleurothotonus | Foreign Study Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| SEE IMAGE | | | Other | Zyprexa (Olanzapine) | SS | | ORAL |
| SEE IMAGE | | | | Aricept (Donepezil Hydrochloride) | SS | | ORAL |
| SEE IMAGE | | | | Thombran (Trazodone) | | | |

Hydrochloride) C
Acetylsalicylate C

Date:11/14/01ISR Number: 3823926-6Report Type:Direct
Age: Gender: I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|------------------|---------------|---------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Methylphenidate (5 Mg) | PS | | |
| 5 MG Q AM & 2.5 MG Q PM | | | | | | | |

Date:11/16/01ISR Number: 3825932-4Report Type:Expedited (15-DaCompany Report #PHNU2001DE02393
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------------|--|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - 30MG/DAY, Initial or Prolonged ORAL | | Eosinophilia | Foreign Health Professional Other | Ritaline | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/16/01ISR Number: 3827521-4Report Type:Expedited (15-DaCompany Report #PHEH2001US09161
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|---------------|---|------|--------------|-------|
| Dose Other | | Haematochezia | Consumer | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | |

Date:11/16/01ISR Number: 3827883-8Report Type:Expedited (15-DaCompany Report #PHEH2001US09260
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|------------------------------------|--|----------|--------------|-------|
| Dose Death | | Accidental Overdose Medication Error | Consumer Health Professional | Methyphenidate (Methylphenidate Hydrochloride) Tablet Methadone (Methadone) | PS SS | | |

Date:11/19/01ISR Number: 3827316-1Report Type:Expedited (15-DaCompany Report #HQ6112118SEP2001
Age:41 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|---------------|--|---|---|------|--------------|-------|
| Dose Other | | Clonic Convulsion Drug Interaction Loss Of Consciousness | Health Professional Company Representative | Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release) | PS | | ORAL |
| | 150 MG 3X PER | | | | | | |
| | 1 DAY, ORAL | | | Klonopin (Clonazepam) | SS | | ORAL |
| | 0.5 MG 1X PER | | | | | | |
| | 1 DAY, ORAL; | | | | | | |
| | 1 MG 1X PER 1 | | | | | | |

DAY, ORAL

Ritalin
(Methylphenidate
Hydrochloride)

SS

ORAL

20 MG 3X PER

1 DAY, ORAL

Date:11/20/01ISR Number: 3827907-8Report Type:Expedited (15-DaCompany Report #PHNU2001DE02391
Age:63 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Agitation Amnestic Disorder Cerebral Ischaemia Confusional State | Foreign Health Professional Other | Ritaline (Methylphenidat Hydrochloride) Tablet | PS | | ORAL |
| 20 MG/DAY, ORAL | | Disorientation Malaise Memory Impairment Pyrexia Simple Partial Seizures Vasculitis Cerebral Vasospasm | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/20/01ISR Number: 3828074-7Report Type:Expedited (15-DaCompany Report #PHNU2001DE02641
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---------------------------------------|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Difficulty In Walking Paraesthesia | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, BID, ORAL | | | | | | | |

Date:11/21/01ISR Number: 3827119-8Report Type:Expedited (15-DaCompany Report #D0022804A
Age:43 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------|---------------|-------------------------------|----------|----------------|--------------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Bowel Sounds Abnormal Coma | | Zyban Amphetamine Sulphate | PS SS | Glaxo Wellcome | ORAL ORAL |
| 800MG per day | | Drug Toxicity | | Ritalin | SS | | ORAL |
| 60MG per day | | Fatigue | | Wine | SS | | ORAL |
| 3BT per day | | Suicide Attempt Tachycardia | | | | | |

Date:11/21/01ISR Number: 3829479-0Report Type:Expedited (15-DaCompany Report #MPI-2001-06087
Age:36 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyskinesia Tic | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride Extended-Release | PS | | |
| 40 MG | | | | | | | |

Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anger Depression Social Avoidant Behaviour Suicidal Ideation | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride Extended-Release | PS | | |
| 20 MG OR 40MG | | | | Benadryl (Diphenhydramine Hydrochloride) | C | | |

Age:18 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine Phosphokinase Increased | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | Rtaline (Methylphenidate Hydrochloride) Slow Release Tablet | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/23/01ISR Number: 3829381-4Report Type:Expedited (15-DaCompany Report #11775
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|---------------|------------------------------|--------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Gastric Ulcer | Consumer Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 18MG 1X/1DAY, ORAL | | | | | | | |

Date:11/27/01ISR Number: 3830985-3Report Type:Direct Company Report #
Age:15 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|------------------------------|---------|--------------|-------|
| Dose | | | | | | | |
| | | Drug Ineffective | | Methylphenidate Ritalin 20mg | PS C | | |

Date:11/27/01ISR Number: 3832629-3Report Type:Direct Company Report #
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------|---------------|-----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening Required | | Medication Error | | Ritalin 10 Mg Tablets | PS | | ORAL |
| 15-17 TABLE Intervention to PER DAY ORAL Prevent Permanent Impairment/Damage | | | | | | | |

Date:11/28/01ISR Number: 3831419-5Report Type:Expedited (15-DaCompany Report #2001UW14835
Age:47 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Accidental Overdose | Other | Seroquel | PS | | ORAL |
| 50 MG BID PO | | | | | | | |

| | | | | |
|-------------------------------------|-------------------------------------|------------------|----|------|
| Initial or Prolonged A FEW YEARS | Blood Creatine | | | |
| 500 MG HS PO | Phosphokinase Increased | Seroquel | SS | ORAL |
| A FEW YEARS | Blood Creatine | | | |
| 14 MG QD PO | Phosphokinase Mb | Gabitril | SS | ORAL |
| 30 MG QD PO | Increased | Paxil | SS | ORAL |
| 20 MG QID PO | Complex Partial Seizures | Ritalin | SS | ORAL |
| | Delirium | Lamictal | C | |
| | Faecal Incontinence | Biaxin | C | |
| | Grand Mal Convulsion | Neurontin | C | |
| | Leukocytosis | Zomig | C | |
| | Major Depression | Imitrex | | |
| | Mental Impairment | "Glaxo-Wellcome" | C | |
| | Migraine | Ranitidine | C | |
| | Urinary Incontinence | Remeron | C | |
| | White Blood Cell Count Increased | Synthroid | C | |

Date:11/28/01ISR Number: 3844334-8Report Type:Periodic
Age:37 YR Gender:Female I/FU:I

Company Report #A0160503A

| | |
|----------------------|--------------------|
| Outcome | PT |
| Hospitalization - | Crying |
| Initial or Prolonged | Depression |
| | Feeling Abnormal |
| | Hypoaesthesia |
| | Hypoaesthesia Oral |
| | Sedation |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Suicide Attempt

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------------|----------|---------------|---|------|--------------|-------|
| 150 MG / TWICE PER DAY / ORAL | | Consumer | Wellbutrin Sr Tablet-Controlled Release (Bupropion Hydrochloride) | PS | | ORAL |
| | | | Paracetamol (Formulation Unknown) (Acetaminophen) | SS | | |
| 100 MG / PER DAY | | | Sertraline Hydrochloride (Formulation Unknown) (Sertraline Hydrochloride) | SS | | |
| 20 MG | | | Methylphenidate Hcl (Formulation Unknown) (Methylphenidate Hcl) | SS | | |
| 250 MG / PER DAY | | | Disulfiram (Formulation Unknown) (Disulfiram) | SS | | |
| 5 MG / AS REQUIRED / ORAL | | | Lorazepam (Formulation Unknown) (Lorazepam) | SS | | ORAL |

Date:11/29/01ISR Number: 3832143-5Report Type:Expedited (15-DaCompany Report #PHNU2001DE02716
Age:13 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------------------------|-----------------------------------|--|------|--------------|-------|
| Dose Duration | | | | | | |
| Hospitalization - Initial or Prolonged | Diplopia Strabismus | Foreign Health Professional | Ritaline (Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| 20MG/DAY, ORAL | | Other | | | | |

Date:11/29/01ISR Number: 3832509-3Report Type:Expedited (15-DaCompany Report #PHBS2001DK11767
Age:15 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose Duration | | | | | | |
| Hospitalization - Initial or Prolonged | Atrial Fibrillation Syncope | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | |
| 30 MG/DAY | | Other | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/29/01ISR Number: 3832525-1Report Type:Expedited (15-DaCompany Report #PHNU2001DE00522
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Activated Partial Thromboplastin Time Prolonged Coagulation Factor | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 30 MG/DAY, ORAL | | Decreased Factor Ix Deficiency | | | | | |

Date:11/29/01ISR Number: 3832526-3Report Type:Expedited (15-DaCompany Report #PHNU2001DE02710
Age:39 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged Other | | Aphasia Blood Immunoglobulin G Increased Cerebral Artery | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 20-30 MG/DAY, ORAL | | Thrombosis Cerebrovascular Accident Hemiparesis Vasculitis Cerebral | | | | | |

Date:11/29/01ISR Number: 3832543-3Report Type:Expedited (15-DaCompany Report #PHRM2001FR02590
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hyperaemia Pain Pain In Extremity | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 15 MG/DAY, ORAL | | | | | | | |

Date:11/29/01ISR Number: 3832552-4Report Type:Expedited (15-DaCompany Report #PHBS2001JP09045
 Age:80 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--|--|--|-------------------------------|--------------|-------|
| Dose Duration Hospitalization - Initial or Prolonged 10 MG/DAY, ORAL | Depressed Level Of Consciousness Neuroleptic Malignant Syndrome Urinary Tract Infection White Blood Cell Count Increased | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Bufferin (Aluminium Glycinate, Magnesium Carbonate) Mexetil (Mexilentine Hydrochloride) Adalat Xl | PS C C C | | ORAL |

Date:11/29/01ISR Number: 3837056-0Report Type:Periodic Company Report #US009033
 Age:47 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|---|--|----------------------|--------------|------------------------------|
| Dose Duration Hospitalization - 2 MG QD ORAL Initial or Prolonged 16 MG QD ORAL 16 MG QD ORAL 50 MG BID ORAL A FEW | Accidental Overdose Complex Partial Seizures Faecal Incontinence Urinary Incontinence | Health Professional Company Representative | Gabitril Gabitril Gabitril Seroquel | PS SS SS SS | | ORAL ORAL ORAL ORAL |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | |
|-------------|--|--|------------|----|----------------|
| YEARS | | | | | |
| 500 MG QHS | | | Seroquel | SS | ORAL |
| ORAL A FEW | | | | | |
| YEARS | | | | | |
| 20 MG QID | | | Ritalin | SS | ORAL |
| ORAL | | | | | |
| 30 MG DAILY | | | Paxil | SS | ORAL |
| ORAL | | | | | |
| | | | Lamictal | C | |
| | | | Biaxin | C | |
| | | | Neurontin | C | |
| | | | Zomig | C | |
| | | | Imitrex | C | Glaxo-Wellcome |
| | | | Ranitidine | C | |
| | | | Remeron | C | |
| | | | Synthroid | C | |

Date:11/30/01ISR Number: 3833165-0Report Type:Expedited (15-DaCompany Report #PHNU2001DE02711
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Chills Diplopia Dyskinesia Oculogyration | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | Strabismus | | | | | |

Date:12/03/01ISR Number: 3833892-5Report Type:Expedited (15-DaCompany Report #PHNU2001DE02391
 Age:63 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------|-------------------|------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Agitation Amnestic Disorder | Foreign Health | Ritaline (Methylphenidate | | | |

| | | | | | |
|-------------|-------------------------|--------------|----------------|----|------|
| 200 MG/DAY, | Cerebral Ischaemia | Professional | Hydrochloride) | PS | ORAL |
| | Confusional State | Other | Tablet | | |
| ORAL | Disorientation | | | | |
| | Memory Impairment | | | | |
| | Nervous System Disorder | | | | |
| | Pyrexia | | | | |
| | Simple Partial Seizures | | | | |
| | Vasculitis Cerebral | | | | |
| | Vasospasm | | | | |

Date:12/03/01ISR Number: 3844166-0Report Type:Periodic Company Report #11437
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | Consumer | Concerta | | | |
| | | Anxiety | | (Methylphenidate | | | |
| 18MG 1X/DAY, | | Personality Disorder | | Hcl) | PS | | ORAL |
| ORAL | | | | Prozac | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/04/01ISR Number: 3834953-7Report Type:Expedited (15-DaCompany Report #MPI-2001-06121 (0)
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------------------------|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Homicidal Ideation | Health Professional | Metadate Cd Capsule 20 Mg (Methylphenidate Hydrochloride Extended-Release | PS | | ORAL |
| 20MG QD PO | | | | | | | |

Date:12/06/01ISR Number: 3836979-6Report Type:Expedited (15-DaCompany Report #PHBS2001CA03983
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia Weight Decreased | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG/DAY, ORAL | | | | | | | |
| | | | Other | Trazodone (Trazodone) | C | | |

Date:12/06/01ISR Number: 3837293-5Report Type:Expedited (15-DaCompany Report #PHNU2001DE02711
 Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Chills Diplopia Dyskinesia Oculogyration | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | | | | |
| | | Strabismus | | | | | |

Date:12/06/01ISR Number: 3837306-0Report Type:Expedited (15-DaCompany Report #PHNU2001DE02753
 Age:30 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---|---|---------------|--|------|--------------|-------|
| Dose | Hospitalization - Initial or Prolonged | Cerebral Venous Thrombosis Headache | | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | Marcumar (Phenprocoumon) | C | | |

Date:12/06/01ISR Number: 3837308-4Report Type:Expedited (15-DaCompany Report #PHNU2001DE02785
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--|--|------|--------------|-------|
| Dose | Other | Bleeding Time Prolonged Oedema Peripheral Platelet Disorder | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | | | | |

Date:12/07/01ISR Number: 3837529-0Report Type:Expedited (15-DaCompany Report #MPI-2001-06089(1)
Age:10 YR Gender:Male I/FU:F

| Outcome | PT |
|---------|---------------------|
| Other | Anger Depression |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---|------------------------|---|-------------|--------------|-------|
| 20 MG QAM PO | | Educational Problem Irritability Personality Change Social Avoidant Behaviour Suicidal Ideation | Health Professional | Metadate Cd Capsules 20mg (Methylphenidate Hydrochloride Extended-Release Benadryl (Diphenhydramine Hydrochloride) | PS C | | ORAL |

Date:12/07/01ISR Number: 3837533-2Report Type:Expedited (15-DaCompany Report #MPI-2001-06106 (0)
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|------------------------|--|-------------|--------------|-------|
| 20 MG QAM PO | | Aggression Agitation Belligerence Delusion Depression Hallucination, Auditory Negativism Psychotic Disorder Social Avoidant Behaviour Suicidal Ideation | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride Extended-Release Depakote (Valproate Semisodium) | PS C | | ORAL |

Date:12/10/01ISR Number: 3837493-4Report Type:Expedited (15-DaCompany Report #PHBS2001NZ12212
Age:24 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|---|---|--|---|------|--------------|-------|
| INJECTION NOS | Hospitalization - Initial or Prolonged | Drug Dependence Medication Error Oedema Peripheral Skin Discolouration | Foreign Literature Health Professional Other | Methylphenidate (Methylphenidate Hydrochloride) | PS | | |

Date:12/10/01ISR Number: 3839244-6Report Type:Expedited (15-DaCompany Report #PHBS2001NZ12213
Age:42 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-------------------------|---------------|------------------|------|--------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - | Drug Abuser | Foreign | Methylphenidate | | | |
| Initial or Prolonged | Erythema | Literature | (Methylphenidate | | | |
| | Groin Pain | Health | Hydrochloride) | PS | | |
| INJECTION,NOS | | | | | | |
| | Inguinal Mass | Professional | | | | |
| | Medication Error | Other | | | | |
| | Oedema Peripheral | | | | | |
| | Pitting Oedema | | | | | |
| | Sepsis | | | | | |
| | Vascular Pseudoaneurysm | | | | | |

Date:12/11/01ISR Number: 3838344-4Report Type:Expedited (15-DaCompany Report #PHEH2001US09873
Age:17 YR Gender:Male I/FU:I

| Outcome | PT |
|---------|-------------------------|
| Other | Growth Retardation |
| | Mentally Late Developer |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Underweight

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|------|----------|---------------|---|------|--------------|-------|
| | | Consumer | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | |

Date:12/12/01ISR Number: 3839057-5Report Type:Direct Company Report #
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|-----------------------|---------------|-----------------|------|--------------|-------|
| Other | 15MG-10MG-10M | Drug Effect Decreased | | Ritalin Generic | PS | | ORAL |

G ORAL LACK

OF EFFECT

Date:12/12/01ISR Number: 3839425-1Report Type:Expedited (15-DaCompany Report #PHNU2001DE02819
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|-------------------------|-----------------------------------|--|------|--------------|-------|
| Other | 15MG/DAY, | Hallucination, Auditory | Foreign Health Professional | Ritaline(Methyphenid ate Hydrochloride) Tablet | PS | | ORAL |
| | ORAL | | Other | | | | |

Date:12/12/01ISR Number: 3839772-3Report Type:Expedited (15-DaCompany Report #PHBS2001US12331
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------|----------------------|------------------------------|------|--------------|-------|
| Death | | Cardiac Arrest Neonatal Coma | Literature Health | Ritaline (Methylphenidate | | | |

| | | | | | |
|----------------|---------------|--------------------------|--------------|------------------|----|
| TRANSPLACENTAL | TRANSPLACENTA | Cyanosis Neonatal | Professional | Hydrochloride) | PS |
| L | | Hyporeflexia | | | |
| | | Hypotonia Neonatal | | Wellbutrin | |
| | | Maternal Drugs Affecting | | (Amfebutamone | |
| | | Foetus | | Hydrochloride) | SS |
| TRANSPLACENTAL | TRANSPLACENTA | Neonatal Apnoeic Attack | | | |
| L | | Oliguria | | Benadryl | |
| | | Tremor Neonatal | | (Diphenhydramine | |
| | | | | Hydrochloride) | SS |
| TRANSPLACENTAL | TRANSPLACENTA | | | | |
| L | | | | | |

Date:12/12/01ISR Number: 3839930-8Report Type:Expedited (15-DaCompany Report #PHRM2001FR02590
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------------|---------------|------------------|------|--------------|-------|
| Dose | | C-Reactive Protein | Foreign | Ritaline | | | |
| Other | | Increased | Health | (Methylphenidate | | | |
| | | Hyperaemia | Professional | Hydrochloride) | | | |
| 17.5 MG/DAY, | | Hyperaesthesia | Other | Tablet | PS | | ORAL |
| ORAL | | Pain | | | | | |
| | | Red Blood Cell | | | | | |
| | | Sedimentation Rate | | | | | |
| | | Increased | | | | | |
| | | White Blood Cell Count | | | | | |
| | | Increased | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/12/01ISR Number: 3839931-XReport Type:Expedited (15-DaCompany Report #PHNU2001DE02391
Age:63 YR Gender:Female I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---|--|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Agitation Amnestic Disorder Cerebral Ischaemia Confusional State | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG/DAY, ORAL | Disorientation Malaise Memory Impairment Nuclear Magnetic Resonance Imaging Abnormal Pyrexia Simple Partial Seizures Vasculitis Cerebral Vasospasm | | | | | |

Date:12/12/01ISR Number: 3839932-1Report Type:Expedited (15-DaCompany Report #PHBS2001NZ12212
Age:24 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|---|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Drug Abuser Medication Error Oedema Peripheral Peripheral Ischaemia | Foreign Literature Health Professional | Ritaline (Methylpenidate Hydrochloride) Unknown | PS | | |
| INJECTION NOS | Skin Discolouration | Other | | | | |

Date:12/12/01ISR Number: 3839945-XReport Type:Expedited (15-DaCompany Report #PHBS2001NZ12213
Age:42 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---|---------------------------------|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Drug Abuser Erythema Medication Error | Foreign Literature Health | Ritaline (Methylphenidate Hydrochloride) | PS | | |
| INJECTION NOS | | | | | | |

Mycotic Aneurysm
Necrosis
Oedema Peripheral
Pain
Pitting Oedema
Postoperative Infection
Sepsis
Vascular Pseudoaneurysm

Professional
Other

Date:12/13/01ISR Number: 3841455-0Report Type:Expedited (15-DaCompany Report #2001-10-1935
Age:66 YR Gender:Male I/FU:F

Outcome PT
Hospitalization - Blood Folate Abnormal
Initial or Prolonged Csf Cell Count Abnormal
Csf Lymphocyte Count
Abnormal
Decreased Appetite
Demyelinating
Polyneuropathy
Difficulty In Walking
Dysphagia
Faecal Incontinence

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------------------------|---|--|--------------|-------|
| | | Guillain-Barre Syndrome Haemoglobin Decreased Joint Stiffness | | | | | |
| | | Metabolic Acidosis Metastasis Muscular Weakness | Study Health Professional | Intron A (Interferon Alfa-2b Recombinant) Injectable | PS | | |
| SUBCUTANEOUS | 10-6MU* | Oral Candidiasis | Other | | | | |
| SUBCUTANEOUS; | | Oxygen Saturation Decreased | | | | | |
| 10 MU | | Platelet Count Abnormal | | | | | |
| SUBCUTANEOUS; | | Pneumonia Renal Cyst | | Ritalin Blinded Study | SS | | ORAL |
| 6 MU | | Serum Ferritin Abnormal Urinary Incontinence Vitamin B12 Abnormal Weight Decreased White Blood Cell Count Abnormal | | Lipitor (Atorvastatin) Prilosec Lasix Glucophage Micronase K-Dur (Potassium Chloride) Inderal Zyloprim Multivitamins Tylenol | C C C C C C C C C C | | |

Date:12/14/01ISR Number: 3841056-4Report Type:Expedited (15-DaCompany Report #PHFR2001GB03375
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|--|--|------|--------------|-------|
| Death | | Cardiomegaly | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) | PS | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Educational Problem | | Ritalin (Generic) | PS | | ORAL |
| 20MG SR Q AM | | Fight In School | | | | | |
| ORAL | | | | | | | |
| 15MG REGULAR | | | | Ritalin(Generic) | SS | | |
| PM | | | | | | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|--------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Attention Deficit/Hyperactivity Disorder | Literature Health Professional | Methylphenidate (Methylphenidate Hydrochloride) | PS | | |
| 10 MG, TID | | Condition Aggravated Depression Hallucination, Auditory Headache Middle Insomnia Nightmare Psychotic Disorder | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/19/01
 Age: 12/19/01
 Gender:Male
 ISR Number: 3841595-6
 Report Type:Direct
 I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Ritalin | PS | | |

Date:12/20/01
 Age: 12/20/01
 Gender:Male
 ISR Number: 3843304-3
 Report Type:Direct
 I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin (Novartis) | PS | Novartis | |
| 10MG IN AM | | | | | | | |

Date:12/21/01
 Age: 12/21/01
 Gender:Female
 ISR Number: 3843674-6
 Report Type:Direct
 I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Unevaluable Event | | Ritalin | PS | | ORAL |
| 5 MG PM PO | | | | | | | |

PRN

Date:12/21/01
 Age: 12/21/01
 Gender:Male
 ISR Number: 3843679-5
 Report Type:Direct
 I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------------|---------------|--------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Unevaluable Event | | Ritalin 5 Mg | PS | | ORAL |
| 5 MG TID PO | | | | | | | |

Date:12/21/01
 Age:7 YR
 Gender:Male
 ISR Number: 3844008-3
 Report Type:Direct
 I/FU:I

Company Report #

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Sedation | | Methylphenidate (5 | | | |

7.5 MG BID

ORAL

Date:12/27/01ISR Number: 3845579-3Report Type:Expedited (15-DaCompany Report #MPI-2001-06344 (0)
Age:6 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--|------------------------|---|---------------------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent 200 MG AT Impairment/Damage ONCE PO | Bruxism Drug Ineffective Feeling Hot Insomnia Medication Error Muscle Twitching Speech Disorder Thinking Abnormal Tremor | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride Extended-Release Ritalin (Methylphenidate Hydrochloride) | PS C | | ORAL |

Date:12/28/01ISR Number: 3846028-1Report Type:Direct Company Report #157914
Age:5 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|------------------|------------------------|-------------------------------|------|--------------|-------|
| Dose Other | Drug Ineffective | Health Professional | Methylphenidate 5mg Geneva | PS | Geneva | ORAL |

7.5MG PO BID

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/28/01ISR Number: 3846480-1Report Type:Expedited (15-DaCompany Report #PHBS2001CH12577
 Age:8 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Duration Hallucination, Tactile | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| 15 MG/DAY, ORAL | | Other | | | | |

Date:12/28/01ISR Number: 3846509-0Report Type:Expedited (15-DaCompany Report #PHNU2001DE02553
 Age:72 YR Gender:Female I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------------------|----------------------------|---|--------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Duration Dystonia | Foreign Study Health | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| SEE IMAGE | | Professional | Zyprexa(Olanzapine) | SS | | ORAL |
| SEE IMAGE | | Other | Aricept(Donepezil Hydrochloride) | SS | | ORAL |
| SEE IMAGE | | | Thrombran(Trazodone Hydrochloride) Acetylsalicylate | C C | | |

Date:12/28/01ISR Number: 3846524-7Report Type:Expedited (15-DaCompany Report #PHNU2001DE02819
 Age:12 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|-------------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose Other | Duration Hallucination, Auditory | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| 15MG/DAY, ORAL | | Other | Tablet | | | |

Date:12/31/01ISR Number: 3845997-3Report Type:Direct Company Report #CTU 157928
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Affect Lability | | Methylphenidate | PS | | ORAL |
| 5 MG TID PO | | Affective Disorder | | Risperdal | C | | |
| | | Drug Effect Decreased | | Clonidine | C | | |
| | | Irritability | | | | | |
| | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |

Date:01/03/02ISR Number: 3847567-XReport Type:Direct Company Report #
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| 20 MG | | Medication Error | | Metadate Cd | PS | | |

Date:01/03/02ISR Number: 3848170-8Report Type:Expedited (15-DaCompany Report #PHNU2001DE02753
Age:30 YR Gender:Male I/FU:F

| | |
|----------------------|-----------------|
| Outcome | PT |
| Hospitalization - | Cerebral Venous |
| Initial or Prolonged | Thrombosis |
| Other | Coagulopathy |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Headache

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--|---|------|--------------|-------|
| 20 MG/DAY, ORAL | | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| | | | Marcumar (Phenprocoumon) Tablet | C | | |
| | | | Edronax (Reboxetine) Tablet | C | | |
| | | | Doxycycline (Doxycycline) | C | | |
| | | | Omnice (Tamsulosin Hydrochloride) Slow Release Capsules | C | | |

Date:01/03/02ISR Number: 3848715-8Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 158206

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|----------------------|------|--------------|-------|
| Other | | Drug Ineffective | | Ritalin 20mg Generic | PS | | |
| 1 1/ 2 Q 7AM; | | Pharmaceutical Product | | | | | |
| 1 1/ 2 Q | | Complaint | | | | | |
| 10AM; 1/ 2 Q | | | | | | | |
| 2 PM; 1/ 2 PM | | | | | | | |
| PRN | | | | | | | |

Date:01/04/02ISR Number: 3849615-XReport Type:Expedited (15-DaCompany Report #PHNU2001DE02785
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|-------|-------------------------|--------------|------------------|----|------|
| Other | Bleeding Time Prolonged | Foreign | Ritaline | | |
| | Injury | Health | (Methylphenidate | | |
| | Oedema Peripheral | Professional | Hydrochloride) | | |
| ORAL | Platelet Disorder | Other | Tablet | PS | ORAL |
| | Platelet Function Test | | Aspirin "Bayer" | | |
| | Abnormal | | (Acetylsalicylic | | |
| ORAL | | | Acid) | SS | ORAL |

Date:01/04/02ISR Number: 3849617-3Report Type:Expedited (15-DaCompany Report #PHBS2001SE12774
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pancytopenia | Foreign | Ritalina(Methylpheni | | | |
| | | | Health | date Hydrochloride) | PS | | |
| | | | Professional | | | | |
| | | | Other | | | | |

Date:01/07/02ISR Number: 3852719-9Report Type:Expedited (15-DaCompany Report #2001-10-1935
Age:66 YR Gender:Male I/FU:F

| | |
|----------------------|---------------|
| Outcome | PT |
| Hospitalization - | Anorexia |
| Initial or Prolonged | Atelectasis |
| | Demyelinating |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------------------|---------------|---------|------|--------------|-------|
| Dose | | Drug Ineffective | | Ritalin | PS | | ORAL |
| 20 MG BID PO | | Pharmaceutical Product Complaint | | | | | |

Date:01/09/02ISR Number: 3850212-0Report Type:Expedited (15-DaCompany Report #FLUV00301005243
 Age:31 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Depressed Level Of Consciousness Dysarthria | Foreign Literature Health | Luvox 25 (Fluvoxamine Maleate) | PS | | ORAL |
| 75 MG DAILY | | Pulmonary Infarction | Professional | | | | |
| PO | | Respiratory Disorder Somnolence Speech Disorder | | Tryptanol (Amitriptyline Hydrochloride) | SS | | ORAL |
| 75 MG DAILY; | | | | Wypax (Lorazepam) | SS | | ORAL |
| PO | | | | Myonal (Eperisone | | | |
| 6 MG DAILY; | | | | | | | |
| PO | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | |
|----------------------|---|----|------|
| 300 MG DAILY; PO | Hydrochloride) | SS | ORAL |
| 3 DF DAILY; PO | Perphenazine (Perphenazine) | SS | ORAL |
| 15 MG DAILY; PO | Lexotan (Bromazepam) | SS | ORAL |
| 0.75 MG DAILY; PO | Halcion (Triazolam) | SS | ORAL |
| 20 MG DAILY; PO | Ritalin (Methylphenidate Hydrochloride) | SS | ORAL |
| 150 MG DAILY; PO | Ravona (Pentobarbital Calcium) | SS | ORAL |
| 6 MG DAILY;PO | Depas (Etizolam) | SS | ORAL |
| 0.5 G DAILY; PO | Brovarin (Bromisoval) | SS | ORAL |

Date:01/09/02ISR Number: 3850524-0Report Type:Direct
Age:8 YR Gender:Male I/FU:I

Company Report #CTU 158662

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|------------------------------|---------------|---------------------|------|--------------|-------|
| Dose Other 5MG Q AM, NOON | Duration Drug Ineffective | | Methylphenidate Hci | PS | | |

Methylphenidate Hci SS

20MG Q AM,

NOON

Date:01/10/02ISR Number: 3851100-6Report Type:Direct
Age:37 YR Gender:Male I/FU:I

Company Report #CTU 158836

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|---------------------------------|------|--------------|-------|
| Life-Threatening | | Abnormal Behaviour Anger | | Methylphenidate Tablets 20mg | PS | | |
| 3 TABS, 5 TIMES/DAY (300 MG DAILY)/ 4 1/2 - 5 YRS OR | | Belligerence Chest Pain Delusion Myocardial Infarction | | Zoloft | C | | |

Date:01/10/02ISR Number: 3852294-9Report Type:Direct
Age: Gender:Female I/FU:I

Company Report #CTU 158905

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|------------------------------|------|--------------|-------|
| | | Drug Ineffective Pharmaceutical Product Complaint | | Methylphenidate - Generic | PS | | |

Date:01/11/02ISR Number: 3852041-0Report Type:Expedited (15-DaCompany Report #PHBS2002CH00502
Age:15 YR Gender:Male I/FU:I

| Outcome | PT |
|---------|-----------------------------------|
| Other | Aggression Agitation Crying |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Depression Disturbance In Attention Drug Interaction | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| 20 MG/DAY, ORAL | | | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 GOUTES/DAY, ORAL | | | Other | St. John'S Wort (Hypericum Perforatum) | SS | | ORAL |

Date:01/11/02ISR Number: 3852111-7Report Type:Direct Company Report #CTU 158975
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------------------|---------------|------------------------------|------|--------------|-------|
| Dose Other | | Abnormal Behaviour Aggression | | Methylphenidate (Generic) | PS | | ORAL |
| 20MG PO BID | | Agitation | | Clonidine | C | | |

Date:01/11/02ISR Number: 3852282-2Report Type:Direct Company Report #CTU 158914
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---|---------------|-----------------|------|--------------|-------|
| Dose Other | | Abnormal Behaviour | | Generic Ritalin | PS | | ORAL |
| 20 MG PO 2 TID | | Agitation | | | | | |
| | | Drug Effect Decreased Pharmaceutical Product Complaint Screaming | | | | | |

Date:01/11/02ISR Number: 3852284-6Report Type:Direct Company Report #CTU 158916
Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin (10mg) | PS | | |
| 2 AM AND 1 | | Pharmaceutical Product | | | | | |
| 1/2 NOON | | Complaint | | | | | |
| EVERY DAY | | | | | | | |

Date:01/11/02ISR Number: 3852290-1Report Type:Direct Company Report #CTU 158898
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Methylphenidate | | | |
| RITALIN 5MG 2 | | Pharmaceutical Product | | (Generic) | PS | | |
| QAM 2 NOON 1 | | Complaint | | | | | |
| 1/2 PM | | | | | | | |

Date:01/14/02ISR Number: 3852289-5Report Type:Direct Company Report #CTU 158897
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Methylphenidate | PS | | |
| 20 MG AM AND | | Pharmaceutical Product | | | | | |
| NOON | | Complaint | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/14/02ISR Number: 3852748-5Report Type:Direct
Age:13 YR Gender:Male I/FU:I

Company Report #CTU 159131

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|--|---------------|---------------------------------------|------|--------------|-------|
| Dose Other 20 MG PO TID | | Abnormal Behaviour Agitation Drug Effect Decreased Pharmaceutical Product Complaint Screaming | | Methylphenidate (20 Mg-Apothecon) | PS | Apothecon | ORAL |

Date:01/14/02ISR Number: 3867402-3Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 161311

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---------------|---------------|------------------------------|------|--------------|-------|
| Dose 5MG 1 BID | 1 YR | Hallucination | | Methylphenidate (Generic) | PS | | |

Date:01/15/02ISR Number: 3852683-2Report Type:Direct
Age:57 YR Gender:Female I/FU:I

Company Report #CTU 159129

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------------|----------|--|---------------|----------------------------|------|--------------|-------|
| Disability Other 20 MG PO TID | | Disturbance In Attention Drug Effect Decreased Homeless Pharmaceutical Product Complaint Relationship Breakdown | | Ritalin Sr Generic 20mg | PS | | ORAL |

Date:01/15/02ISR Number: 3852755-2Report Type:Direct
Age:11 YR Gender:Male I/FU:I

Company Report #CTU 159098

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Other Drug Effect Decreased Ritalin 10mg PS

10MG 1 1/2

Pharmaceutical Product

TAB BID

Complaint

Date:01/15/02ISR Number: 3852759-XReport Type:Direct

Company Report #CTU 159126

Age:57 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Disturbance In Attention | | Ritalin Sr 20mg | | | |
| Other | | Drug Effect Decreased | | Generic | PS | Generic | ORAL |
| 20MG 1 PO | | Homeless | | | | | |
| TID | | Pharmaceutical Product | | Psychopharm | C | | |
| | | Complaint | | | | | |
| | | Relationship Breakdown | | | | | |

Date:01/15/02ISR Number: 3853289-1Report Type:Expedited (15-DaCompany Report #PHEH2001US10491

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------|---------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Death | Health Professional | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/15/02ISR Number: 3853313-6Report Type:Direct
Age:13 YR Gender:Male I/FU:I

Company Report #CTU 159204

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | (Methylphenidate | | | |
| | | Condition Aggravated | | Hcl) (20mg) | PS | | |
| 20MG Q AM, | | Drug Ineffective | | | | | |
| NOON | | Impulsive Behaviour | | Methylphenidate Hcl | | | |
| | | Pharmaceutical Product | | 10mg | SS | | |
| 10MG Q Y PM | | Complaint | | | | | |

Date:01/15/02ISR Number: 3853362-8Report Type:Direct
Age:14 YR Gender:Female I/FU:I

Company Report #CTU 159315

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Concerta Er 36mg | PS | | ORAL |
| 36MG 1 DAY | | Aggression | | | | | |
| ORAL | | Alcoholism | | Claritin | C | | |
| | | Pyromania | | | | | |
| | | Tobacco Abuse | | | | | |

Date:01/16/02ISR Number: 3854034-6Report Type:Expedited (15-DaCompany Report #PHBS2002GB00557
Age:11 YR Gender:Female I/FU:I

Company Report #PHBS2002GB00557

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper | Foreign | Methylphenidate | | | |
| | | Aggression | Literature | (Methylphenidate | | | |
| | | Headache | Health | Hydrochloride) | | | |
| | | Insomnia | Professional | Tablet | PS | | ORAL |
| 10 MG, TID, | | Suicidal Ideation | Other | | | | |
| ORAL | | Vomiting | | | | | |

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---|--|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged Disability | Agitation Amnestic Disorder C-Reactive Protein Increased | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG/DAY, ORAL | Cerebral Artery Occlusion Cerebral Ischaemia Confusional State Disorientation Electroencephalogram Abnormal Headache Malaise Memory Impairment Monoparesis Paresis Pyrexia Sensorimotor Disorder Simple Partial Seizures Speech Disorder Vasculitis Cerebral Vasospasm Visual Disturbance Visual Field Defect | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/16/02ISR Number: 3854077-2Report Type:Expedited (15-DaCompany Report #PHBS2002GB00561
Age:20 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---|---|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper Aggression Drug Abuser Nausea | Foreign Literature Health Professional | Methylphenidate (Methylphenidate Hydrochloride) Unknown | | | |
| 100 MG/DAY, ORAL | | Suicide Attempt Weight Decreased | Other | | PS | | ORAL |

Date:01/16/02ISR Number: 3854097-8Report Type:Expedited (15-DaCompany Report #PHBS2002GB00556
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper Aggression Anorexia | Foreign Literature Health | Methylphenidate (Methylphenidate Hydrochloride) | | | |
| 75 MG/DAY | | Chest Pain Diarrhoea Headache Nightmare Suicidal Ideation Thirst Vomiting | Professional Other | | PS | | |

Date:01/16/02ISR Number: 3854099-1Report Type:Expedited (15-DaCompany Report #PHBS2002GB00559
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|---------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Depression Eyelid Function Disorder | Foreign Literature Health | Methylphenidate (Methylphenidate Hydrochloride) | | | |
| 10 MG, TID, ORAL | | Headache Insomnia | Professional Other | | PS | | ORAL |

Suicidal Ideation
Tic
Weight Decreased

Date:01/17/02ISR Number: 3855648-XReport Type:Direct Company Report #CTU 159538
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|-------------------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | Abnormal Behaviour | | Methylphenidate | PS | Apothecon | |
| 20MG AM, NOON, 4 PM | | Drug Ineffective | | | | | |
| | | Pharmaceutical Product Complaint | | | | | |

Date:01/17/02ISR Number: 3855905-7Report Type:Expedited (15-DaCompany Report #11973
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------|---------------|--------------------------|------|--------------|-------|
| Dose | | Idiopathic | Consumer | Concerta | | | |
| Hospitalization - Initial or Prolonged | | Thrombocytopenic Purpura | | (Methylphenidate Hcl) | PS | | ORAL |
| 36MG 1X/1DAY, ORAL | | | | Zyrtec | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/18/02ISR Number: 3856602-4Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 159618

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper | | Methylphenidate 10mg | PS | | |
| 10MG 1 TAB | | Decreased Appetite | | | | | |
| T.I.D. | | Fatigue | | | | | |
| | | Nausea | | | | | |

Date:01/18/02ISR Number: 3856763-7Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 159685

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper | | Methylphenidate | | | |
| 10MG 1T TAB | | Decreased Appetite | | 10mg Watson | PS | Watson | |
| TID | | Fatigue | | | | | |
| | | Nausea | | | | | |

Date:01/22/02ISR Number: 3856949-1Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 159714

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|----------------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anger | | Methylphenidate 5 Mg | | | |
| 5 MG TID | | Drug Effect Decreased | | Screin | PS | Screin | |
| | | Pharmaceutical Product Complaint | | | | | |

Date:01/22/02ISR Number: 3857625-1Report Type:Expedited (15-DaCompany Report #FLUV00301005243
 Age:31 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Depressed Level Of | Foreign | Luvox 25 | | | |

| | | | | | |
|----------------------|---|----------------------|---|----|------|
| Initial or Prolonged | Consciousness Dysarthria | Literature Health | (Fluvoxamine Maleate) | PS | ORAL |
| 75 MG DAILY; PO | Pulmonary Infarction | Professional | | | |
| | Refusal Of Treatment By Relative Somnolence | Other | Tryptanol (Amitriptyline Hydrochloride) | SS | ORAL |
| 75 MG DAILY; PO | Ventilation/Perfusion Scan Abnormal | | Wypax (Lorazepam) | SS | ORAL |
| 6 MG DAILY; PO | | | Myonal (Eperisone Hydrochloride) | SS | ORAL |
| 300 MG DAILY; PO | | | Perphenazine (Perphenazine) | SS | ORAL |
| 3 DF DAILY; PO | | | Lexotan (Bromazepam) | SS | ORAL |
| 15 MG DAILY; PO | | | Halcion (Triazolam) | SS | ORAL |
| 0.75 MG DAILY; PO | | | Ritalin (Methylphenidate Hydrochloride) | SS | ORAL |
| 20 MG DAILY; PO | | | Ravona (Pentobarbital Calcium) | SS | ORAL |
| 150 MG DAILY; PO | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | |
|--------------------|--------------------------|----|------|
| 6 MG DAILY; PO | Depas (Etizolam) | SS | ORAL |
| 0.5 G DAILY; PO | Brovarin (Bromisoval) | SS | ORAL |

Date:01/23/02ISR Number: 3856927-2Report Type:Direct Company Report #CTU 159736
Age: Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|-----------------|------|--------------|-------|
| | | Abnormal Behaviour Drug Effect Decreased Pharmaceutical Product Complaint | | Methylphenidate | PS | | |

Date:01/23/02ISR Number: 3857933-4Report Type:Expedited (15-DaCompany Report #PHBS2001JP06554
Age:16 YR Gender:Male I/FU:F

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Cataplexy Hallucination Hallucinations, Mixed | Foreign Literature Health | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | Professional Other | Anafranil (Clomipramine Hydrochloride) | SS | | ORAL |
| ORAL | | | | Pemoline (Pemoline) | SS | | |

Date:01/23/02ISR Number: 3858190-5Report Type:Direct Company Report #CTU 159758
Age:5 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----|---------------|---------|------|--------------|-------|
|--------------|----------|----|---------------|---------|------|--------------|-------|

Other Drug Ineffective Methylphenidate PS
 5MG IN AM 15
 MG @ NOON
 Date:01/23/02ISR Number: 3859599-6Report Type:Direct Company Report #CTU 159974
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|-----------------|------|--------------|-------|
| | | Abnormal Behaviour | | Methylphenidate | PS | | |

Date:01/23/02ISR Number: 3859792-2Report Type:Periodic Company Report #NSADSS2001002131
 Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------------------|---------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Suicide Attempt Weight Increased | Consumer | Risperdal (Unspecified) (Risperidone) | PS | | ORAL |

0.5 MG, 3 IN
 1 DAY(S),
 ORAL
 ORAL
 ORAL
 Ritalin
(Methylphenidate
Hydrochloride) SS ORAL
 Ddavn (Desmopressin) C
 Zoloft (Sertraline
Hydrochloride) C
 Buspar (Buspirone)

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hydrochloride) C

Date:01/24/02ISR Number: 3860016-0Report Type:Expedited (15-DaCompany Report #PHBS2002BR01038
 Age:28 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---|------------------------------|---|------------|--------------|-------|
| Dose Other | | Anorexia Anxiety Crying Depressed Mood | Foreign Consumer Other | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, BID, ORAL | | Dry Mouth | | | | | |
| | | Dysphemia Hyperhidrosis Mood Swings Nervousness Tachycardia Tremor | | Flurazepam (Flurazepam) Tablet Tryptanol (Amitriptline Hydrochloride) Tablet | C C | | |

Date:01/24/02ISR Number: 3860033-0Report Type:Direct Company Report #CTU 159933
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------------------|---------------|----------------------|------|--------------|-------|
| Dose Other | | Dyspepsia | | Methylphenidate 20mg | PS | | ORAL |
| 20MG TID/PO | | Pharmaceutical Product Complaint | | | | | |

Date:01/24/02ISR Number: 3860037-8Report Type:Direct Company Report #CTU 159937
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|-------------------------------------|---------------|---------------|------|--------------|-------|
| Dose Other | | Abnormal Behaviour | | Ritalin (Daw) | PS | Daw | |
| 10MG 2 1/2 TAB TID | | Drug Effect Decreased | | | | | |
| | | Pharmaceutical Product Complaint | | | | | |

Psychomotor Hyperactivity

Date:01/24/02ISR Number: 3860100-1Report Type:Direct
 Age:39 YR Gender:Female I/FU:I

Company Report #CTU 159932

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|--------------|--|---------------|---------------------------------|------|--------------|-------|
| Disability | 20 MG PO TID | Drug Ineffective Pharmaceutical Product | | Methylphenidate (20mg 1 Tid) | PS | | ORAL |
| | | Complaint | | Lorazepam | C | | |
| | | | | Tylenol #4 | C | | |
| | | | | Protriptyline | C | | |

Date:01/25/02ISR Number: 3860247-XReport Type:Direct
 Age: Gender: I/FU:I

Company Report #USP 54716

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-------------|------|--------------|-------|
| Other | | Medication Error | | Metadate Cd | PS | Medeva | |
| | | | | Metadate Er | SS | Medeva | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/25/02ISR Number: 3860610-7Report Type:Expedited (15-DaCompany Report #MPI-2002-00008 (0)
 Age:4 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Aggression Medication Error Screaming | Health Professional Company Representative | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride Extended-Release | PS | | ORAL |
| 40 MG QD PO | | | | | | | |

Date:01/28/02ISR Number: 3862130-2Report Type:Direct Company Report #CTU 160276
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|-----------------|------|--------------|-------|
| Other | | Appetite Disorder Drug Effect Decreased Pharmaceutical Product Complaint | | Methylphenidate | PS | | |

Date:01/29/02ISR Number: 3860905-7Report Type:Direct Company Report #CTU 160382
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|-----------------------|---------------|-------------------|------|--------------|-------|
| Other 20MG SR IN | | Drug Effect Decreased | | Ritalin - Generic | PS | | |
| AM & 10 MG | | | | | | | |
| -BETWEEN 2-3 | | | | | | | |
| PM | | | | | | | |
| Educational Problem | | | | | | | |
| Pharmaceutical Product | | | | | | | |
| Complaint | | | | | | | |

Date:01/29/02ISR Number: 3862102-8Report Type:Direct Company Report #CTU 160360
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

20 MG AM AND Drug Effect Decreased Ritalin [Generic] PS ORAL
PM PO Pharmaceutical Product
Complaint

Date:01/30/02ISR Number: 3861745-5Report Type:Direct Company Report #CTU 160380
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Methylphenidate (5 | | | |
| | | Drug Effect Decreased | | Mg) - (Medeva) | PS | Medeva | |
| 5 MG | 3-TABS | | | | | | |
| | | Pharmaceutical Product | | | | | |
| BID | | Complaint | | | | | |
| | | Psychomotor Hyperactivity | | | | | |

Date:01/30/02ISR Number: 3862336-2Report Type:Direct Company Report #CTU 160448
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| | | Drug Effect Decreased | | Ritalin | PS | | ORAL |
| 20 MG | AM & | | | | | | |
| | | Pharmaceutical Product | | | | | |
| PM | PO | Complaint | | Generic Ritalin | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/30/02ISR Number: 3862360-XReport Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 160459

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Disability | | Drug Effect Decreased | | Methylphenidate | PS | | |
| ONE IN AM | | Pharmaceutical Product | | Methylphenidate | SS | | |
| Other | | Complaint | | Tenex | C | | |
| ONE TID | | | | | | | |

Date:01/30/02ISR Number: 3862504-XReport Type:Expedited (15-DaCompany Report #PHBS2001JP06554
 Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------|---|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hallucination | Foreign Literature Health Professional | Ritaline (Methlpenidate Hydrochloride) Unknown | PS | | ORAL |
| ORAL | | | | Anafranil (Clomipramine Hydrochloride) Unknown | SS | | ORAL |
| ORAL | | | | Pemoline (Pemoline) | SS | | |

Date:01/30/02ISR Number: 3863606-4Report Type:Periodic
 Age:41 YR Gender:Male I/FU:I

Company Report #PHEH2000US11744

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Anorexia Dry Skin Insomnia | Consumer | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 3 TABS DAILY, | | Skin Discolouration | | | | | |
| ORAL | | Weight Decreased | | Prozac (Fluoxetine Hydrochloride) | SS | | ORAL |
| ORAL | | | | | | | |

Zantac C
Prilosec
(Omeprazole) C

Date:01/30/02ISR Number: 3863609-XReport Type:Periodic Company Report #PHEH2001US01007
Age:73 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---|------------------------|--|------|--------------|-------|
| Dose Other | | Convulsion Fall Loss Of Consciousness | Health Professional | Ritalin(Methylphenidate Hydrochloride) Tablet, 10mg | PS | | ORAL |
| 5 0MG QD, ORAL | 2190 DAY | | | | | | |
| | | | | Wellbutrin-Slow Release (Amfebutamone Hydrochloride) 150mg | SS | | ORAL |
| 150 MG, BID, ORAL | 30 DAY | | | | | | |

Date:01/30/02ISR Number: 3863612-XReport Type:Periodic Company Report #PHEH2001US01545
Age: Gender:Male I/FU:I

Outcome PT
Other Aggression
Depression
Panic Attack

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Somnolence

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|------|----------|---------------|---|------|--------------|-------|
| ORAL | | Consumer | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | Accutane(Isotretinoin) | SS | | |

Date:01/30/02ISR Number: 3863615-5Report Type:Periodic Company Report #PHEH2001US03183
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------------|---------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Petit Mal Epilepsy Staring | Health Professional | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 15-25 MG QD, | | | | Multivitamins (Panthenol, Retinol, Ascorbic Acid) | C | | |
| ORAL | | | | | | | |

Date:01/30/02ISR Number: 3863617-9Report Type:Periodic Company Report #PHEH2001US03784
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Tourette'S Disorder | Consumer | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 22.5 MG | | | | | | | |
| DAILY, ORAL | | | | | | | |

Date:01/30/02ISR Number: 3863620-9Report Type:Periodic Company Report #PHEH2001US04868
 Age:86 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|------------------------|--|------|--------------|-------|
| Dose Other | | Delirium | Health Professional | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 40 MG, QD, | | | | | | | |
| ORAL | | | | Fluvoxamine(Fluvoxamine) | SS | | ORAL |
| 75 MG, QD, | | | | | | | |
| ORAL | | | | Loramet(Lormetazepam) | SS | | |
| 2 MG, QD | | | | | | | |

Date:01/30/02ISR Number: 3863622-2Report Type:Periodic Company Report #PHEH2001US08877
Age:47 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Accidental Overdose Faecal Incontinence Grand Mal Convulsion | Health Professional | Ritalin(Methylphenidate Hydrochloride) Tablet, 20mg | PS | | ORAL |
| 20 MG, QID, | | Mental Status Changes | | | | | |
| ORAL | | Urinary Incontinence | | Gabitril(Tiagabine Hydrochloride) | SS | | ORAL |
| 2 MG, QD, | | | | | | | |
| ORAL; 16 MG, | | | | | | | |
| QD, ORAL; 32 | | | | | | | |
| MG, QD | | | | | | | |

5MG QD

eva)

PS

Date:02/01/02ISR Number: 3863268-6Report Type:Direct
Age:8 YR Gender:Female I/FU:I

Company Report #CTU 160576

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---|---------------|-----------------------|----------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression | | Methylphenidate Mg | 20 PS | | ORAL |
| 20 MG TID PO | | Disturbance In Attention Pharmaceutical Product Complaint | | | | | |

Date:02/01/02ISR Number: 3863271-6Report Type:Direct
Age:6 YR Gender:Male I/FU:I

Company Report #CTU 160578

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Ritalin Generic | PS | | |
| 7.5 MG TID | | Pharmaceutical Product Complaint | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/02ISR Number: 3863871-3Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 160684

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | Methylphenidate | | | |
| | | Drug Ineffective | | 10mg Watson | PS | Watson | |
| 10 MG TAB TID | | | | | | | |

Date:02/04/02ISR Number: 3863885-3Report Type:Direct
Age:6 YR Gender:Male I/FU:I

Company Report #CTU 160688

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | Ritalin (Brand Name) | | | |
| Other | | Drug Effect Decreased | | Manufacturer Schein | | | |
| | | | | 5mg Tid | PS | Schein | |
| ADHD | | | | | | | |

Date:02/04/02ISR Number: 3863887-7Report Type:Direct
Age:40 YR Gender:Female I/FU:I

Company Report #CTU 160690

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | Methylphenidate | PS | | |
| 20 MG TID | | Drug Ineffective | | | | | |
| | | | | Alprazolam | C | | |
| | | | | Darvocet | C | | |
| | | | | Hctz | C | | |
| | | | | Hydroxyzine | C | | |
| | | | | Protriptyline | C | | |
| | | | | Nexium | C | | |

Date:02/04/02ISR Number: 3865366-XReport Type:Expedited (15-DaCompany Report #PHBS2002DK01472
Age:13 YR Gender:Male I/FU:I

Company Report #PHBS2002DK01472

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | Ritaline(Methylpheni | | | |
| Other | | Colitis Ulcerative | Foreign | date Hydrochloride) | PS | | |
| | | | Health | | | | |
| | | | Professional | | | | |

Other

Date:02/05/02ISR Number: 3865327-0Report Type:Direct
Age:11 YR Gender:Male I/FU:I

Company Report #CTU 160859

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|---------------|-------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Attention | | Methylphenidate 5mg Medeva | PS | Medeva | |
| 5MG 3 TABS | | Deficit/Hyperactivity | | | | | |
| BID | | Disorder Drug Effect Decreased Pharmaceutical Product Complaint | | | | | |

Date:02/05/02ISR Number: 3865806-6Report Type:Expedited (15-DaCompany Report #MPU-2002-00041(0)
Age: Gender:Female I/FU:I

| | |
|---------|---|
| Outcome | PT |
| Other | Abdominal Pain Upper Aggression Headache Insomnia Suicidal Ideation |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Vomiting | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|----------|--|---|------|--------------|-------|
| 10MG THREE TIMES DAILY | | | Foreign Health Professional Other | Methylphenidate Tablets (Unspecified) (Methylphenidate Hydrochloride) | PS | | |

Date:02/05/02ISR Number: 3865809-1Report Type:Expedited (15-DaCompany Report #MPU-2002-00040(0)
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|--|-----------------|------|--------------|-------|
| Dose Other 10MG THREE TIMES DAILY | | Aggression Depression Headache Insomnia Self-Injurious Ideation Suicidal Ideation Tic Weight Decreased | Foreign Health Professional Other | Methylphenidate | PS | | |

Date:02/05/02ISR Number: 3865816-9Report Type:Expedited (15-DaCompany Report #MPU-2002-00039(0)
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|--|--|-----------------|------|--------------|-------|
| Dose Other 75MG DAILY | | Abdominal Pain Upper Aggression Chest Pain Decreased Appetite Diarrhoea Headache Medication Error Nightmare | Foreign Health Professional Other | Methylphenidate | PS | | |

Self Injurious Behaviour
Suicidal Ideation
Thirst
Vomiting

Date:02/05/02ISR Number: 3865820-0Report Type:Expedited (15-DaCompany Report #MPU-2002-00032(0)
Age:20 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper Aggression Nausea | Foreign Health Professional | Methylphenidate Methylphenidate Hydrochloride) | PS | | |
| 100 MG/DAY | | Suicide Attempt Weight Decreased | Other | | | | |

Date:02/05/02ISR Number: 3865977-1Report Type:Expedited (15-DaCompany Report #MK200201-0326-1
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------|---|----------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Hallucination Hallucination, Tactile Hallucinations, Mixed | Foreign Literature | Anafranil 25mg Capsules 100 Ritalin | PS SS | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Pemoline SS

Date:02/05/02ISR Number: 3866813-XReport Type:Expedited (15-DaCompany Report #MPI-2002-00044 (0)
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Medication Error | Health Professional Company Representative | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride Extended-Release | PS | | |
| INTRAVENOUS | IV | | | | | | |

Date:02/05/02ISR Number: 3866902-XReport Type:Expedited (15-DaCompany Report #MPI-2002-00008(1)
 Age:4 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Aggression Medication Error Physical Assault Screaming | Health Professional Company Representative | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride Extended-Release | PS | | ORAL |
| 40MG QD PO | | | | | | | |

Date:02/06/02ISR Number: 3865148-9Report Type:Direct Company Report #CTU 160957
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|---|------|--------------|-------|
| Other | | Pharmaceutical Product Complaint Social Avoidant Behaviour | | Methylphenidate 20mg Am, 15mg At Noon & 75 Mg At 3 Pm | PS | | |
| 20MG AM, 15MG AT NOON & 75 MG AT 3 PM | | Tic | | | | | |

Date:02/06/02ISR Number: 3866329-0Report Type:Expedited (15-DaCompany Report #PHBS2002DK01505
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Eye Pain Glaucoma | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Unknown | PS | | ORAL |
| 40 MG/DAY, | | | Other | | | | |
| ORAL | | | | | | | |

Date:02/06/02ISR Number: 3866477-5Report Type:Expedited (15-DaCompany Report #PHNU2001DE02641
Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia Difficulty In Walking Paraesthesia | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, BID, | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/07/02ISR Number: 3866152-7Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 161215

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|---------------|---|------|--------------|-------|
| Dose Other | | Crying Emotional Disorder Headache | | Ritalin 10mg 1 8am, 12 Pm, 4 Pm Generic | PS | | |
| 10MG, 8 AM, 12 PM, 4 PM | | Pharmaceutical Product Complaint | | Trazadone | C | | |

Date:02/07/02ISR Number: 3866154-0Report Type:Direct
Age:13.5 YR Gender:Male I/FU:I

Company Report #CTU 161217

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|---------------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged 25 MG AM, 25MG NOON 10MG @ 1600 | | Abnormal Behaviour Condition Aggravated Homicidal Ideation Impulsive Behaviour | | Ritalin 20mg & Generic Ritalin 5mg | PS | Novartis | |

Date:02/07/02ISR Number: 3866315-0Report Type:Direct
Age: Gender:Female I/FU:I

Company Report #CTU 161153

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|---------|------|--------------|-------|
| Dose Other | | Drug Ineffective Pharmaceutical Product Complaint | | Ritalin | PS | | |

Date:02/07/02ISR Number: 3866319-8Report Type:Direct
Age:7 YR Gender:Male I/FU:I

Company Report #CTU 161164

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------------|------|--------------|-------|
| Dose Other | | Abnormal Behaviour | | Methylfenidate | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/07/02ISR Number: 3867761-1Report Type:Expedited (15-DaCompany Report #2002-01-2338
 Age:31 YR Gender:Male I/FU:I

| Outcome Dose Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|-------------------------------------|-----------------------|----------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged 3 DF QD ORAL | Depressed Level Of Consciousness | Foreign Literature | Trilafon (Perphenazine) | PS | | ORAL |
| Other 75 MG QD ORAL | Dysarthria | Health | Luvox | SS | | ORAL |
| 75 MG QD ORAL | Electrocardiogram | Professional | Tryptanol | SS | | ORAL |
| 6 MG QD ORAL | Abnormal | Other | Wypax | SS | | ORAL |
| 300 MG QD ORAL | Pulmonary Infarction | | Myonal | SS | | ORAL |
| 15 MG QD ORAL | Respiratory Disorder | | | | | |
| 0.75 MG QD ORAL | Somnolence | | Lexotan | SS | | ORAL |
| 20 MG QD ORAL | | | Halcion | SS | | ORAL |
| 150 MG QD ORAL | | | Ritalin | SS | | ORAL |
| 6 MG QD ORAL | | | Ravona | SS | | ORAL |
| 0.5 G QD ORAL | | | Depas | SS | | ORAL |
| | | | Brovarin | SS | | ORAL |

Date:02/08/02ISR Number: 3866155-2Report Type:Direct Company Report #CTU 161218
 Age: Gender:Male I/FU:I

| Outcome Dose Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|------------------|---------------|---------|------|--------------|-------|
| | Drug Ineffective | | Ritalin | PS | | |

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|-----------------------------------|------|--------------|-------|
| 1 1/2 TID PO | | Drug Effect Decreased Pharmaceutical Product Complaint | | Methylphenidate Made By Geneva | PS | Geneva | ORAL |

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged ORAL | | Depressed Level Of Consciousness | Foreign Literature | Halcion (Triazolam) Tablet | PS | | ORAL |
| ORAL | | Drug Interaction Gamma-Glutamyltransferase | Other | Luvox (Fluvoxamine Maleate) | SS | | ORAL |
| ORAL | | Increased Hypothermia Pulmonary Infarction | | Tryptanol (Amitriptyline Hydrochloride) | SS | | ORAL |
| ORAL | | Respiratory Disorder | | Wypax (Lorazepam) | SS | | ORAL |
| ORAL | | Somnolence Speech Disorder | | Myonal (Eperisone Hydrochloride) | SS | | ORAL |
| ORAL | | Stupor Tachycardia | | Perphenazine (Perphenazine) | SS | | ORAL |
| ORAL | | | | Lexotan (Bromazepam) | SS | | ORAL |
| ORAL | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |
| ORAL | | | | Ravona (Pentobarbital Calcium) | SS | | ORAL |
| ORAL | | | | Depas (Etizolam) | C | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/08/02ISR Number: 3868544-9Report Type:Expedited (15-DaCompany Report #11973
 Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------------------|--------------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Idiopathic Thrombocytopenic Purpura | Consumer Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 36MG 1X/1DAY, ORAL | | | | Zyrtec | C | | |

Date:02/11/02ISR Number: 3868515-2Report Type:Expedited (15-DaCompany Report #PHBS2002JP01199
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|-----------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged SEE IMAGE | | Anaemia Aplasia Pure Red Cell | Foreign Health | Tegretol (Carbamazepi ne) | PS | | ORAL |
| 5 MG/DAY, ORAL | | Dizziness Dyspnoea Exertional Nausea Pallor Vomiting | Professional Other | Ritaline (Methylphenidate Hydrochloride) Unknown | SS | | ORAL |

Date:02/12/02ISR Number: 3868427-4Report Type:Direct Company Report #CTU 161455
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--|---------------|-------------------------------------|------|--------------|-------|
| Other 10MG TID | 1 MON | Condition Aggravated Diarrhoea Disturbance In Attention Drug Ineffective Dyspepsia Headache Insomnia Irritability | | Ritalin(Generic) Methylphenidate | PS | | |

Pharmaceutical Product
 Complaint
 Restlessness

Date:02/13/02ISR Number: 3870462-7Report Type:Expedited (15-DaCompany Report #PHBS2002JP01502
 Age:32 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Drug Interaction Dysarthria Electrocardiogram | Foreign Literature Health | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG/DAY | | Abnormal | Professional | | | | |
| ORAL | | Gamma-Glutamyltransferase Increased | Other | Luvox (Fluvoxamine Maleate) | SS | | ORAL |
| 75 MG/DAY | | Hypothermia | | | | | |
| ORAL | | Pulmonary Infarction Refusal Of Treatment By Patient | | Tryptanol (Amitriptyline Hydrochloride) | SS | | ORAL |
| 75 MG/DAY | | Respiratory Disorder | | | | | |
| ORAL | | Somnolence | | Wypax (Lorazepam) | SS | | ORAL |
| 6 MG/DAY ORAL | | Speech Disorder Stupor | | Myonal (Eperisone Hydrochloride) | SS | | ORAL |
| 300MG/DAY | | Tachycardia | | | | | |
| ORAL | | Ventilation/Perfusion Scan Abnormal | | Perphenazine (Perphenazine) | SS | | ORAL |
| 3 DF/DAY ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|---------------|--|--|--|--------------------------------------|----|--|------|
| 15 MG/DAY | | | | Lexotan (Bromazepam) | SS | | ORAL |
| ORAL | | | | | | | |
| 150 MG/DAY, | | | | Ravona (Pentobarbital Calcium) | SS | | ORAL |
| ORAL | | | | | | | |
| 6 MG/DAY ORAL | | | | Depas (Etizolam) | SS | | ORAL |
| 0.75 MG /DAY | | | | Halcion (Triazolam) | SS | | ORAL |
| ORAL | | | | | | | |
| 0.5 G/DAY | | | | Brovarin (Bromisoval) | SS | | ORAL |
| ORAL | | | | | | | |

Date:02/13/02ISR Number: 3877738-8Report Type:Periodic Company Report #2013023
 Age:45 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------------------------|------------------------------|------|--------------|-------|
| Death | | Intentional Misuse | Health Professional Other | Oxycodone Hydrochloride | PS | | |
| | | | | Bupropion | SS | | |
| | | | | Meperidine | SS | | |
| | | | | Acetaminophen | SS | | |
| | | | | Ketamine Hydrochloride | SS | | |
| | | | | Ritalin (Methylphenidate) | SS | | |

Date:02/15/02ISR Number: 3870865-0Report Type:Direct Company Report #CTU 161733
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

10 MG QAM & Q
NOON
Appetite Disorder
Attention
Deficit/Hyperactivity Disorder
Drug Effect Decreased
Pharmaceutical Product
Complaint
Ritalin
PS

Date:02/19/02ISR Number: 3870763-2Report Type:Direct Company Report #CTU 161769
Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Methylphenidate | PS | | |
| 5MG 1 IN AM | | | | | | | |

15 MG @ NOON

Date:02/19/02ISR Number: 3871241-7Report Type:Direct Company Report #CTU 161842
Age:6 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| | | Nausea Pharmaceutical Product Complaint | | Ritalin (Generic) Methylphenidate By Watson | PS | Watson | |

10MG PO Q AM,

Q NOON, 5MG Q

3:30

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/19/02ISR Number: 3871972-9Report Type:Expedited (15-DaCompany Report #PHFR2002GB00758
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Systemic Lupus Erythematosus | Foreign Health Professional Other | Ritaline(Methylphenidate Hydrochloride) | PS | | |

Date:02/20/02ISR Number: 3872639-3Report Type:Direct Company Report #CTU 161943
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|--------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased Pharmaceutical Product | | Methylphenidate(Generic) | PS | | ORAL |
| 5MG, PO CP UP | | | | | | | |
| TO TID | | | | | | | |
| Complaint | | | | | | | |

Date:02/21/02ISR Number: 3872778-7Report Type:Direct Company Report #CTU 162062
Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased Pharmaceutical Product | | Ritalin 10mg Generic Medeva Rochester Ny | PS | Medeva | |
| 2 AM + 1 1/2 | | | | | | | |
| NOON EVERY | | | | | | | |
| DAY | | | | | | | |
| Complaint | | | | | | | |

Date:02/21/02ISR Number: 3906552-XReport Type:Periodic Company Report #300991
Age:52 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Diarrhoea | Consumer | Xenical (Orlistat) | | | |

| | | | | |
|--------------|------------------|---|----|------|
| 120 MG 2 PER | Haematochezia | 120 Mg | PS | ORAL |
| DAY ORAL | Rectal Discharge | | | |
| | | Herbal Medicine (Herbal Extract Nos) | SS | |
| | | Ritalin (Methylphenidate Hydrochloride) | SS | |
| | | Effexor (Vanlafaxine Hydrochloride) | C | |

Date:02/22/02ISR Number: 3875210-2Report Type:Expedited (15-DaCompany Report #PHBS2002JP01199
Age:8 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|-----------------------|--|------|--------------|-------|
| Dose Duration Hospitalization - Initial or Prolonged SEE IMAGE | Anaemia Aplasia Pure Red Cell | Foreign Health | Tegretol (Carbamazepine) | PS | | ORAL |
| 5 MG/DAY, ORAL | Dizziness Dyspnoea Exertional Nausea Pallor Vomiting | Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/02ISR Number: 3874259-3Report Type:Expedited (15-DaCompany Report #2002UW02017
 Age:31 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|----------|---|-----------------------|-----------------|----------|--------------|--------------|
| Hospitalization - 75 MG DAILY | | Blood Pressure Increased | Foreign | Elavil | PS | | ORAL |
| Initial or Prolonged PO | | Body Temperature Decreased | Literature Health | Luvox | SS | | ORAL |
| 75 MG QD PO | | Depressed Level Of Consciousness | Professional Other | Wypax Myonal | SS SS | | ORAL ORAL |
| 6 MG QD PO | | Dysarthria | | | | | |
| 300 MG DAILY PO | | Electrocardiogram | | Perphenazine | SS | | ORAL |
| 3 DF QD PO | | Abnormal | | Lexotan | SS | | ORAL |
| 15 MG DAILY PO | | Hypothermia | | | | | |
| 0.75 MG QD PO | | Lung Disorder | | Halcion | SS | | ORAL |
| 20 MG QD PO | | Po2 Decreased | | Ritalin | SS | | ORAL |
| 150 MG QD PO | | Pulmonary Infarction | | Ravona | SS | | ORAL |
| 6 MG QD PO | | Respiratory Disorder | | Depas | SS | | ORAL |
| 0.5 G DAILY PO | | Scintigraphy | | Brovarin | SS | | ORAL |
| | | Somnolence | | | | | |
| | | Tachycardia Ventilation/Perfusion Scan Abnormal | | | | | |

Date:02/25/02ISR Number: 3875151-0Report Type:Direct Company Report #CTU 162272
 Age: Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|----|---------------|---------|------|--------------|-------|
|-----------------|----------|----|---------------|---------|------|--------------|-------|

10MG PO TID

Attention

Methylphenidate

PS

ORAL

PRIOR TO

Deficit/Hyperactivity

11/18/1998

Disorder

Pharmaceutical Product
Complaint

Date:02/25/02ISR Number: 3875165-0Report Type:Direct
Age:7 YR Gender:Male I/FU:I

Company Report #CTU 162289

| | |
|----------------------|---------------------------|
| Outcome | PT |
| Life-Threatening | Abdominal Pain |
| Hospitalization - | Adjustment Disorder |
| Initial or Prolonged | Aggression |
| Disability | Agitation |
| Required | Anxiety |
| Intervention to | Catatonia |
| Prevent Permanent | Chest Pain |
| Impairment/Damage | Constipation |
| | Decreased Appetite |
| | Depression |
| | Dry Mouth |
| | Headache |
| | Keratoconjunctivitis |
| | Sicca |
| | Mood Altered |
| | Obsessive-Compulsive |
| | Disorder |
| | Palpitations |
| | Personality Disorder Of |
| | Childhood |
| | Post-Traumatic Stress |
| | Disorder |
| | Psychomotor Hyperactivity |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------|----------|---|---------------|-------------------|------|--------------|-------|
| | | Psychomotor Skills Impaired Psychotic Disorder | | | | | |
| | | Pyrexia | | Ritalin .5mg Then | | | |
| | | Sleep Disorder | | 10mg | PS | | |
| | | Suicidal Ideation | | Clondine | SS | | |
| | | Vision Blurred | | | | | |
| | | Vomiting | | | | | |

Date:02/26/02ISR Number: 3873642-XReport Type:Expedited (15-DaCompany Report #306100
Age:31 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|-------------------------------------|---------------|--------------|------|--------------|-------|
| Hospitalization - 1 DAY | | Drug Interaction | Health | Cercine | PS | Roche | |
| Initial or Prolonged | | Gamma-Glutamyltransferase Increased | Professional | Lexotan | I | Roche | |
| | | Hypothermia | | Luvox | I | | |
| | | Pulmonary Infarction | | Tryptanol | I | | |
| | | Stupor | | Wypax | I | | |
| | | Tachycardia | | Myonal | I | | |
| | | | | Perphenazine | I | | |
| | | | | Halcion | I | | |
| | | | | Ritalin | I | | |
| | | | | Ravona | I | | |
| | | | | Depas | I | | |
| | | | | Brovarin | I | | |
| | | | | Vegetamin A | I | | |
| | | | | Kefral | I | | |
| | | | | Cefzon | I | | |
| | | | | Voltaren | I | | |
| | | | | Erispan | I | | |

Date:02/26/02ISR Number: 3873643-1Report Type:Expedited (15-DaCompany Report #306100
Age:31 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|---------------------------|---------------|---------|------|--------------|-------|
| Hospitalization - 1 DAY | | Drug Interaction | Health | Cercine | PS | Roche | |
| Initial or Prolonged | | Gamma-Glutamyltransferase | Professional | Lexotan | I | Roche | |

Increased
Hypothermia
Pulmonary Infarction
Stupor
Tachycardia

Luvox I
Tryptanol I
Wypax I
Myonal I
Perphenazine I
Halcion I
Ritalin I
Ravona I
Depas I
Brovarin I
Vegetamin A I
Kefral I
Cefzon I
Voltaren I
Erispan I

2 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/26/02ISR Number: 3874972-8Report Type:Direct
Age:10 YR Gender:Male I/FU:I

Company Report #CTU 162337

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| 10 MG PO QID | | Drug Effect Decreased | | Methylphenidate 10mg | PS | Geneva | ORAL |
| | | Pharmaceutical Product Complaint | | | | | |

Date:02/27/02ISR Number: 3876472-8Report Type:Expedited (15-DaCompany Report #FLUV00301005243
Age:31 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Depressed Level Of Consciousness | | Luvox 25 (Fluvoxamine Maleate) | PS | | ORAL |
| 75 MG DAILY PO | | Electrocardiogram | | | | | |
| | | Abnormal Overdose Pulmonary Infarction | | Tryptanol (Amitriptyline Hydrochloride) | SS | | ORAL |
| 75 MG DAIL PO | | Respiratory Disorder | | Wypax (Lorazepam) | SS | | ORAL |
| 6 MG DAILY PO | | Somnolence Speech Disorder | | Myonal (Eperisone Hydrochloride) | SS | | ORAL |
| 300 MG DAILY PO | | | | Perphenazine (Perphenazine) | SS | | ORAL |
| 3 DF DAILY PO | | | | Lexotan (Bromazepam) | SS | | ORAL |
| 15 DAILY PO | | | | Halcion (Triazolam) | SS | | ORAL |
| 0.75 MG DAILY PO | | | | | | | |
| | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |
| 20 MG DAILY | | | | | | | |

| | | | | | | |
|---------------|--|--|--|--------------------------------------|----|------|
| PO | | | | Ravona (Pentobarbital Calcium) | SS | ORAL |
| 150 MG DAILY | | | | | | |
| PO | | | | Depas (Etizolam) | SS | ORAL |
| 6 MG DAILY PO | | | | | | |
| | | | | Brovarin (Bromisoval) | SS | ORAL |
| 0.5 G DAILY | | | | | | |
| PO | | | | | | |

Date:02/28/02ISR Number: 3878392-1Report Type:Expedited (15-DaCompany Report #306100
Age:31 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|----------------------|--|------|--------------|-------|
| Dose Duration Hospitalization - INTRAMUSCULAR INTRAMUSCULAR | Depressed Level Of Consciousness Dilatation Atrial | Foreign | Cercine (Diazepam) | PS | | |
| Initial or Prolonged 15 MG DAILY | | Literature Health | Lexotan (Bromazepam) 50 Unit | SS | | ORAL |
| ORAL | Drug Interaction | Professional | | | | |
| 75 MG DAILY | Dysarthria Dyspnoea | Other | Luvox (Fluvoxamine) 25 Unit | SS | | ORAL |
| ORAL | Gamma-Glutamyltransferase | | | | | |
| 75 MG DAILY | Increased Hypothermia Pulmonary Infarction Somnolence | | Tryptanol (Amitriptyline Hydrochloride) 25 Unit | SS | | ORAL |
| ORAL | Speech Disorder | | | | | |
| 6 MG DAILY | Stupor Tachycardia | | Wypax (Lorazepam) 1 Unit | SS | | ORAL |
| ORAL | Tremor | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | |
|---------------|--|----|------|
| 300 MG DAILY | Myonal (Eperisone) 5 Unit | SS | ORAL |
| ORAL | | | |
| 3 DOSE FORM | Perphenazine (Perphenazine) 4 Unit | SS | ORAL |
| DAILY ORAL | | | |
| 0.75 MG DAILY | Halcion (Triazolam) 0.25 Unit | SS | ORAL |
| ORAL | | | |
| 20 MG DAILY | Ritalin (Methylphenidate Hydrochloride) | SS | ORAL |
| ORAL | | | |
| 150 MG DAILY | Ravona (Pentobarbital) | SS | ORAL |
| ORAL | | | |
| 6 MG DAILY | Depas (Etizolam) | SS | ORAL |
| ORAL | | | |
| 0.5 GRAM | Brovarin (Bromisovalum) | SS | ORAL |
| DAILY ORAL | | | |
| ORAL | Vegetamin A (Chlorpromazine Hydrochloride/Phenobarbital/Promethazine Hydrochloride) | SS | ORAL |
| ORAL | | | |
| ORAL | Kefral (Cefaclor) 250 Unit | SS | ORAL |
| ORAL | | | |
| ORAL | Cefzon (Cefdinir) | SS | ORAL |

| | | | | | | | |
|------|--|--|--|------------------------------|----|--|------|
| ORAL | | | | Voltaren (Diclofenac Sodium) | SS | | ORAL |
| ORAL | | | | Erispan (Fludiazepam) | SS | | ORAL |

Date:02/28/02ISR Number: 3886280-XReport Type:Periodic Company Report #12137
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------|--------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Agitation Hallucination Headache | Consumer | Concerta (Methylphenidate Hcl) | PS | | |
| 108MG (2-54MG TABS) X/1 DAY | | Hostility | | Risperdal | C | | |
| | | | | Remeron | C | | |
| | | | | Clonidine | C | | |

Date:03/01/02ISR Number: 3876673-9Report Type:Expedited (15-DaCompany Report #PHNU2002DE00855
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|-----------------------------------|---|------|--------------|-------|
| Other | | Growth Retardation Skin Striae Weight Increased | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | Captagon (Fenetylline Hydrochloride) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/04/02ISR Number: 3877938-7Report Type:Direct
 Age: Gender: I/FU:I

Company Report #

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|---|------|--------------|-------|
| | | Medication Error | | Metadate Er Tablets (Methylphenidate Hydrochloride Extended-Release Tablets, Usp) | PS | | |

Date:03/04/02ISR Number: 3879763-XReport Type:Direct
 Age: Gender:Female I/FU:I

Company Report #CTU 162732

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---|---------------|-------------------------|------|--------------|-------|
| 1 Q AM | | Abdominal Pain Upper Agitation Disturbance In Attention Drug Effect Decreased Mood Altered Restlessness | | Methylphenidate 20mg Sr | PS | Apothecon | |

Date:03/04/02ISR Number: 3879764-1Report Type:Direct
 Age: Gender:Female I/FU:I

Company Report #CTU 162733

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|--|------|--------------|-------|
| 1 TAB AM, 2 TABS LUNCH, 1 TO 2 AT 6PM | | Abdominal Pain Upper Agitation Condition Aggravated Disturbance In Attention Drug Effect Decreased Mood Altered Restlessness | | Methylphenidate 10mg Tablets Schein | PS | Schein | |

Date:03/05/02ISR Number: 3879121-8Report Type:Direct Company Report #CTU 162836
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|------------------------------|------|--------------|-------|
| Dose | | Drug Effect Decreased Pharmaceutical Product Complaint | | Methylphenidate (Generic) | PS | | |

Date:03/05/02ISR Number: 3879129-2Report Type:Direct Company Report #CTU 162838
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---|---------------|-----------------|------|--------------|-------|
| Dose | | Drug Effect Decreased | | Methylphenidate | PS | | ORAL |
| Other | | Drug Tolerance Decreased Pharmaceutical Product Complaint | | | | | |
| 5MG PO DAILY | | | | | | | |

Date:03/06/02ISR Number: 3879623-4Report Type:Direct Company Report #CTU 162881
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|---------------|------------------------------------|------|--------------|-------|
| Dose | | Drug Ineffective Pharmaceutical Product Complaint | | Ritalin 10 Mg (Methylphenidate) | PS | | ORAL |
| P.O. - TID | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/06/02ISR Number: 3880047-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE00870
Age:44 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Basedow'S Disease Drug Abuser Hyperthyroidism | Foreign Health Professional Other | Ritaline (Methylphenidat Hydrochloride) Tablet | PS | | ORAL |
| 5 MG, Q4H, ORAL | | | | | | | |

Date:03/06/02ISR Number: 3880565-9Report Type:Expedited (15-DaCompany Report #PHBS2002CA02858
Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------------------|------------------------------|--|---------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Depression | Foreign Consumer Other | Ritalin-Sr (Methylphenidate Hydrochloride) Celexa | PS C | | |
| 20 MG/DAY | | | | | | | |

Date:03/06/02ISR Number: 3880576-3Report Type:Expedited (15-DaCompany Report #PHNU2002DE00904
Age:36 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---------------------|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Visual Field Defect | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 80 MG/DAY, ORAL | | | | | | | |

Date:03/08/02ISR Number: 3882010-6Report Type:Expedited (15-DaCompany Report #PHNU2002DE00915
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypertension Hypoaesthesia Nervous System Disorder Paraesthesia | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 50MG/DAY, ORAL | | | | | | | |

Date:03/11/02ISR Number: 3881514-XReport Type:Direct Company Report #CTU 163217
 Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|----------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased Pharmaceutical Product | | Generic Methylphenidate | PS | | ORAL |
| 10 PO TIP | 2 MON | Complaint | | Buspar | C | | |

Date:03/12/02ISR Number: 3882768-6Report Type:Expedited (15-DaCompany Report #PHNU2002DE00619
 Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|--|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Activated Partial Thromboplastin Time Prolonged Factor Viii Deficiency Haematoma Von Willebrand'S Disease | Foreign Health Professional Other | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | PS | | ORAL |
| 20 MG, QD, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/13/02ISR Number: 3883301-5Report Type:Expedited (15-DaCompany Report #12222
 Age:39 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--------------------------------------|---|---------------|--------------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | 144 MG (36 MG X 4 TAB) 1 X/DAY | Agitation Condition Aggravated Irritability Memory Impairment Paranoia Personality Change Suicidal Ideation | Consumer | Concerta (Methylphenidate Hcl) | PS | | |
| | | | | Zoloft | C | | |
| | | | | Clonazepam | C | | |
| | | | | Hydroxyzine | C | | |
| | | | | Trazadone | C | | |

Date:03/14/02ISR Number: 3884852-XReport Type:Expedited (15-DaCompany Report #PHBS2002JP01502
 Age:32 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--------------------|--|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | 20 MG/DAY, ORAL | Depressed Level Of Consciousness Drug Interaction Gamma-Glutamyltransferase | Foreign Literature Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | Increased | Other | | | | |
| | 75 MG/DAY, ORAL | Hypothermia Overdose | | Luvox (Fluvoxamine Maleate) | SS | | ORAL |
| | | Pulmonary Infarction | | | | | |
| | 75 MG/DAY, ORAL | Respiratory Disorder Somnolence Speech Disorder | | Tryptanol (Amitriptyline Hydrochloride) | SS | | ORAL |
| | | Stupor | | | | | |
| | 6 MG/DAY, ORAL | Tachycardia | | Wypax (Lorazepam) | SS | | ORAL |

| | | | |
|----------------------|--------------------------------------|----|------|
| 300 MG/DAY, ORAL | Myonal (Eperisone Hydrochloride) | SS | ORAL |
| 3 DF/DAY, ORAL | Perphenazine (Perphenazine) | SS | ORAL |
| 15 MG/DAY, ORAL | Lexotan (Bromazepam) | SS | ORAL |
| 150 MG/DAY, ORAL | Ravona (Pentobarbital Calcium) | SS | ORAL |
| 6 MG/DAY, ORAL | Depas (Etizolam) | SS | ORAL |
| 0.75 MG/DAY, ORAL | Halcion (Triazolam) | SS | ORAL |
| 0.5 G/DAY, ORAL | Brovarin (Bromisoval) | SS | ORAL |

Date:03/19/02ISR Number: 3885372-9Report Type:Expedited (15-DaCompany Report #PHBS2002DK01505
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--------------------|-----------------------|---|------|--------------|-------|
| Dose Other | | Eye Pain Iritis | Foreign Health | Ritaline(Methylpheni date Hydrochloride) | PS | | ORAL |
| 40MG/DAY, ORAL | | | Professional Other | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/19/02ISR Number: 3885495-4Report Type:Expedited (15-DaCompany Report #CEL-2002-00037-ROC (0)
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|----------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Coma | Consumer | Metadate Cd Capsules | | | |
| Required | | Electroencephalogram | | 20 Mg | | | |
| Intervention to | | Abnormal | | (Methylphenidate | | | |
| Prevent Permanent | | Syncope | | Hydrochloride) | PS | | ORAL |
| 40 MG | | | | | | | |
| Impairment/Damage | | | | | | | |
| (DAILY), PO | | | | | | | |

Date:03/19/02ISR Number: 3885605-9Report Type:Direct Company Report #CYU 163724
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Methylphenidate 5 | | | |
| 5-4-1 | | Pharmaceutical Product | | Mg | PS | | |
| | | Complaint | | | | | |

Date:03/19/02ISR Number: 3885627-8Report Type:Direct Company Report #CTU 163693
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Methyphenidate 5 Mg | | | |
| 5 MG 1 Q AM | | Aggression | | Geneva | PS | Geneva | ORAL |
| | | Condition Aggravated | | | | | |
| PO 5 MG 1 PO | | Disturbance In Attention | | | | | |
| Q LUNCH | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |

Date:03/19/02ISR Number: 3886090-3Report Type:Expedited (15-DaCompany Report #CEL-2002-00056-ROC(0)
 Age:8 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------|----------|--|---|---|------|--------------|-------|
| Other | | | Crying Depression Social Avoidant Behaviour Suicidal Ideation | Health Professional Company Representative | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

20 MG (20 MG,
QAM), PO

Clonidine
(Clonidine) C
Claritin
(Loratadine) C

Date:03/20/02ISR Number: 3885669-2Report Type:Direct
Age:4 YR Gender:Male I/FU:I

Company Report #CTU 163780

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------|----------|---|---------------|-----------------------------------|------|--------------|-------|
| Other | | | Drug Ineffective Pharmaceutical Product Complaint | | Methylphenidate 10mg 1/2 In Am | PS | | ORAL |

10 MG 1/2 IN
AM 1 1/2 @
NOON PO 1 MON

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/20/02ISR Number: 3886180-5Report Type:Expedited (15-DaCompany Report #PHNU2002DE01023
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other 20MG/DAY, ORAL | | Rhabdomyolysis | Foreign Health Professional Other | Ritaline(Methylpheni dat Hydrochloride) Tablet | PS | | ORAL |

Date:03/22/02ISR Number: 3886726-7Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-11771532
Age:24 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|---|--|--------------|--|
| Hospitalization - Initial or Prolonged | | Blood Creatinine Increased Blood Pressure Decreased C-Reactive Protein Increased Decubitus Ulcer Depressed Level Of Consciousness Hypoventilation Lung Infiltration Pupillary Reflex Impaired Respiratory Rate Increased Suicide Attempt | | Reslin Sulpiride Etizolam Bromperidol Biperiden Hcl Ritalin Flunitrazepam Erimin | PS SS SS SS SS SS SS | Apothecon | ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL |

Date:03/22/02ISR Number: 3887726-3Report Type:Expedited (15-DaCompany Report #12499
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|--|---------------|--------------------------------------|------|--------------|-------|
| Other 18MG 1X/1DAY, ORAL | | Anger Disturbance In Social Behaviour Dysphonia | Consumer | Concerta (Methylphenidate Hcl) | PS | | ORAL |

Homicidal Ideation
Personality Change
Sleep Disorder

Minocycline

C

Date:03/25/02ISR Number: 3887763-9Report Type:Direct
Age: Gender: I/FU:I

Company Report #CTU 163979

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---|------|--------------|-------|
| Dose | | Medication Error | | Metadate Er Tablets(Methylphenid ate Hydrochloride Extended-Releas Tables, Usp) | PS | | |

Date:03/25/02ISR Number: 3889028-8Report Type:Expedited (15-DaCompany Report #2002091771JP
Age:31 YR Gender:Male I/FU:F

| | |
|----------------------|---------------------------|
| Outcome | PT |
| Hospitalization - | Dehydration |
| Initial or Prolonged | Drug Interaction |
| | Dysarthria |
| | Gamma-Glutamyltransferase |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------|----------|---|--------------------|---|------|--------------|-------|
| | | Increased Hypothermia Overdose Pulmonary Infarction | Report Source | | | | |
| ORAL | | Respiratory Disorder Somnolence | Foreign Literature | Halcion (Triazolam) Tablet | PS | | ORAL |
| ORAL | | Speech Disorder Stupor | | Luvox (Fluvoxamine Maleate) | SS | | ORAL |
| ORAL | | Tachycardia | | Tryptanol (Amitriptyline Hydrochloride) | SS | | ORAL |
| ORAL | | | | Wypax (Lorazepam) | SS | | ORAL |
| ORAL | | | | Myonal (Eperisone Hydrochloride) | SS | | ORAL |
| ORAL | | | | Perphenazine (Perphenazine) | SS | | ORAL |
| ORAL | | | | Lexotan (Bromazepam) | SS | | ORAL |
| ORAL | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |
| ORAL | | | | Ravona (Pentobarbital Calcium) | SS | | ORAL |
| ORAL | | | | Depas (Etizolam) | SS | | ORAL |

Date:03/26/02ISR Number: 3889090-2Report Type:Expedited (15-DaCompany Report #12222

Age:39 YR Gender:Female I/FU:F

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------|----------|---|---------------|--------------------------------------|------|--------------|-------|
| | | Hospitalization - Initial or Prolonged Other 144MG(36MGX4T | Consumer | Concerta (Methylphenidate Hcl) | PS | | |

AB) 1X/DAY

Paranoia

Personality Change
Suicidal Ideation

Zoloft C
Clonazepam C
Hydroxyzine C
Trazadone C

Date:03/27/02ISR Number: 3890252-9Report Type:Direct

Company Report #CTU 164348

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|--|------|--------------|-------|
| Dose | | Medication Error | | Methylphenidate Hydrochloride Extended-Release Tablets Usp 20mg | PS | | |

Date:03/27/02ISR Number: 3890931-3Report Type:Expedited (15-DaCompany Report #2002UW02017

Age:31 YR Gender:Male I/FU:F

| Outcome | PT |
|---|--|
| Hospitalization - Initial or Prolonged | Body Temperature Decreased Dehydration Depressed Level Of Consciousness Dysarthria Overdose Po2 Decreased |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Pulmonary Infarction Refusal Of Treatment By Patient | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|--------------|------|--------------|-------|
| 75 MG DAILY | | Respiratory Disorder | Foreign | Elavil | PS | | ORAL |
| PO | | Somnolence | Literature | | | | |
| 75 MG QD PO | | Tachycardia | Health | Luvox | SS | | ORAL |
| 6 MG QD PO | | Ventilation/Perfusion | Professional | Wypax | SS | | ORAL |
| 300 MG DAILY | | Scan Abnormal | Other | Myonal | SS | | ORAL |
| PO | | | | Perphenazine | SS | | ORAL |
| 3 DF QD PO | | | | Lexotan | SS | | ORAL |
| 15 MG DAILY | | | | | | | |
| PO | | | | Halcion | SS | | ORAL |
| 0.75 MG QD PO | | | | Ritalin | SS | | ORAL |
| 20 MG QD PO | | | | Ravona | SS | | ORAL |
| 150 MG QD PO | | | | Depas | SS | | ORAL |
| 6 MG QD PO | | | | Brovarin | SS | | ORAL |
| 0.5 G DAILY | | | | | | | |
| PO | | | | | | | |

Date:03/27/02ISR Number: 3891242-2Report Type:Expedited (15-DaCompany Report #2002-01-2338
 Age:31 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------------|----------|-------------------|---------------|--------------|------|--------------|-------|
| Hospitalization - 3 DF QD ORAL | | Dysarthria | Foreign | Perphenazine | PS | | ORAL |
| Initial or Prolonged 75 MG QD ORAL | | Electrocardiogram | Literature | Luvox | SS | | ORAL |

| | | | | | |
|------------------------|----------------------|--------------|-----------|----|------|
| Other 75 MG QD ORAL | Abnormal | Health | Tryptanol | SS | ORAL |
| 6 MG QD ORAL | Pulmonary Infarction | Professional | Wypax | SS | ORAL |
| 300 MG QD ORAL | Respiratory Disorder | Other | Myonal | SS | ORAL |
| 15 MG QD ORAL | Somnolence | | Lexotan | SS | ORAL |
| 0.75 MG QD ORAL | | | Halcion | SS | ORAL |
| 20 MG QD ORAL | | | Ritalin | SS | ORAL |
| 150 MG QD ORAL | | | Ravona | SS | ORAL |
| 6 MG QD ORAL | | | Depas | SS | ORAL |
| 0.5 G QD ORAL | | | Brovarin | SS | ORAL |

Date:03/28/02ISR Number: 3892173-4Report Type:Expedited (15-DaCompany Report #12545
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------------|---|--------------------------------------|------|--------------|-------|
| Other | | Abdominal Pain Foreign Body Trauma | Literature Health Professional Company Representative | Concerta (Methylphenidate Hcl) | PS | | |

Date:03/29/02ISR Number: 3891960-6Report Type:Direct Company Report #CTU 164481
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|-------------|------|--------------|-------|
| Hospitalization - 5-10 MG DAY Initial or Prolonged INTERMIT ORAL | | Delusion Hallucination Mania Psychotic Disorder | | Ritalin 5mg | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/02ISR Number: 3893266-8Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 164704

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Educational Problem | | Methylphenidate 10mg | | | |
| | | Pharmaceutical Product | | Geneva | PS | Geneva | ORAL |
| 10MG PO TID | | Complaint | | | | | |

Date:04/01/02ISR Number: 3893526-0Report Type:Expedited (15-DaCompany Report #12577
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aplastic Anaemia | Health | Concerta | | | |
| | | Gingival Bleeding | Professional | (Methylphenidate | | | |
| | | Hepatitis Viral | | Hcl) | PS | | |
| 18MG TO | | | | | | | |
| 36MG1X/DAY | | | | | | | |

Date:04/02/02ISR Number: 3893900-2Report Type:Direct
 Age:48 YR Gender:Male I/FU:I

Company Report #CTU 164736

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| 2 TABS TID | | Bone Marrow Depression | | Dexedrine 15mg | PS | | ORAL |
| ORAL | | Bone Pain | | | | | |
| 1 TAB TID | | Hairy Cell Leukaemia | | Desoxyn 15mg | SS | | ORAL |
| ORAL | | Pancytopenia | | | | | |
| 30-40 MG/ DAY | | | | Methylphenidate | SS | | ORAL |
| ORAL | | | | | | | |

Date:04/02/02ISR Number: 3894266-4Report Type:Expedited (15-DaCompany Report #PHEH2002US02950
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------------------|---------------|-----------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Withdrawal Syndrome Epilepsy | Consumer | Ritalin (Methylphenidat) | PS | | |

Date:04/03/02ISR Number: 3895299-4Report Type:Expedited (15-DaCompany Report #PHFR2001GB03375
Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|--|---|------|--------------|-------|
| Death | | Cardiac Disorder Cardiomegaly Circulatory Collapse Sudden Death | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Unknown | PS | | ORAL |
| 0, ORAL | | | | | | | |

Date:04/08/02ISR Number: 3896875-5Report Type:Expedited (15-DaCompany Report #12642
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------------|------------------------------------|--------------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Acute Myeloid Leukaemia Contusion | Consumer Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 36MG 1X/1DAY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/08/02ISR Number: 3896924-4Report Type:Expedited (15-DaCompany Report #CEL-2002-00194-ROC (0)
 Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Balance Disorder Coma Crying Petit Mal Epilepsy | Consumer | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

SEE IMAGE

Date:04/09/02ISR Number: 3897024-XReport Type:Direct Company Report #CTU 165292
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--|---------------|-----------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Disturbance In Attention | | Methylphenidate 10 Mg Novartis | PS | Novartis | ORAL |
| 10 MG PO 1 Q AM | | Drug Effect Decreased | | | | | |
| 10 MG 1 PO Q NOON | | Pharmaceutical Product Complaint | | Methylphenidate 10 Mg Novartis | SS | Novartis | ORAL |
| | | Psychomotor Hyperactivity Restlessness | | | | | |

Date:04/09/02ISR Number: 3897717-4Report Type:Expedited (15-DaCompany Report #CEL-2002-0086-SLO (0)
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Vision Blurred | Foreign Health Professional | Equasym (Strength Unspecified) (Methylphenidate | PS | | ORAL |

50 MG (10 MG,

FIVE TIMES

DAILY), PO

Date:04/10/02ISR Number: 3898153-7Report Type:Expedited (15-DaCompany Report #12784
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|--------------------------------|---------------------|--------------------------------|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Complex Regional Pain Syndrome | Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 18MG 1X/ 1DAY, ORAL | | | | Neurontin Nortriptyline | C C | | |

Date:04/11/02ISR Number: 3899522-1Report Type:Expedited (15-DaCompany Report #CEL-2002-00214-ROC (0)
Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - 80 MG (40 MG, Initial or Prolonged BID), PO | | Agitation Psychotic Disorder Somatic Delusion | Health Professional Company Representative | Metadate Cd | PS | | ORAL |

Date:04/11/02ISR Number: 3899523-3Report Type:Expedited (15-DaCompany Report #CEL-2002-00056-ROC(0)
Age:8 YR Gender:Male I/FU:F

| Outcome | PT |
|---------|----------------------|
| Other | Crying Depression |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|---|--|---|------------------|--------------|-------|
| 20 MG (20 MG, QAM), PO | | Homicidal Ideation Self-Injurious Ideation Social Avoidant Behaviour Suicidal Ideation | Health Professional Company Representative | Metade Cd (Methylphenidate Hydrochloride) Clonidine (Clonidine) Claritin (Loratadine) | PS C C | | ORAL |

Date:04/11/02ISR Number: 3899558-0Report Type:Expedited (15-DaCompany Report #US009560
Age:12 YR Gender:Female I/FU:I

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--|----------------------------------|----------------|--------------|----------------------|
| 2 MG QD ORAL Initial or Prolonged 12 MG TID ORAL | | PT Aphasia Convulsion Depressed Level Of Consciousness | Health Professional Company Representative | Gabitril Gabitril Concerta | PS SS SS | | ORAL ORAL ORAL |
| 36 MG QAM ORAL 18 MG QHS ORAL | | | | Concerta Zarontin | SS C | | ORAL |

Date:04/11/02ISR Number: 3899803-1Report Type:Expedited (15-DaCompany Report #CEL-2002-00212-ROC (0)
Age:55 YR Gender:Female I/FU:I

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|-------|----------|---------------------------------|---------------------|-------------------------------|------|--------------|-------|
| Other | | Affective Disorder Agitation | Health Professional | Metadate Cd Capsules 20 Mg | | | |

| | | | | | |
|-----------|------------------------------|---------------------------|--|----|------|
| (BID), PO | Excitability Irritability | Company Representative | (Methylphenidate Hydrochloride) | PS | ORAL |
| | | | Methylphenidate Tablets (Methylphenidate Hydrochloride) | SS | |

Date:04/12/02ISR Number: 3899673-1Report Type:Direct Company Report #CTU 165582
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|-----------------|------|--------------|-------|
| Dose | | | | Methylphenidate | PS | | |
| | | Drug Ineffective Pharmaceutical Product Complaint | | | | | |

Date:04/16/02ISR Number: 3901883-1Report Type:Expedited (15-DaCompany Report #PHNU2002DE01236
 Age:33 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|--|--|------|--------------|-------|
| Dose | | | | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| Hospitalization - Initial or Prolonged Other | | Csf Oligoclonal Band Present Multiple Sclerosis Optic Neuritis | Foreign Health Professional Other | Tablet | | | |
| ORAL | | Retrobulbar Visual Disturbance | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/16/02ISR Number: 3902185-XReport Type:Expedited (15-DaCompany Report #PHBS2002BR01038
 Age:28 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|------------------------------|---|----------------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia Anxiety Crying Depressed Mood | Foreign Consumer Other | Ritalina (Methylphenidate Hydrochloride) Tablet | | | ORAL |
| 10 MG, BID, ORAL | | Dry Mouth Dysphemia Hyperhidrosis Mood Swings Nervousness Tachycardia Tremor | | Flurazepam (Flurazepam0 Tryptanol (Amitriptyline Hydrochloride) Tablet | PS C C | | |

Date:04/17/02ISR Number: 3902495-6Report Type:Expedited (15-DaCompany Report #CEL-2002-00263-ROC (0)
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|------------------------------------|--|-----------------------------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening Hospitalization - Initial or Prolonged Required SEE IMAGE | | Dialysis Nephrotic Syndrome Renal Failure Chronic | Consumer Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | | | ORAL |
| Intervention to Prevent Permanent Impairment/Damage SEE IMAGE | | | | Metadate Er Tablets 20 Mg (Methylphenidate Hydrochloride) Albuterol (Salbutamol) Singulair | PS SS SS C | | ORAL |

Date:04/18/02ISR Number: 3901933-2Report Type:Direct Company Report #CTU 166047
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|-------------|-----------------------|----------------------|----|-----------|------|
| Other | Condition Aggravated | Methylphenidate 10mg | PS | Apothecon | ORAL |
| | Drug Effect Decreased | Apothecon | | | |
| 10MG Q AM, | | | | | |
| | Irritability | | | | |
| 10MG Q NOON | | | | | |
| PO | | | | | |

Date:04/18/02ISR Number: 3902426-9Report Type:Direct Company Report #CTU 166099
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Methylphenidate 5mg | PS | | |
| | | Pharmaceutical Product | | Tab (Generic) | | | |
| 3 TABS BID | | Complaint | | | | | |

Date:04/18/02ISR Number: 3902428-2Report Type:Direct Company Report #CTU 166100
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Methylphenidate 20 | PS | | |
| | | Pharmaceutical Product | | Mg Tab (Generic) | | | |
| 20 MG TID | | Complaint | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/18/02ISR Number: 3903039-5Report Type:Expedited (15-DaCompany Report #PHNU2002DE00915
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Antibody Test Positive Complement Factor Increased Herpes Zoster | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Talbet | | | ORAL |
| ORAL; 60 MG/DAY, ORAL | | Hypertension Hypoaesthesia Inflammation Nervous System Disorder Paraesthesia | | | PS | | |

Date:04/18/02ISR Number: 3903102-9Report Type:Expedited (15-DaCompany Report #PHBS2002AU04398
Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--|------------------------------|--|---------|--------------|-------|
| Other | | Dry Skin Movement Disorder Nightmare | Foreign Consumer Other | Ritaline(Methylpheni date Hydrochloride) Tablet | | | ORAL |
| 10 MG/DAY ORAL | | Rash Sleep Terror Tic | | Efalex (Evening Primrose Oil, Omega-3 Marine Triglycerides, Thyme Oil) | PS C | | |

Date:04/22/02ISR Number: 3904542-4Report Type:Expedited (15-DaCompany Report #CEL-2002-00284-ROC (0)
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|---|------|--------------|-------|
| Other | | Aggression Hallucination Insomnia | Consumer | Metadate Cd Capsules 20 Mg (Methylphenidate | | | |

| | | | | |
|--------------------------------|---|---------------------------------------|----|------|
| 20 MG (20 MG, EVERY AM), PO | Psychomotor Hyperactivity Vision Blurred | Hydrochloride) | PS | ORAL |
| | | Zoloft (Sertraliine Hydrochloride) | C | |
| | | Ddavp (Desmopressin) | C | |

Date:04/23/02ISR Number: 3906679-2Report Type:Expedited (15-DaCompany Report #PHNU2002DE01357
Age:15 YR Gender:Male I/FU:I

| Outcome Dose Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | Intentional Misuse Suicide Attempt Tachycardia | Foreign Health Professional | Ritalin(Methylphenid ate Hydrochloride) Tablet, 10mg | PS | | ORAL |
| SEE IMAGE | | Other | | | | |

Date:04/23/02ISR Number: 3906732-3Report Type:Expedited (15-DaCompany Report #PHNU2002DE01391
Age:6 YR Gender:Male I/FU:I

| Outcome Dose Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--------------------------------|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | Concussion Fall Tinnitus | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| 5 MG/DAY, ORAL | | Other | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/23/02ISR Number: 3906733-5Report Type:Expedited (15-DaCompany Report #PHNU2002DE01373
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Glucose Increased | Foreign Health Professional | Ritaline(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | Other | | | | |

Date:04/23/02ISR Number: 3906735-9Report Type:Expedited (15-DaCompany Report #PHNU2002DE01023
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Rhabdomyolysis | Foreign Health Professional | Ritaline(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| Other | | | Other | | | | |
| 20MG/DAY, | | | | | | | |
| ORAL | | | | | | | |

Date:04/25/02ISR Number: 3906986-3Report Type:Direct Company Report #CTU 166591
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|-----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin 10 Mg Generic | PS | | ORAL |
| 10 MG PO BID | | | | | | | |

Date:04/26/02ISR Number: 3907934-2Report Type:Expedited (15-DaCompany Report #PHRM2002FR01172
Age:53 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------------------------------|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Movement Disorder Paraesthesia | Foreign Consumer Other | Ritaline (Methylphenidate Hydrochloride) | | | |

20 MG, BID,

Tablet

PS

ORAL

ORAL

| | |
|-------------------------------------|---|
| Levothyrox | C |
| Teralithe | C |
| Effexor (Venlafaxine Hydrochloride) | C |

Date:04/26/02ISR Number: 3908135-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE01407

Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Glucose Increased Diabetes Mellitus Glycosylated Haemoglobin Increased | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG TID | | Hypertriglyceridaemia | | | | | |
| ORAL | | Thirst Weight Decreased | | | | | |

Date:04/26/02ISR Number: 3908801-0Report Type:Expedited (15-DaCompany Report #PHNU2002DE01236

Age:33 YR Gender:Male I/FU:F

Outcome
Hospitalization -
Initial or Prolonged

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------|----------|--|-----------------------------|---|------|--------------|-------|
| | | Csf Oligoclonal Band Present Multiple Sclerosis | Foreign Health Professional | Ritaline(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | Optic Neuritis Retrobular Visual Disturbance | Other | | | | |

Date:04/29/02ISR Number: 3908383-3Report Type:Direct Company Report #CTU 166767
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|---------------|---------------------------------------|--------------|--------------|-------|
| Dose | | | | Concerta Depakote Wellbutrin Sr | PS C C | | |
| Other | | Hallucination | | | | | |

Date:04/30/02ISR Number: 3911387-8Report Type:Expedited (15-DaCompany Report #12785
Age:18 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|--|-----------------------------------|------|--------------|-------|
| Dose | | | | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| Other | | Hepatic Failure | Health Professional Company Representative | | | | |
| 18MG 1X/1 DAY | | | | Celebrex | C | | |
| ORAL | | | | | | | |

Date:05/01/02ISR Number: 3910574-2Report Type:Direct Company Report #CTU 167149
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | Generic Ritalin | PS | | ORAL |
| Other | | Abnormal Behaviour | | | | | |
| ORAL | 1 MON | | | | | | |

Condition Aggravated
Drug Ineffective
Educational Problem
Pharmaceutical Product
Complaint

Date:05/01/02ISR Number: 3911122-3Report Type:Expedited (15-DaCompany Report #PHBS2002CA05190
Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------|-----------------------------------|--|------|--------------|-------|
| Other | | Depression | Foreign Health Professional | Ritalin-Sr (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 180MG/DAY, | | | | | | | |
| ORAL | | | | | | | |

Date:05/01/02ISR Number: 3911124-7Report Type:Expedited (15-DaCompany Report #PHFR2002GB01415
Age:6 YR Gender:Female I/FU:I

| | |
|---------|--|
| Outcome | PT |
| Other | Attention Deficit/Hyperactivity Disorder |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|--|---|------|--------------|-------|
| 5MG/DAY, ORAL | | Muscle Twitching Restlessness Screaming Urinary Incontinence | Foreign Health Professional Other | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

Date:05/01/02ISR Number: 3911156-9Report Type:Expedited (15-DaCompany Report #PHBS2002AU04398
Age:7 YR Gender:Female I/FU:F

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---|---------------------|--|-----------------|--------------|-------|
| 10MG/DAY, ORAL | | PT Dry Skin Movement Disorder Nightmare Rash Sleep Terror Tic | Foreign Consumer | Ritaline (Methylphenidate Hydrochloride) Tablet Efalex (Evening Primrose Oil, Omega-3 Marine Triglycerides, Thyme Oil) | PS C | | ORAL |

Date:05/01/02ISR Number: 3911195-8Report Type:Expedited (15-DaCompany Report #PHFR2002GB01418
Age:10 YR Gender:Male I/FU:I

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|------|----------|-----------------------------------|-----------------------------------|--|------|--------------|-------|
| ORAL | | Electrocardiogram Qt Prolonged | Foreign Health Professional | Ritaline(Methylpheni dat Hydrochloride) Tablet | PS | | ORAL |

Date:05/01/02ISR Number: 3911413-6Report Type:Expedited (15-DaCompany Report #12965
Age:15 YR Gender:Male I/FU:I

| | | | | | | | |
|----------------------|----------|--------------------|---------------|------------------|------|--------------|-------|
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Hospitalization - | | Fatigue | Consumer | Concerta | | | |
| Initial or Prolonged | | Pancreatitis Acute | | (Methylphenidate | | | |
| Other | | | | Hcl) | PS | | |
| 54MG | 1X/1DAY | | | | | | |

Date:05/03/02ISR Number: 3911656-1Report Type:Direct Company Report #CTU 167241
 Age:12 YR Gender:Male I/FU:I

| | | | | | | | |
|---------|----------|-----------------------|---------------|----------------------|------|--------------|-------|
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Other | | Drug Effect Decreased | | Ritalin (Generic) Sr | | | |
| | | | | 20mg Tabs | PS | | ORAL |
| 20MG | 2 PO QD | | | | | | |

Date:05/06/02ISR Number: 3912489-2Report Type:Direct Company Report #CTU 167392
 Age:6 YR Gender:Male I/FU:I

| | | | | | | | |
|------------|----------|------------------------|---------------|--------------------|------|--------------|-------|
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Other | | Drug Effect Decreased | | Methylphenidate 10 | | | |
| | | Pharmaceutical Product | | Mg Watson | PS | Watson | |
| 10 MG | IN AM | | | | | | |
| AND | | Complaint | | | | | |
| AFTERNOON/ | | | | | | | |
| 5-6 MONTHS | | | | Concerta | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Tenex

C

Date:05/07/02ISR Number: 3913418-8Report Type:Expedited (15-DaCompany Report #PHNU2002DE01517

Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Infection Myositis Pain In Extremity | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| 20MG/DAY, ORAL | | | Other | | | | |

Date:05/07/02ISR Number: 3913722-3Report Type:Expedited (15-DaCompany Report #PHFR2001GB03227

Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--|--|------|--------------|-------|
| Other | | Eosinophil Count Decreased Epistaxis Lymphocyte Count | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | Decreased Neutropenia Pharyngolaryngeal Pain White Blood Cell Count Decreased | | | | | |

Date:05/07/02ISR Number: 3913723-5Report Type:Expedited (15-DaCompany Report #PHBS2002CA05418

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|--|--|------|--------------|-------|
| Other | | Haemolytic Anaemia | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) | PS | | |

Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---------------------------|---------------|-----------------|------|--------------|-------|
| Dose Required | | Abnormal Behaviour | Health | Zoloft Tablets | PS | | |
| Intervention to | 20.00 | Aggression | Professional | Methylphenidate | SS | | ORAL |
| Prevent Permanent | | Hallucination | | | | | |
| MG/TOTAL/DAIL | | Insomnia | | | | | |
| Impairment/Damage | | Psychomotor Hyperactivity | | Desmopressin | C | | |
| Y/ORAL | | Pyromania | | | | | |
| | | Vision Blurred | | | | | |

Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | Abnormal Behaviour | | Ritalin Sr 20mg Bid | PS | | |
| Other | 3 WK | Aggression | | Ritalin 15mg Tid | | | |
| 20MG BID | | Pharmaceutical Product | | (10mg Tab) | SS | | |
| 15MG TID | | Complaint | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/08/02ISR Number: 3913261-XReport Type:Direct
 Age:8 YR Gender:Male I/FU:I

Company Report #USP 54855

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Metadate Er (Methylphenadate Hydrochloride) | PS | Medeva | |
| | | | | Metadate Cd (Methylphenadate Hydrochloride) | SS | Alltech | |

Date:05/08/02ISR Number: 3914332-4Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 167668

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin 10 Mg | PS | | ORAL |
| 10 MG PO BID | | | | | | | |

Date:05/09/02ISR Number: 3915338-1Report Type:Expedited (15-DaCompany Report #12784
 Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------------------|------------------------|-----------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Complex Regional Pain Syndrome | Health Professional | Concerta(Methylpheni date Hcl) | PS | | ORAL |
| 18 MG 1X/1DAY | | | | | | | |
| Other | | | | Neurontin | C | | |
| ORAL | | | | Nortriptyline | C | | |

Date:05/09/02ISR Number: 3915441-6Report Type:Expedited (15-DaCompany Report #PHRM2002FR01329
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alanine Aminotransferase Increased Aspartate | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | | | |

| | | | | |
|------------|--|---|----|------|
| 5 MG, BID, | Aminotransferase | Tablet | PS | ORAL |
| ORAL | Increased | | | |
| ORAL | Drug Interaction Hepatic Enzyme Increased | Dafalgan (Paracetamol) | SS | ORAL |
| | Hyperpyrexia Lung Disorder | Augmentin (Clavulanate Potassium) | C | |

Date:05/14/02ISR Number: 3916573-9Report Type:Expedited (15-DaCompany Report #13166
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------|-----------------------------------|--------------------------------------|------|--------------|-------|
| Other | | Convulsion | Health Professional Company | Concerta (Methylphenidate Hcl) | PS | | |
| 54MG 1X/1DAY | | | Representative | Ritalin | C | | |

Date:05/14/02ISR Number: 3916619-8Report Type:Expedited (15-DaCompany Report #CEL-2002-00364-ROC(0)
Age:33 YR Gender:Female I/FU:I

| | |
|---|---------------------------------------|
| Outcome | PT |
| Hospitalization - Initial or Prolonged | Blood Pressure Increased Dizziness |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|--------------------------------------|----------|---------------------------------|-----------------------------------|---|------|--------------|-------|
| | | Orthostatic Hypotension Rash | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | Health Professional Company | Metadate Cd (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG (20 MG, TWICE A DAY), PO | | | Representative | | | | |
| | | | | Paxil (Paroxetine Hydrochloride) | C | | |

Date:05/14/02ISR Number: 3916621-6Report Type:Expedited (15-DaCompany Report #CEL-2002-00388-ROC(0)
Age:45 YR Gender:Female I/FU:I

| | | | | | | | |
|-----------------------------|----------|------------|---|---|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Convulsion | Consumer Health Professional Company | Metadate Cd 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| Other | | | Representative | | | | |
| 20 MG (20 MG, DAILY), PO | 4 DAY | | | Verapamil (Verapamil) | C | | |
| | | | | Proventil (Salbutamol) | C | | |
| | | | | Motrin (Ibuprofen) | C | | |

Date:05/14/02ISR Number: 3916622-8Report Type:Expedited (15-DaCompany Report #CEL-2002-00194-ROC(1)
Age:5 YR Gender:Male I/FU:F

| | | | | | | | |
|--------------|----------|----------------------------------|------------------------------------|---|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Convulsion Petit Mal Epilepsy | Consumer Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| Other | | | | | | | |
| 1/2 CAPSULE, | | | | | | | |

PO:20MG QD,PO

Date:05/14/02ISR Number: 3916937-3Report Type:Expedited (15-DaCompany Report #12785

Age:18 YR Gender:Female I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-----------------|----------------|------------------|------|--------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - | Abdominal Pain | Health | Concerta | | | |
| Initial or Prolonged | Hepatic Failure | Professional | (Methylphenidate | | | |
| Other | Vomiting | Company | Hcl) | PS | | ORAL |
| 18 MG | | Representative | | | | |
| 1X/1DAY, ORAL | | | Celebrex | C | | |

Date:05/15/02ISR Number: 3917456-0Report Type:Expedited (15-DaCompany Report #12965

Age:15 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|--------------------|---------------|------------------|------|--------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - | Pancreatitis Acute | Health | Concerta | | | |
| Initial or Prolonged | | Professional | (Methylphenidate | | | |
| Other | | | Hcl) | PS | | |
| 54MG 1X/1DAY | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/16/02ISR Number: 3917822-3Report Type:Expedited (15-DaCompany Report #A0367651A
 Age:33 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Blood Potassium Decreased Dehydration Dizziness | Health Professional Company | Paxil (Formulation Unknown) (Paroxetine Hydrochloride) | PS | | ORAL |
| ORAL | | Mitral Valve Prolapse Nervous System Disorder Orthostatic Hypotension Tachycardia | Representative | Methylphenidate Hcl (Formulation Unknown) (Methylphenidate Hcl) | SS | | ORAL |
| ORAL | | | | Clozapine (Formulation Unkown) (Clozapine) | SS | | ORAL |

Date:05/17/02ISR Number: 3918783-3Report Type:Expedited (15-DaCompany Report #PHNU2002DE01592
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|--|--|------|--------------|-------|
| Other | | Abscess Limb Red Blood Cell Sedimentation Rate Increased | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 1 DF, QD, | | White Blood Cell Count Decreased | | | | | |
| ORAL | | | | | | | |

Date:05/17/02ISR Number: 3918918-2Report Type:Expedited (15-DaCompany Report #12642
 Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------|------------------------------------|--------------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Acute Myeloid Leukaemia | Consumer Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 36MG 1X/1DAY, | | | | | | | |

ORAL

Date:05/20/02ISR Number: 3918860-7Report Type:Direct
Age:13 YR Gender:Female I/FU:I

Company Report #CTU 168426

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|---------------|--|------|--------------|-------|
| Dose | | Abnormal Behaviour Aggression Agitation | | Metadate Cd (Methylphenidate Extended Release) | PS | | |
| 40 MG Q AM | | Decreased Appetite Headache Psychomotor Hyperactivity Screaming | | Trazodone | C | | |

Date:05/20/02ISR Number: 3919280-1Report Type:Expedited (15-DaCompany Report #PHNU2002DE01646
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------------------------|------------------------------|--|------|--------------|-------|
| Dose | | Depression Suicide Attempt | Foreign Consumer Other | Ritalin(Methylphenid at Hydrochloride) Tablet, 10 Mg | PS | | ORAL |
| Other | | | | | | | |
| 10 MG, QID, | | | | | | | |
| ORAL | | | | L-Thyroxin | C | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/20/02ISR Number: 3919321-1Report Type:Direct
Age:11 YR Gender:Male I/FU:I

Company Report #CTU 168453

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------------------------------------|---------------|---------------------|------|--------------|-------|
| Dose Other 20MG 3 PO QD DAILY | | Drug Effect Decreased | | Ritalin(Generic) Sr | PS | | ORAL |
| | | Pharmaceutical Product Complaint | | | | | |

Date:05/20/02ISR Number: 3919345-4Report Type:Expedited (15-DaCompany Report #12863
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------------------|--------------------------------------|------|--------------|-------|
| Dose Other 54MG 1X/ 1DAY, ORAL | | Abnormal Behaviour Palpitations Paranoia | Consumer Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |

Date:05/20/02ISR Number: 3919505-2Report Type:Expedited (15-DaCompany Report #PHNU2002DE01637
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-----------------|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other 10 TO 15 MG/DAY, ORAL | | Dermatomyositis | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

Date:05/22/02ISR Number: 3922336-0Report Type:Expedited (15-DaCompany Report #PHNU2002DE00904
Age:36 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|------------|---------------------|--------------|----------------------|----|------|
| Other | Optic Neuritis | Foreign | Ritaline(Methylpheni | | |
| | Visual Field Defect | Health | date Hydrochloride) | | |
| 80 MG/DAY, | | Professional | Tablet | PS | ORAL |
| ORAL | | Other | | | |

Date:05/22/02ISR Number: 3922401-8Report Type:Expedited (15-DaCompany Report #PHNU2002DE01666
 Age:15 YR Gender:Female I/FU:I

| | | | | | | |
|------------|----------|---------------|----------------------|------|--------------|-------|
| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | |
| Other | Shock | Foreign | Ritaline(Methylpheni | | | |
| | | Health | date Hydrochloride) | | | |
| 15 MG/DAY; | | Professional | Slow Release Tablet | PS | | ORAL |
| ORAL | | Other | | | | |

Date:05/22/02ISR Number: 3922402-XReport Type:Expedited (15-DaCompany Report #PHNU2002DE01667
 Age:23 YR Gender:Male I/FU:I

| | | | | | | |
|------------|--------------------|---------------|----------------------|------|--------------|-------|
| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | |
| Other | Aggression | Foreign | Ritaline(Methylpheni | | | |
| | Depression | Health | date Hydrochloride) | | | |
| 30 MG/DAY, | Psychotic Disorder | Professional | Tablet | PS | | ORAL |
| ORAL | | Other | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/23/02ISR Number: 3921807-0Report Type:Expedited (15-DaCompany Report #12863

Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---|------------------------------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Bruxism Hallucination Hyperhidrosis | Consumer Health Professional | Concreta (Methylphenidate Hcl) | PS | | ORAL |
| 54MG | | Overdose | | | | | |
| 1X/DAY, ORAL | | Palpitations Paranoia | | | | | |

Date:05/24/02ISR Number: 3922960-5Report Type:Expedited (15-DaCompany Report #12784

Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------------------|------------------------|--------------------------------------|--------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Complex Regional Pain Syndrome | Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| Other | | | | | | | |
| 18MG 1X/1DAY, ORAL | | | | Neurontin Nortriptyline | C C | | |

Date:05/28/02ISR Number: 3923383-5Report Type:Direct Company Report #CTU 168983

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Pharmaceutical Product Complaint | | Methylphenidate | PS | | |

Date:05/29/02ISR Number: 3925231-6Report Type:Direct Company Report #CTU 169114

Age:10 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------|----------|----------------------------------|---------------|----------------------|------|--------------|-------|
| | PO 20 MG TID | 4 WK | Drug Ineffective | | Ritalin Generic Form | PS | | ORAL |
| | | | Pharmaceutical Product Complaint | | | | | |

Date:05/29/02ISR Number: 3926275-0Report Type:Expedited (15-DaCompany Report #PHBS2002BE06071
Age:14 YR Gender:Female I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------------|----------|---------------------------------------|------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | 25 MG/DAY, | | Abdominal Pain Hepatitis Nausea | Foreign Consumer Other | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | | | | | |

Date:05/31/02ISR Number: 3926900-4Report Type:Expedited (15-DaCompany Report #200215052US
Age:10 YR Gender:Male I/FU:I

| Outcome | PT |
|---------|--|
| Other | Abnormal Behaviour Aggression Hallucination Injury Insomnia Psychomotor Hyperactivity |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Vision Blurred

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------|--|------|--------------|-------|
| PO | | | Desmopressin (Ddavp) Tablets | PS | | ORAL |
| 20 MG QAM PO | 3 DAY | | Methylphenidate Hydrochloride Capsules | SS | | ORAL |
| | | | Sertraline Hydrochloride (Zoloft) | C | | |

Date:05/31/02ISR Number: 3927123-5Report Type:Expedited (15-DaCompany Report #13166
Age:5 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|------------------------------------|---------------------------|-----------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion Grand Mal Convulsion | Health Professional | Concerta(Methylpheni date Hcl) | PS | | ORAL |
| 54MG 1X/1DAY, PO | | Petit Mal Epilepsy | Company Representative | Ritalin | C | | |

Date:06/03/02ISR Number: 3926877-1Report Type:Direct Company Report #CTU 169351
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Concerta 54mg | PS | | ORAL |
| 54MG 1 Q DAY ORAL | | Anhedonia Anxiety Decreased Appetite Depression Feeling Of Despair Irritability Suicidal Ideation | | | | | |

Date:06/03/02ISR Number: 3968568-7Report Type:Periodic Company Report #12551
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------------|--------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Leukopenia | Health Professional | Concerta (Methylphenidate Hci) | PS | | |
| 36MG 1X/1 DAY | | | | | | | |

Date:06/03/02ISR Number: 3968570-5Report Type:Periodic Company Report #12636
Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--|------------------------------|--------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Anorexia Insomnia | Consumer Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 54MG 1X/1DAY, ORAL | | | | | | | |
| Weight | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/03/02ISR Number: 3968575-4Report Type:Periodic Company Report #12640
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------|---------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination | Consumer | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 36MG 1X/1 | | | | | | | |
| DAY; ORAL | | | | | | | |

Date:06/03/02ISR Number: 3968579-1Report Type:Periodic Company Report #13104
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|------------------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 36MG 1X/1DAY, | | | | | | | |
| ORAL | | | | | | | |

Date:06/04/02ISR Number: 3928278-9Report Type:Expedited (15-DaCompany Report #USA-2002-0001129
 Age:48 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Alcohol Problem Biliary Cirrhosis Hepatic Failure Overdose | Health Professional | Oxycontin Tablets(Oxycodon Hydrochloride) Cr Tablet | PS | | |
| MG UNKNOWN | | | | | | | |
| | | | | Ritalin(Methylphenid ate Hydrochloride) | SS | | |
| | | | | Cocaine(Cocaine) | SS | | |
| | | | | Insulin (Insulin) | C | | |

Date:06/04/02ISR Number: 3928967-6Report Type:Expedited (15-DaCompany Report #PHBS2002BE06222
 Age:9 YR Gender:Male I/FU:U

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Accommodation Disorder Binocular Eye Movement Disorder Visual Disturbance | Foreign Consumer Other | Ritaline (Methylphenidate Hydrochloride) Unknown | | | |
| 10 MG, BID, ORAL | | | | | PS | | ORAL |
| | | | | Zyrtec (Cetirizine Hydrochloride) | C | | |

Date:06/05/02ISR Number: 3928552-6Report Type:Direct Company Report #CTU 169572
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin 20 Mg Sr Po | PS | | |
| 2 TABS Q AM | | Pharmaceutical Product Complaint | | | | | |

Date:06/05/02ISR Number: 3929863-0Report Type:Expedited (15-DaCompany Report #CEL-2002-00466-ROC(0)
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------------|------------------------|-------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Interaction Dysphoria | Health Professional | Metadate Cd Capsules 20 Mg | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | |
|---|--|-------------------------|
| <p>20 MG (20 MG, Q AM), PO</p> <p>60 MG (30 MG, TWICE QD), PO</p> | <p>(Methylphenidate Hydrochloride) PS</p> <p>Allegra (Fexofenadine Hydrochloride) SS</p> <p>Augmentin (Clavulin) C</p> | <p>ORAL</p> <p>ORAL</p> |
|---|--|-------------------------|

Date:06/07/02 ISR Number: 3934082-8 Report Type:Expedited (15-DaCompany Report #B0269193A
Age:42 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|-----------------------------------|--|---------|--------------|-------|
| Life-Threatening Hospitalization - Initial or Prolonged PER DAY/ ORAL | | Gingival Bleeding Hepatocellular Damage Idiopathic | Foreign Health Professional | Paxil Tablet (Paroxetine Hydrochloride) | PS | | ORAL |
| | | Thrombocytopenic Purpura | Company Representative | Methylphenidate Hcl (Formulation Unknown) (Methylphenidate Hcl) Magnesium Oxide | SS C | | |

Date:06/10/02 ISR Number: 3930890-8 Report Type:Direct Company Report #CTU 169806
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|--|---------------|-----------------|------|--------------|-------|
| 10MG TID | | Dyspepsia Flatulence Nausea Pharmaceutical Product Complaint | | Methylphenidate | PS | | |

Date:06/12/02ISR Number: 3931663-2Report Type:Direct Company Report #CTU 169942
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Ritalin 20mg Sr | PS | | ORAL |
| 3 TABS Q AM | | Disturbance In Attention | | | | | |
| PO | | Drug Ineffective Pharmaceutical Product Complaint | | | | | |

Date:06/12/02ISR Number: 3932830-4Report Type:Expedited (15-DaCompany Report #PHFR2002GB00758
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------------------|-----------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Systemic Lupus Erythematosus | Foreign Health | Ritaline(Methylpheni date Hydrochloride) | PS | | |
| 40 MG, QD | | | Professional Other | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/12/02ISR Number: 3932906-1Report Type:Expedited (15-DaCompany Report #PHEH2002US04957
Age:74 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|-----------------------------------|---------|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | 5 MG, 2-3 TIMES DAILY, ORAL | Syncope | Health Professional | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| | | | | Zoloft (Sertraline Hydrochloride) | C | | |
| | | | | Lipitor (Atorvastatin) | C | | |
| | | | | Prevacid (Lansoprazole) | C | | |

Date:06/12/02ISR Number: 3933230-3Report Type:Expedited (15-DaCompany Report #13400
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------------------|---------------|------------------------|--------------------------------------|------|--------------|-------|
| Other | 36MG 1X/DAY, ORAL | Hypoglycaemia | Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |

Date:06/12/02ISR Number: 3933261-3Report Type:Expedited (15-DaCompany Report #PHNU2002DE01874
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|----------------------------------|------------------------------|--|------|--------------|-------|
| Other | ORAL; SEE | Obsessive-Compulsive Disorder | Foreign Consumer Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

IMAGE

| | | |
|---|----|------|
| Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | SS | ORAL |
|---|----|------|

ORAL; SEE

IMAGE

Date:06/12/02ISR Number: 3933267-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE01895
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Depressed Mood Tearfulness | Foreign Other | Ritalin (Methylphenidate Hydrochloride) | PS | | ORAL |

SEE IMAGE

Date:06/12/02ISR Number: 3933349-7Report Type:Expedited (15-DaCompany Report #PHNU2002DE01782
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Electrocardiogram Abnormal Pulmonary Hypertension | Foreign Health Professional Other | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/12/02ISR Number: 3933635-0Report Type:Expedited (15-DaCompany Report #PHFR2002GB01687
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|-------------------------------|-----------------------------------|---|------|--------------|-------|
| Dose Other | | Dysarthria Speech Disorder | Foreign Health Professional | Methylphenidate (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36MG/DAY, ORAL | | | Other | | | | |

Date:06/14/02ISR Number: 3934694-1Report Type:Expedited (15-DaCompany Report #13467
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------|----------|---|------------------------|--------------------------------------|------|--------------|-------|
| Dose Other | | Influenza Like Illness Platelet Count Decreased Pyrexia | Health Professional | Concerta (Methylphenidate Hcl) | PS | | |
| 18MG TO 36MG 1X/1DAY | | White Blood Cell Count Decreased | | | | | |

Date:06/14/02ISR Number: 3934695-3Report Type:Expedited (15-DaCompany Report #13483
Age:38 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--|------------------------|--|----------------------------------|--------------|-------|
| Dose Other | | Arthralgia Iron Deficiency Anaemia Pruritus | Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 54MG 1X/DAY, ORAL | | Red Blood Cell Sedimentation Rate Increased Serum Sickness Urticaria | | Ortho-Tri-Cyclen Celexa Seroquel Nexium Singulair Advair Nasonex | SS C C C C C C | | |

Albuterol

C

Date:06/14/02ISR Number: 3978957-2Report Type:Periodic
Age: Gender:Female I/FU:I

Company Report #02040196

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|-------------|------------|---------------|-----------------|------|--------------|-------|
| Other | | Convulsion | Health | Enbrel 25 Mg | PS | | |
| SUBCUTANEOUS | 25 MG, BIW, | | Professional | | | | |
| SUBCUTANEOUS | | | | Concerta | SS | | |
| SUBCUTANEOUS | 25 MG, BIW, | | | | | | |
| SUBCUTANEOUS | | | | Loratadine | C | | |
| | | | | Ibuprofen | C | | |
| | | | | Diphenhydramine | C | | |

Date:06/17/02ISR Number: 3934799-5Report Type:Direct
Age:42 YR Gender:Female I/FU:I

Company Report #CTU 170281

Outcome
Hospitalization -
Initial or Prolonged
Disability
Required
Intervention to
Prevent Permanent

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Impairment/Damage

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------|----------|-------------------------|---------------|----------|------|--------------|-------|
| | | Anger | | Ritalin | PS | | |
| | | Bipolar Disorder | | Adderall | SS | | |
| | | Crying | | | | | |
| | | Fear | | | | | |
| | | Feeling Abnormal | | | | | |
| | | Hallucination, Auditory | | | | | |
| | | Loss Of Employment | | | | | |
| | | Memory Impairment | | | | | |
| | | Paranoia | | | | | |
| | | Personality Change | | | | | |
| | | Thinking Abnormal | | | | | |

Date:06/18/02ISR Number: 3936126-6Report Type:Expedited (15-DaCompany Report #PHRM2001FR02804
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Decreased Appetite | Foreign | Ritaline(Methylpheni | | | |
| | | Hypertension | Health | date Hydrochloride) | | | |
| | | Tachycardia | Professional | Tablet | PS | | ORAL |
| SEE IMAGE | | Weight Decreased | Other | | | | |

Date:06/19/02ISR Number: 3936538-0Report Type:Expedited (15-DaCompany Report #NSADSS2002020120
 Age:38 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|-------------------------|---------------|-----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Arthralgia | Health | Ortho Tri-Cyclen | | | |
| Required | | Iron Deficiency Anaemia | Professional | (Tablet) | | | |
| Intervention to | | Pruritus | | (Norgestimate/Ethinyl | | | |
| Prevent Permanent | | Red Blood Cell | | lestradiol) | PS | | ORAL |
| 1 TABLE, | | | | | | | |
| Impairment/Damage | | Sedimentation Rate | | | | | |
| DAILY, ORAL | | Increased | | Concerta (54 Mg | | | |
| | | Serum Sickness | | Tablet) | | | |
| | | Urticaria | | (Methylphenidate | | | |

54 MG, 1 IN 1

Hydrochloride)

SS

ORAL

DAILY, ORAL

| | |
|----------------------|---|
| Celexa (Citalopram | |
| Hydrobromide) | C |
| Seroquel (Seroquel) | C |
| Singulair | |
| (Montelukast Sodium) | C |
| Advair | C |
| Nasonex (Mometasone | |
| Furoate) | C |
| Albuterol | |
| (Salbutamol) | C |

Date:06/21/02ISR Number: 3937806-9Report Type:Expedited (15-DaCompany Report #13624

Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper | Consumer | Concerta | PS | | ORAL |
| 36MG 1X/1DAY | | Grand Mal Convulsion | | | | | |
| ORAL | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/25/02ISR Number: 3938541-3Report Type:Direct
Age:10 YR Gender:Male I/FU:I

Company Report #CTU 170809

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------------|---------------|--------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin 10mg | PS | | |
| 1-1 1/2 TAB | | Pharmaceutical Product | | | | | |
| AFTER SCHOOL | | Complaint | | | | | |

Date:06/25/02ISR Number: 3938565-6Report Type:Direct
Age:12 YR Gender:Male I/FU:I

Company Report #CTU 170814

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---|---------------|----------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper Jaundice | | Concerta 54 Mg 1 Po Qam | PS | | ORAL |
| 1 PO QAM | | Liver Function Test Abnormal Malaise Pyrexia Rash | | | | | |

Date:06/25/02ISR Number: 3939623-2Report Type:Expedited (15-DaCompany Report #13693
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Aphasia Complex Partial Seizures Convulsion | Health Professional Company | Concerta (Methylphenidate Hci) | PS | | |
| 36MG QAM+18MG QPM | | Depressed Level Of Consciousness | Representative | Gabitril | SS | | |
| 2MG QD TO | | Petit Mal Epilepsy | | | | | |
| 12MG TID | | Status Epilepticus | | Zarontin | C | | |

Date:06/25/02ISR Number: 3939624-4Report Type:Expedited (15-DaCompany Report #13624
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|--|---------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper Grand Mal Convulsion | Consumer | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 36MG 1X/1DAY, ORAL | | | | | | | |

Date:06/25/02ISR Number: 3940388-9Report Type:Direct Company Report #CTU 170847
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening Disability Required Intervention to Prevent Permanent Impairment/Damage | | Insomnia Irritability Self-Injurious Ideation Sleep Terror Tourette'S Disorder | | Ritalin | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/26/02ISR Number: 3940262-8Report Type:Expedited (15-DaCompany Report #PHNU2002DE02013
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|----------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Obsessive-Compulsive | Foreign | Ritaline | PS | | ORAL |
| 1 DF, QD, | | Disorder | Consumer | | | | |
| ORAL | | | Other | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release | SS | | ORAL |
| 1 DF, QD, | | | | | | | |
| ORAL | | | | | | | |

Date:06/26/02ISR Number: 3940305-1Report Type:Expedited (15-DaCompany Report #13715
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Grand Mal Convulsion | Foreign | Concerta | | | |
| Hospitalization - | | Vomiting | Health | (Methylphenidate | PS | | ORAL |
| Initial or Prolonged | | | Professional | Mcl) | | | |
| 54MG 1X/1DAY, | | | | | | | |
| ORAL | | | | Fluoxetine | SS | | |
| 4MG 1X/1DAY | | | | Fluoxetine | SS | | |
| 12MG 1X/1DAY | | | | Lactulose | C | | |

Date:06/26/02ISR Number: 3940488-3Report Type:Expedited (15-DaCompany Report #PHFR2002GB01755
 Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cyanosis | Foreign | Ritaline | | | |
| | | | Health | (Methylphenidate | | | |
| | | | Professional | Hydorochloride) | | | |

ORAL

Date:06/27/02ISR Number: 3940940-0Report Type:Expedited (15-DaCompany Report #872475F001
Age:25 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|-------------|---|--------------------------------------|---|------|--------------|-------------|
| Death | | Bundle Branch Block Cardiomegaly Dissociative Disorder Drug Abuser | Literature Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | | | PS |
| INTRAVENOUS | INTRAVENOUS | Dyspnoea Granuloma Hypotension Liver Disorder Pulmonary Granuloma Tachycardia Ventricular Hypertrophy | | Talwin Tablet Darvon-N Tablet Acetaminophen (Acetaminophen (Paracetamol)) Tablet | | | C C C |

Date:06/27/02ISR Number: 3941374-5Report Type:Expedited (15-DaCompany Report #PHBS2002BE06071
Age:14 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------------------|--|---|------|--------------|------------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Hepatitis Nausea | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Unknown | | | PS ORAL |

25 MG/DAY,

ORAL

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/28/02ISR Number: 3941498-2Report Type:Direct
Age:10 YR Gender:Male I/FU:I

Company Report #CTU 171264

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin 10 Mg | PS | | |
| 1-1 1/2 TAB | | Pharmaceutical Product | | | | | |
| AFTER SCHOOL | | Complaint | | | | | |

Date:07/01/02ISR Number: 3941974-2Report Type:Direct
Age:7 YR Gender:Male I/FU:I

Company Report #CTU 171286

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| 10 MG 1 1/2 | | Attention | | Ritalin | PS | | |
| TABS TID | | Deficit/Hyperactivity | | | | | |
| | | Disorder | | | | | |
| | | Condition Aggravated | | | | | |
| | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |

Date:07/01/02ISR Number: 3943032-XReport Type:Expedited (15-DaCompany Report #CEL-2002-00206-SLO (0)
Age:12 YR Gender:Male I/FU:I

Company Report #CEL-2002-00206-SLO (0)

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Attention | Foreign | Equasym (Strength | | | |
| | | Deficit/Hyperactivity | Health | Unspecified) | | | |
| | | Disorder | Professional | (Methylphenidate | | | |
| | | Condition Aggravated | | Hydrochloride) | PS | | ORAL |
| 60 MG (20 MG, | | Drug Ineffective | | | | | |
| THREE TIMES | | Emotional Disorder | | | | | |
| DAILY), PO | | Tic | | Ritalin | | | |
| | | | | (Methylphenidate | | | |
| | | | | Hydrochloride) | C | | |

Date:07/01/02ISR Number: 3943805-3Report Type:Expedited (15-DaCompany Report #PHBS2002CA05418
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haemolytic Anaemia | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Unknown | PS | | ORAL |
| ORAL | | | | | | | |

Date:07/02/02ISR Number: 3943518-8Report Type:Expedited (15-DaCompany Report #PHFR2002GB01989
Age:20 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Obsessive-Compulsive Disorder Psychotic Disorder | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| 60MG/DAY, ORAL | | | | | | | |

Date:07/02/02ISR Number: 3943692-3Report Type:Expedited (15-DaCompany Report #13754
Age:14 YR Gender:Female I/FU:I

| Outcome | PT | Report Source |
|---------|-----------------|---------------------|
| Other | Suicide Attempt | Health Professional |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Company Representative | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|--------------------------------------|------|--------------|-------|
| 18 MG | | | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 1X/1DAY, ORAL | | | | | | |

Date:07/03/02ISR Number: 3944659-1Report Type:Expedited (15-DaCompany Report #PHNU2002DE01373
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-------------------|--|--|------|--------------|-------|
| Dose Other | | Diabetes Mellitus | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 20 MG/DAY; ORAL | | | | | | | |

Date:07/03/02ISR Number: 3944785-7Report Type:Expedited (15-DaCompany Report #200216620US
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|------------------------|--|--------|--------------|-------|
| Dose Other | | Condition Aggravated Drug Interaction Dysphoria | Health Professional | Fexofenadine Hydrochloride (Allegra) | PS | | ORAL |
| 30 MG BID PO | 4 DAY | Major Depression Suicide Attempt | | Methylphenidate Hydrochloride Capsules | SS | | ORAL |
| 20 MG QAM PO | 10 MON | | | Clavulanate Potassium Amoxicillin Trihydrate (Augmentin) | C C | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------|----------------|----------|------|--------------|-------|
| Hospitalization - | | Convulsion | Health | Gabitril | PS | | ORAL |
| 2 MG QD ORAL | | | | | | | |
| Initial or Prolonged | | Status Epilepticus | Professional | Gabitril | SS | | ORAL |
| 4 MG TID ORAL | | | | | | | |
| 12 MG TID | | | Company | Gabitril | SS | | ORAL |
| ORAL | | | Representative | | | | |
| | | | | Gabitril | SS | | ORAL |
| 12 MG QID | | | | | | | |
| ORAL | | | | | | | |
| | | | | Concerta | SS | | ORAL |
| 36 MG QAM | | | | | | | |
| ORAL | | | | | | | |
| | | | | Concerta | SS | | ORAL |
| 18 MG QHS | | | | | | | |
| ORAL | | | | | | | |
| | | | | Concerta | SS | | ORAL |
| 18 MG BID | | | | | | | |
| ORAL | | | | | | | |
| | | | | Concerta | SS | | |
| 32 MG DAILY | | | | | | | |
| | | | | Zarontin | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/05/02ISR Number: 3946648-XReport Type:Expedited (15-DaCompany Report #13774
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|-----------|-----------------------------|--------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Epistaxis | Foreign Health Professional | Concerta (Methylphenidate Hcl) | PS | | ORAL |
| 18MG 1X/1DAY, ORAL | | | | | | | |

Date:07/09/02ISR Number: 3945650-1Report Type:Direct Company Report #CTU 171855
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|------------------------------------|---------------|------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Headache Pharmaceutical Product | | Ritalin Sr 20mg - Generic | PS | | ORAL |
| 40MG PO QAM Complaint | | | | | | | |

Date:07/09/02ISR Number: 3947254-3Report Type:Expedited (15-DaCompany Report #PHNU2002DE02251
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------------|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Acute Abdomen Constipation | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| Other | | Flatulence | | | | | |
| ORAL Other | | | | | | | |

Date:07/09/02ISR Number: 3947317-2Report Type:Expedited (15-DaCompany Report #PHNU2002DE02147
 Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Anaemia Contusion | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | | | |
| Other | | Haematoma | | | | | |

| | | | | | |
|------------|--------------------------|-------|--------|----|------|
| 7.5MG/DAY, | Leukopenia | Other | Tablet | PS | ORAL |
| ORAL | Myelodysplastic Syndrome | | | | |
| | Thrombocytopenia | | | | |

Date:07/11/02ISR Number: 3948183-1Report Type:Expedited (15-DaCompany Report #PHNU2002DE02271
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Discomfort Dyspnoea Exertional Electrocardiogram St Segment Depression | Foreign Health Professional Other | Ritalin (Methylphenidate Hydrochloride)Tablet , 10mg | PS | | ORAL |
| 10 MG, QD, | | Electrocardiogram T Wave | | | | | |
| ORAL | | Biphasic | | | | | |

Date:07/11/02ISR Number: 3948974-7Report Type:Expedited (15-DaCompany Report #PHNU2002DE01637
 Age:12 YR Gender:Male I/FU:F

| | |
|----------------------|--|
| Outcome | PT |
| Hospitalization - | Arthropathy |
| Initial or Prolonged | Blood Creatine |
| Other | Phosphokinase Increased Blood Immunoglobulin E Increased |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---|---|------|--------------|-------|
| 15MG/DAY, ORAL | | Blood Lactate Dehydrogenase Increased Dermatomyositis | Foreign Health Professional | PS | | ORAL |
| | | Electrophoresis Protein Abnormal Erythema | Ritaline(Methylpheni date Hydrochloride) Tablet | | | |
| | | Infection | Other | | | |
| | | Influenza Like Illness Muscular Weakness Pruritus Red Blood Cell Sedimentation Rate Increased Skin Disorder | | | | |

Date:07/15/02ISR Number: 3948475-6Report Type:Direct Company Report #CTU 172279
Age: Gender:Male I/FU:I

| Outcome | Duration | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|-------------------------------------|------------|------|--------------|-------|
| Dose Other 20 G TID | | PT Drug Ineffective | Ritalin Sr | PS | | |
| | | Pharmaceutical Product Complaint | | | | |

Date:07/15/02ISR Number: 3949749-5Report Type:Expedited (15-DaCompany Report #PHFR2002GB02090
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|--|---|------|--------------|-------|
| Dose Other 25 MG, TID | | PT Deafness Neurosensory | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | |
| 0.5 MG, QID, ORAL | | Foreign Health Professional Other | Risperdal (Risperidone) | SS | | ORAL |

Date:07/16/02ISR Number: 3949384-9Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 172423

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Concerta 54 Mg + 18 | | | |
| | | Pharmaceutical Product | | Mg | PS | | ORAL |
| 72 MG PO QD | | Complaint | | | | | |

Date:07/16/02ISR Number: 3949755-0Report Type:Expedited (15-DaCompany Report #PHNU2002DE01391
Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Concussion | Foreign | Ritaline | | | |
| Initial or Prolonged | | Fall | Health | (Methylphenidate | | | |
| | | Tinnitus | Professional | Hydrochloride) | | | |
| | | | Other | Tablet | PS | | ORAL |

5 MG/DAY,

ORAL

Tropisetron
(Tropisetron
Hydrochloride)
Unknown SS

Date:07/25/02ISR Number: 3953275-7Report Type:Expedited (15-DaCompany Report #WAES 0207SWE00008
Age:76 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------|---------------|------------------------------|------|------------------|-------|
| Hospitalization - Initial or Prolonged | | Liver Disorder | | Zocor | PS | Merck & Co., Inc | ORAL |
| | | | | Enalapril Maleate | SS | | ORAL |
| | | | | Methylphenidate | SS | | |
| | | | | Clindamycin Hydrochloride | SS | | |
| 36 DAY | | | | Bisacodyl | C | | |
| | | | | Metformin Hydrochloride | C | | |
| | | | | Furosemide Sodium | C | | |
| | | | | Metoprolol Tartrate | C | | |
| | | | | Aspirin | C | | |
| | | | | Isosorbide Mononitrate | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/25/02ISR Number: 3953899-7Report Type:Expedited (15-DaCompany Report #CEL-2002-00577-SLO(0)
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------------------------|----------------------------------|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | 54 MG (54 MG, DAILY) PO | Grand Mal Convulsion Vomiting | Foreign Health Professional | Methylphenidate (Brand Unspecified) | PS | | ORAL |
| | | | | Fluoxetine (Fluoxetine) | C | | |
| | | | | Lactulose (Lactulose) | C | | |

Date:07/25/02ISR Number: 3953968-1Report Type:Expedited (15-DaCompany Report #13754
 Age:8 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------------------|-----------------|---|--------------------------------------|------|--------------|-------|
| Other | 18MG 1X/1DAY, ORAL | Suicide Attempt | Health Professional Company Representative | Concerta (Methylphenidate Hcl) | PS | | ORAL |

Date:07/25/02ISR Number: 3954094-8Report Type:Expedited (15-DaCompany Report #CEL-2002-00571-ROC(0)
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---------------------------|---|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | 20 MG, (20 MG, QD), PO | Abnormal Behaviour Hallucination Thrombocytopenic Purpura | Health Professional Company Representative | Metadate Cd Capsule 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:07/26/02ISR Number: 3956673-0Report Type:Expedited (15-DaCompany Report #PHNU2002DE02392
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cerebral Perfusion Pressure Decreased Nuclear Magnetic Resonance Imaging Brain | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | Abnormal Paraesthesia | | | | | |

Date:07/29/02ISR Number: 3956344-0Report Type:Expedited (15-DaCompany Report #PHBS2002DK01472
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------------|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Colitis Ulcerative Diarrhoea | Foreign Health Professional Other | Ritaline (Methylphenidat Hydrochloride) Tablet | PS | | ORAL |
| 30 MG/DAY, | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/31/02ISR Number: 3956299-9Report Type:Direct
Age: Gender: I/FU:I

Company Report #CTU 173263

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|--|------|--------------|-------|
| Dose | | Medication Error | | Metadate Cd (Methylphenidate Hcl, Usp) Extended-Release Capsules | PS | | |

Date:08/01/02ISR Number: 3957547-1Report Type:Expedited (15-DaCompany Report #PHFR2002GB02307
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|--|---|------|--------------|-------|
| Dose | | Chest Pain | Foreign Health Professional Other | Ritaline (Methylphenidat Hydrochloride) Tablet | PS | | |

Date:08/02/02ISR Number: 3959865-XReport Type:Periodic
Age:18 YR Gender: I/FU:I

Company Report #2001AP05245

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|--------------------------------------|--|----------------|--------------|-------|
| Death | | Completed Suicide | Literature Health Professional | Amitriptylline Hydroxyzine Methylphenidate | PS SS SS | | |

Date:08/06/02ISR Number: 3959112-9Report Type:Expedited (15-DaCompany Report #FLUV00301003977
Age:30 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|---------------------------------------|-----------------------------------|--------------------------------------|------|--------------|-------|
| Death | | Accidental Overdose | Foreign Health Professional | Luvox 25 (Fluvoxamine Maleate) | PS | | ORAL |
| Life-Threatening | | Alanine Aminotransferase Increased | Other | | | | |
| 50 MG DAILY | | Aspartate | | | | | |
| PO | | | | | | | |

| | | | | |
|--------------|--|---|----|------|
| 150 MG DAILY | Aminotransferase Increased | Toledomin (Milnacipran) | SS | ORAL |
| PO | Blood Lactate | | | |
| 300 MG DAILY | Dehydrogenase Increased | Amoxan (Amoxapine) | SS | ORAL |
| PO | Blood Pressure Increased | | | |
| 10 MG DAILY | Depressed Level Of Consciousness | Paxil (Paroxetine Hydrochloride) | SS | ORAL |
| PO | Drug Toxicity | | | |
| 10 MG DAILY | Grand Mal Convulsion Haemodialysis Haemorrhagic Cerebral | Ritalin (Methylphenidate Hydrochloride) | SS | ORAL |
| PO | Infarction | | | |
| | Neuroleptic Malignant Syndrome | Rize (Clotiazepam) | C | |
| | Pyrexia | Solanax (Alprazolam) | C | |
| | Renal Disorder | | | |
| | Renal Failure Acute | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/07/02ISR Number: 3959526-7Report Type:Direct
 Age: Gender:Female I/FU:I

Company Report #CTU 173699

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Coordination Abnormal | | Ritalin | PS | | ORAL |
| 20 MG PO TID | | Disturbance In Attention Pharmaceutical Product Complaint | | | | | |

Date:08/07/02ISR Number: 3959541-3Report Type:Direct
 Age:15 YR Gender:Male I/FU:I

Company Report #CTU 173708

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Methylphenidate 5mg | PS | | ORAL |
| AS NEEDE | | Delinquency | | | | | |
| SCHOOL DAYS | | Theft | | | | | |
| ORAL | | | | Methylphenidate 10mg | SS | | ORAL |
| AS NEEDE | | | | | | | |
| SCHOOL DAYS | | | | | | | |
| ORAL | | | | | | | |

Date:08/07/02ISR Number: 3960115-9Report Type:Expedited (15-DaCompany Report #US0225000
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Feeling Cold | Consumer | Adderall Xr | PS | | |
| SEE NARRATIVE | | Hypothyroidism | | Ritalin | SS | | |
| | | Memory Impairment | | Birth Control Pills | C | | |
| | | | | Wellbutrin (Bupropion Hydrochloride) ("Not On Long") | C | | |
| | | | | Prozac (Fluoxetine | | | |

Hydrochloride) (Not
On Long) C

Date:08/08/02ISR Number: 3959900-9Report Type:Direct
Age:20 YR Gender:Female I/FU:I

Company Report #CTU 173809

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------------|---------------|----------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyspepsia Headache | | Ritalin (Generic Given) | PS | | ORAL |
| 10MG 1T PO | | Pharmaceutical Product | | | | | |
| BID | | Complaint | | | | | |

Date:08/08/02ISR Number: 3960798-3Report Type:Expedited (15-DaCompany Report #13467
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|------------------------|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Influenza Like Illness Pancytopenia | Health Professional | Concerta (Methylphenidate Hcl) | PS | | |
| 18MG TO 36MG | | | | | | | |
| 1X/1DAY | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/08/02ISR Number: 3961109-XReport Type:Expedited (15-DaCompany Report #PHNU2002DE02392
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cerebrovascular Disorder | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | Paraesthesia | Other | | | | |

Date:08/08/02ISR Number: 3961122-2Report Type:Expedited (15-DaCompany Report #PHNU2002DE00915
 Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Blood Creatinine Increased | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| Other | | Candidiasis | Other | | | | |
| SEE IMAGE, | | Central Nervous System | | | | | |
| ORAL | | Viral Infection | | | | | |
| | | Chlamydial Infection | | | | | |
| | | Drug Withdrawal Syndrome | | | | | |
| | | Herpes Zoster Infection | | | | | |
| | | Neurological | | | | | |
| | | Hypertension | | | | | |
| | | Hypoaesthesia | | | | | |
| | | Multiple Sclerosis | | | | | |
| | | Nervous System Disorder | | | | | |
| | | Nuclear Magnetic Resonance Imaging Brain Abnormal | | | | | |
| | | Paraesthesia | | | | | |
| | | White Blood Cell Count Increased | | | | | |

Date:08/08/02ISR Number: 3961323-3Report Type:Expedited (15-DaCompany Report #PHNU2002DE02597
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other ORAL | | Cold Sweat Dizziness Fatigue Hypotension Miosis Neck Pain | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:08/09/02ISR Number: 3962437-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE02251
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other 10MG/DAY, ORAL | | Acute Abdomen Constipation Flatulence | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/09/02ISR Number: 3962441-6Report Type:Expedited (15-DaCompany Report #PHFR2002IE02406

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------------------|---------------|------------------|------|--------------|-------|
| Dose | | Diabetes Mellitus | Foreign | Ritaline | | | |
| Other | | Inadequate Control | Health | (Methylphenidate | | | |
| | | | Professional | Hydrochloride) | | | |
| | | | Other | Tablet | PS | | ORAL |
| 5 MG, QD, | | | | | | | |
| ORAL | | | | | | | |

Date:08/09/02ISR Number: 3993984-7Report Type:Periodic Company Report #PHEH2002US05111

Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------|----------------|------------------|------|--------------|-------|
| Dose | | Attention | Health | Trileptal | | | |
| | | Deficit/Hyperactivity | Professional | (Oxcarbazepine) | | | |
| | | Disorder | Company | Tablet | PS | | ORAL |
| 900 MG/DAY, | | Concomitant Disease | Representative | | | | |
| ORAL | | Aggravated | | Concerta | | | |
| | | Drug Interaction | | (Methylphenidate | | | |
| | | Inhibition | | Hydrochloride) | SS | | ORAL |
| 54 MG/DAY, | | | | | | | |
| ORAL | | | | | | | |

Date:08/14/02ISR Number: 3962127-8Report Type:Direct Company Report #CTU 174166

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | Drug Ineffective | | Methylphenidate | | | |
| | | Pharmaceutical Product | | Mallinckrodt | PS | Mallinckrodt | ORAL |
| 10MG PO BID | | Complaint | | | | | |

Date:08/14/02ISR Number: 3962133-3Report Type:Direct Company Report #CTU 174167
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|--------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin 10mg | PS | | ORAL |
| 1 1/2 AM PO 1 | | Pharmaceutical Product | | | | | |
| NOON PO | 7 YR | Complaint | | | | | |

Date:08/15/02ISR Number: 3963676-9Report Type:Expedited (15-DaCompany Report #PHNU2002DE02713
Age:31 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Coronary Artery Occlusion Myocardial Infarction | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| Other | | | | | | | |
| 7.5 MG/DAY; | | | | | | | |
| ORAL | | | | | | | |

Date:08/15/02ISR Number: 3963711-8Report Type:Expedited (15-DaCompany Report #PHNU2002DE00915
Age:14 YR Gender:Male I/FU:F

| Outcome | PT |
|---|---|
| Hospitalization - Initial or Prolonged | Antibody Test Abnormal Blood Creatinine Increased |
| Other | Central Nervous System |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------------------------|---------------|------------------|------|--------------|-------|
| | | Viral Infection | | | | | |
| | | Drug Withdrawal Syndrome | | | | | |
| | | Flushing | | | | | |
| | | Hypertension | | | | | |
| UNK, UNK, | | Hypoaesthesia | Foreign | Ritaline | | | |
| | | Multiple Sclerosis | Health | (Methylphenidate | | | |
| | | Nervous System Disorder | Professional | Hydrochloride) | | | |
| | | Nuclear Magnetic | Other | Tablet | PS | | ORAL |
| | | Resonance Imaging Brain | | | | | |
| ORAL; | | Abnormal | | | | | |
| 60MG/DAY | | Paraesthesia | | | | | |

Date:08/15/02ISR Number: 3963712-XReport Type:Expedited (15-DaCompany Report #PHNU2002DE02597
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------------|---------------|-----------------------|------|--------------|-------|
| Hospitalization - | | Cold Sweat | Foreign | Ritaline | | | |
| Initial or Prolonged | | Dizziness | Health | (Methylphenidate | | | |
| Other | | Fatigue | Professional | Hydrochloride) | | | |
| | | Hypotension | Other | Tablet | PS | | ORAL |
| UNK, UNK, | | Miosis | | | | | |
| ORAL | | Neck Pain | | Pipamperone (Pipamper | | | |
| | | Urine Analysis Abnormal | | one) Unknown | SS | | ORAL |
| UNK, UNK, | | | | | | | |
| ORAL | | | | | | | |

Date:08/15/02ISR Number: 3964053-7Report Type:Expedited (15-DaCompany Report #14192
 Age:40 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------|---------------|------------------|------|--------------|-------|
| Hospitalization - | | Appendicitis | Health | Concerta | | | |
| Initial or Prolonged | | Volvulus Of Bowel | Professional | (Methylphenidate | | | |
| | | | | Hci) | PS | | ORAL |
| 36MG 1X/1 | | | | | | | |

Date:08/15/02ISR Number: 3964124-5Report Type:Expedited (15-DaCompany Report #PHFR2002GB02307
 Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine Phosphokinase Increased Chest Pain Electrocardiogram | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | | | ORAL |
| SEE IMAGE | | Repolarisation Abnormality Electrocardiogram St Segment Elevation Palpitations | | Clonidine (Clonidine) | | | |

Date:08/15/02ISR Number: 3964125-7Report Type:Expedited (15-DaCompany Report #PHNU2002DE01637
 Age:12 YR Gender:Male I/FU:F

| Outcome | PT |
|--|---|
| Hospitalization - Initial or Prolonged Other | Angiotensin Converting Enzyme Increased Autoimmune Disorder Blood Parathyroid Hormone Decreased Cardiomegaly |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---|--|--|------|--------------|-------|
| 15MG/DAY, ORAL | | Dermatomyositis Glomerular Vascular Disorder | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| | | Hepatomegaly Influenza Like Illness Livedo Reticularis Lymphadenopathy | | | | | |
| | | Pruritus | | | | | |
| | | Serum Ferritin Increased | | | | | |

Date:08/16/02ISR Number: 3962951-1Report Type:Direct Company Report #CTU 174334
Age:39 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------------------|---------------|---|------|--------------|-------|
| 10 MG QD X 2 WKS AND THEN 10MG BID | | Headache Nausea | | Methylphenidate (Ritalin) 10 Mg Qd X 2 Wks And Then 10mg Bid | PS | | |

Date:08/19/02ISR Number: 3964780-1Report Type:Expedited (15-DaCompany Report #PHBS2002BR09348
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|----------------------------------|--|--|------|--------------|-------|
| 10 MG/DAY, ORAL | | Hypertrichosis Penis Disorder | Foreign Health Professional Other | Ritalina(Methylpheni date Hydrochloride) Unknown | PS | | ORAL |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-------------|------------------------|---------------|----------------------|------|--------------|-------|
| Other | 1.5 TABS AM | Drug Ineffective | | Methylphenidate 10mg | PS | | |
| | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------------|--|---------------------------------|--|------|--------------|-------|
| Death | 5 MG/DAY, | Anorexia Depression Diarrhoea | Foreign Literature Health | Parlodel (Bromocriptine Mesilate) | PS | | ORAL |
| | ORAL | Disease Progression | Professional | | | | |
| | | Dizziness Drug Effect Decreased Dysuria Extrapyramidal Disorder | Other | Ludiomil Tablet (Maprotiline Hydrochloridle) Tablet | SS | | ORAL |
| | 10 UG/DAY, | Gait Disturbance | | | | | |
| | ORAL | Irritability Nausea Somnolence | | Methylphenidate Hydrochloride (Methylphenidate Hydrochloride) | SS | | ORAL |
| | 10 MG/DAY, | | | Sulpiride | | | |
| | ORAL | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Sulpiride) C
 Trazodone
 (Trazodone) C
 Lithium Carbonate C
 Mianserin
 (Mianserin) C
 Pergolide
 (Pergolide) C
 Levothyrox C

Date:08/21/02ISR Number: 3965784-5Report Type:Expedited (15-DaCompany Report #PHFR2002GB02520
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------------------------------|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Disability Other 60 MG MANE + 30 MG TID, ORAL | | Dystonia Emotional Distress | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 0.5 G MANE, ORAL | | | | Risperidone (Risperidone) | SS | | ORAL |

Date:08/21/02ISR Number: 3966622-7Report Type:Expedited (15-DaCompany Report #CEL-2002-00967-SLO(0)
 Age:24 YR Gender:Male I/FU:U

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Other SEE IMAGE | | Alanine Aminotransferase Increased Aspartate | Foreign Health Professional | Equasym 5mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | Aminotransferase Increased Haematocrit Decreased Haemoglobin Decreased Thrombocytopenia | | Neurontin (Gabapentin) | C | | |

Date:08/26/02ISR Number: 3966953-0Report Type:Direct
Age:8 YR Gender:Male I/FU:I

Company Report #CTU 175042

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------|---------------|---------|------|--------------|-------|
| Dose | | | | Ritalin | PS | | ORAL |
| 15 MG PO BID | | Antiphospholipid | | | | | |
| | | Antibodies Positive | | | | | |
| | | Coagulopathy | | | | | |

Date:08/26/02ISR Number: 3966954-2Report Type:Direct
Age:10 YR Gender:Male I/FU:I

Company Report #CTU 175043

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------|---------------|---------|------|--------------|-------|
| Dose | | | | Ritalin | PS | | ORAL |
| Other | | Antiphospholipid | | | | | |
| 10 MG PO BID | | Antibodies Positive | | | | | |
| | | Coagulopathy | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/26/02ISR Number: 3966955-4Report Type:Direct
 Age:8 YR Gender:Male I/FU:I

Company Report #CTU 175044

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Antiphospholipid | | Ritalin | PS | | ORAL |
| 15 MG PO BID | | Antibodies Positive Coagulopathy | | | | | |

Date:08/26/02ISR Number: 3967035-4Report Type:Direct
 Age:5 YR Gender:Male I/FU:I

Company Report #CTU 175041

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Antinuclear Antibody | | Ritalin | PS | | ORAL |
| 10 MG PO BID | | Positive Antiphospholipid Antibodies Positive | | | | | |

Date:08/26/02ISR Number: 3967037-8Report Type:Direct
 Age:12 YR Gender:Male I/FU:I

Company Report #CTU 175040

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|--------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Coagulopathy | | Ritalin | PS | | ORAL |
| 30 MG PO | | | | | | | |

DAILY DIVIDED

DOSES

Date:08/26/02ISR Number: 3967121-9Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 175066

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-------------------------------------|---------------|---------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyspepsia Pharmaceutical Product | | Generic Ritalin 20 Bid | PS | | |
| 20MG BID | | | | | | | |

Complaint
Vomiting

Date:08/27/02ISR Number: 3968304-4Report Type:Expedited (15-DaCompany Report #CEL-2002-00991-SLO (0)
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|---------------------------|-------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Formication | Foreign Health | Methylphenidate (Brand Unspecified) | PS | | ORAL |
| 18 MG (18 MG, UNKNOWN), PO | | Hallucination Tic | Professional | | | | |

Date:08/28/02ISR Number: 3968199-9Report Type:Direct Company Report #CTU 175257
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation Headache Pharmaceutical Product Complaint | | Ritalin (Generic) | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/28/02ISR Number: 3968200-2Report Type:Direct
Age:40 YR Gender:Male I/FU:I

Company Report #CTU 175258

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation Headache Pharmaceutical Product Complaint | | Ritalin (Generic) | PS | | |

Date:09/04/02ISR Number: 3970837-1Report Type:Direct
Age:14 YR Gender:Male I/FU:I

Company Report #CTU 175664

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation Headache Pharmaceutical Product Complaint | | Ritalin (Generic) | PS | | |

Date:09/04/02ISR Number: 3970838-3Report Type:Direct
Age:40 YR Gender:Male I/FU:I

Company Report #CTU 175666

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation Headache Pharmaceutical Product Complaint | | Ritalin (Generic) | PS | | |

Date:09/05/02ISR Number: 3973029-5Report Type:Expedited (15-DaCompany Report #PHBS2002BE09839
Age:10 YR Gender:Male I/FU:I

Company Report #PHBS2002BE09839

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|------------------------------------|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Congenital Anomaly Papilloedema | Foreign Health Professional Other | Ritaline(Methylpheni dat Hydrochloride) Unknown | PS | | ORAL |
| 10 MG, BID, ORAL | | | | | | | |

Date:09/06/02ISR Number: 3972444-3Report Type:Direct Company Report #USP 54964
Age:9 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-------------|------|---------------------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Metadate Er | PS | Medeva Pharmaceuticals | |
| | | | | Metadate Cd | SS | Medeva Pharmaceuticals | |

Date:09/06/02ISR Number: 3972519-9Report Type:Direct Company Report #USP 55033
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-------------|------|-----------------------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Metadate Cd | PS | Celltech Pharmaceuticals | |
| | | | | Metadate Er | SS | Celltech Pharmaceuticals | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/06/02ISR Number: 4008042-5Report Type:Periodic Company Report #13130
 Age:21 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|--|--|---------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Health Professional Company Representative | Concerta (Methylphenidate Hcl) Prozac | PS C | | |

Date:09/06/02ISR Number: 4008060-7Report Type:Periodic Company Report #13605
 Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|--|---------------|--------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation Weight Decreased | Consumer | Concerta (Methylphenidate Hcl) | PS | | |
| 72 MG(4-18MG TABS) 1X/1DAY | | | | | | | |

Date:09/06/02ISR Number: 4008064-4Report Type:Periodic Company Report #13714
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|--|---------------|---|-------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety Delusion Hallucination Neurosis | Consumer | Concerta (Methylphenidate Hcl) Risperdal | PS C | | |
| 18MG (1 IN AM-1 @LUNCH) | | | | | | | |

Date:09/06/02ISR Number: 4008066-8Report Type:Periodic Company Report #13787
 Age:6 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Dreams | Consumer | Concerta | | | |

Growth Retardation
Muscle Twitching

(Methylphenidate
Hcl)

PS

ORAL

36 MG

1X/1DAY, ORAL

Date:09/09/02ISR Number: 3973215-4Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 175898

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|-----------------|------|--------------|-------|
| Dose | | | | Generic Ritalin | PS | | |
| Other | | Drug Ineffective Pharmaceutical Product Complaint | | | | | |

Date:09/09/02ISR Number: 3974009-6Report Type:Expedited (15-DaCompany Report #PHBS2002CA10340
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|--|--|------|--------------|-------|
| Dose | | | | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| Other | | Cataract | Foreign Health Professional Other | Risperdal (Risperidone) | C | | |

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/09/02ISR Number: 3974027-8Report Type:Expedited (15-DaCompany Report #ALZ-14192
Age:40 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------------------|------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Appendicitis Volvulus Of Bowel | Health Professional | Concerta (Methylphenidate Hcl) (Unspecified) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 DAY (S), ORAL | | | | | | | |

Date:09/09/02ISR Number: 3974504-XReport Type:Direct Company Report #CTU 175997
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---|------|--------------|-------|
| | | Medication Error | | Metadate Er Tablets (Methylphenidate Hydrochloride Extended-Release Tablets, Usp)20mg | PS | | |

Date:09/11/02ISR Number: 3974530-0Report Type:Expedited (15-DaCompany Report #PHNU2002DE03005
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Accident Angina Pectoris Blood Creatine Phosphokinase Increased | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 12.5 MG/DAY, ORAL Blood Creatine Phosphokinase Mb Increased Electrocardiogram St Segment Elevation Heart Injury Sinus Arrhythmia | | | | | | | |

Date:09/12/02ISR Number: 3975236-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE03018
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Diabetes Mellitus | Foreign Health Professional Other | Ritalin-Sr (Methlphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | | | | |
| | | | | Medikinet (Methylphenidate Hydrochloride) | SS | | ORAL |
| ORAL | | | | | | | |

Date:09/12/02ISR Number: 3975569-1Report Type:Expedited (15-DaCompany Report #PHEH2002US07830
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------------|---------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Completed Suicide | Health Professional | Ritalin La (Methylphenid Hydrochloride) Extended Release Capsules | PS | | ORAL |
| 20 UNK, QD, | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

ORAL

Date:09/13/02ISR Number: 3975684-2Report Type:Direct Company Report #CTU 176334
 Age:39 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|---|------|--------------|-------|
| Dose Other | | Headache Muscle Spasms Muscle Twitching Nausea | | Methylphenidate (Ritalin)10mg Qd X 2wk And Then 10mg Bid | PS | | |
| 10MG PO QD X 2WK AND THEN 10MG BID | | Visual Disturbance | | | | | |
| 20MG 1 TAB QID PO | | | | Amphetamine Salts 20mg | SS | | ORAL |
| | | | | Adderall | C | | |

Date:09/13/02ISR Number: 3975833-6Report Type:Expedited (15-DaCompany Report #PHNU2002DE03023
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose Other | | Blood Fibrinogen Decreased Coagulation Factor | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| 20 MG/DAY, ORAL | | Decreased Coagulation Time Prolonged Prothrombin Time Shortened | Other | | | | |

Date:09/13/02ISR Number: 3975839-7Report Type:Expedited (15-DaCompany Report #PHNU2002DE03067
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-------------------------------|--|--|------|--------------|-------|
| Dose Other | | Haematoma Weight Decreased | Foreign Health Professional Other | Ritalin (Methylphenidate Hydrochloride) Tablet, 10 Mg | PS | | ORAL |
| 5 MG, BID, ORAL | | | | | | | |

Date:09/13/02ISR Number: 3976076-2Report Type:Expedited (15-DaCompany Report #PHEH2002US07830
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|-------------------|------------------------|--|------|--------------|-------|
| Dose Death | | Completed Suicide | Health Professional | Ritalin La (Methylphenidate Hydrochloride) Extended Release Capsules | PS | | ORAL |
| 20 UNK, QD, ORAL | | | | | | | |

Date:09/16/02ISR Number: 3976553-4Report Type:Expedited (15-DaCompany Report #NSADSS2002030267
Age:9 YR Gender:Female I/FU:I

Outcome
Death
Hospitalization -
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Initial or Prolonged

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|--|------------------------|--|-------------|--------------|-------|
| 18 MG, 1 IN 1 DAY(S), ORAL | | Blood Glucose Increased Cardio-Respiratory Arrest Cough Ear Operation Influenza Like Illness Respiratory Disorder Vomiting | Health Professional | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Ceftin (Cefuroxime Axetil) Rocephin (Ceftriaxone Sodium) Albuterol (Salbutamol) | C C C | | |

Date:09/16/02ISR Number: 3977002-2Report Type:Direct Company Report #CTU 176485
Age: Gender:Male I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--------------------------------|---------------|-------------------------------------|------|--------------|-------|
| 18MG QD ORAL | | Chest Pain Muscle Twitching | | Methylphenidate Sr-Concerta-18mg | PS | Concerta | ORAL |

Date:09/17/02ISR Number: 3976701-6Report Type:Expedited (15-DaCompany Report #FLUV00302002273
Age: Gender: I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|-----------------------------------|---|------|--------------|-------|
| DAILY BF | | Complications Of Maternal Exposure To Therapeutic Drugs | Foreign Health Professional | Depromel 25 (Fluvoxamine Maleate) | PS | | |
| DAILY BF | | Condition Aggravated Drug Withdrawal Syndrome | Other | Meilax (Ethyl Loflazepate) | SS | | |
| | | Hypertonia Neonatal Maternal Drugs Affecting | | Anafranil (Clomipramine | | | |

| | | | | |
|-----------|--|---|----|------|
| DAILY BF | Foetus | Hydrochloride) | SS | |
| DAILY BF | Mental Disorder | Amoxan (Amoxapine) | SS | |
| SEE IMAGE | Somnolence Neonatal Tremor Neonatal | Impromen (Bromperidol) | SS | ORAL |
| DAILY BF | | Ritalin (Methylphenidate Hydrochloride) | SS | |

Date:09/17/02ISR Number: 3976805-8Report Type:Expedited (15-DaCompany Report #PHBS2002JP10841
Age:22 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--|-----------------------------------|--|--------|--------------|-------|
| Dose Duration Hospitalization - Initial or Prolonged | Dystonia Muscle Contractions Involuntary | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Unknown | PS | | ORAL |
| SEE IMAGE | Trismus | Other | Miradol (Sulpiride) Depas (Etizolam) | C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/18/02ISR Number: 3978783-4Report Type:Expedited (15-DaCompany Report #NSADSS2002031832
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Grand Mal Convulsion Loss Of Consciousness | Consumer | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 DAY(S), ORAL | | | | | | | |

Date:09/18/02ISR Number: 3978804-9Report Type:Expedited (15-DaCompany Report #CEL-2002-00263-ROC(0)
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|------------------------------------|---|------|--------------|-------|
| Life-Threatening Hospitalization - Initial or Prolonged Required | | Dialysis Nephrotic Syndrome Renal Failure Chronic | Consumer Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG (2DMG, Intervention to OD), PO; SEE Prevent Permanent IMAGE Impairment/Damage | | | | | | | |
| 20 MG (20 MG, QAM), PO | | | | | | | |
| | | | | Metadate Er Tablets 20mg (Methylphenidate Hydrochloride) | SS | | ORAL |
| | | | | Singulair | C | | |

Date:09/19/02ISR Number: 3978460-XReport Type:Expedited (15-DaCompany Report #A0379987A
Age:35 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|---------------|------|--------------|-------|
| Death | | Completed Suicide | Literature | Wellbutrin Sr | | | |

| | | | | | |
|------|--------------------|---------------------|---|----|------|
| ORAL | Intentional Misuse | Health Professional | Tablet-Controlled Release (Bupropion Hydrochloride) | PS | ORAL |
| | | | Venlafaxine Hydrochloride (Formulation Unknown) | | |
| | | | (Venlafaxine Methylphenidate (Formulation Unknown)) | SS | |
| | | | (Methylphenidate) | SS | |

Date:09/20/02ISR Number: 3978632-4Report Type:Direct Company Report #CTU 176901
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | Ritalin Hcl 5mg | | | |
| Other | | Drug Ineffective | | Novartis | PS | Novartis | ORAL |
| 5MG 1 1/2 PO | | Pharmaceutical Product | | | | | |
| Q AM AND NOON | | Complaint | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/23/02ISR Number: 3981279-7Report Type:Direct
Age:30 YR Gender:Female I/FU:I

Company Report #CTU 177036

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|--------------------------------------|----------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Pharmaceutical Product Complaint | | Adderall Ritalin Gen Dexadrine | PS SS SS | | |

Date:09/24/02ISR Number: 3981046-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE03133
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | Foreign Consumer Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

ORAL

Date:09/24/02ISR Number: 3981318-3Report Type:Expedited (15-DaCompany Report #PHNU2002DE03132
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged Other | | Electrocardiogram Abnormal Electrocardiogram Qt Corrected Interval | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

20MG/DAY,

ORAL

Prolonged
Hyperhidrosis
Loss Of Consciousness
Somnolence
Ventricular Extrasystoles

Date:09/24/02ISR Number: 3981839-3Report Type:Expedited (15-DaCompany Report #NSADSS2002030267
Age:9 YR Gender:Female I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------|----------|---------------------------|---------------|-------------------|------|--------------|-------|
| Death | | | Blood Glucose Increased | Health | Concerta (18 Mg | | | |
| Hospitalization - | | | Cardio-Respiratory Arrest | Professional | Sustained Release | | | |
| Initial or Prolonged | | | Cough | | Tablet) | | | |
| | | | Drug Level Increased | | (Methylphenidate | | | |
| | | | Influenza Like Illness | | Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | | |
| DAY(S), ORAL | | | | | | | | |

| | |
|-------------------------------|---|
| Ceftin (Cefuroxime Axetil) | C |
| Rocephin (Ceftriaxone Sodium) | C |
| Albuterol (Salbutamol) | C |

Date:09/25/02ISR Number: 3981379-1Report Type:Direct Company Report #CTU 177222
Age: Gender: I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| | | | Drug Ineffective | | Mallinckrodt | | | |
| | | | Pharmaceutical Product | | (Methylin 10 Mg | | | |
| | | | Complaint | | 9/25/02) | PS | | ORAL |
| 10MG PO BID | | | | | | | | |

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| | | | | |
|-------|-------|--------------|---------------------|----|
| Death | Death | Literature | Concerta (Sustained | |
| | | Health | Release Tablet) | |
| | | Professional | (Methylphenidate | |
| | | | Hydrochloride) | PS |
| | | | Bupropion | SS |

Date:09/27/02ISR Number: 3982891-1Report Type:Expedited (15-DaCompany Report #NSADSS2002032841
 Age:41 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|--------------------|---------------|---------------------|------|--------------|-------|
| Dose | Duration | | | | | |
| Death | Agitation | Literature | Concerta (Sustained | | | |
| Hospitalization - | Coma | Health | Release Tablet) | | | |
| Initial or Prolonged | Pulmonary Oedema | Professional | (Methylphenidate | | | |
| Required | Respiratory Arrest | | Hydrochloride) | PS | | |
| Intervention to | Somnolence | | Methadone | | | |
| Prevent Permanent | Stupor | | (Methadone) | SS | | |
| Impairment/Damage | | | Crack Cocaine | | | |
| | | | (Cocaine) | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/27/02ISR Number: 3984220-6Report Type:Expedited (15-DaCompany Report #PHNU2002DE03165
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------------------|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other ORAL | | Diabetes Mellitus | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | Other | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | SS | | ORAL |
| 40MG/DAY, ORAL | | | | | | | |

Date:09/27/02ISR Number: 3984262-0Report Type:Expedited (15-DaCompany Report #PHBS2002BR09348
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|--|--|--|------|--------------|-------|
| Other | | Growth Accelerated Hair Growth Abnormal Penis Disorder Precocious Puberty | Foreign Health Professional Other | Ritalin (Methylphenidate Hydrochloride) Unknown | PS | | ORAL |
| 10 MG/DAY, ORAL | | | | | | | |

Date:10/02/02ISR Number: 3986870-XReport Type:Expedited (15-DaCompany Report #NSADSS2002030267
Age:9 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|------------------------|---|------|--------------|-------|
| Death Hospitalization - Initial or Prolonged | | Acute Sinusitis Alanine Aminotransferase Increased Aspartate Aminotransferase Increased | Health Professional | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 DAY(S), ORAL | | | | | | | |

Blood Glucose Increased
 Cardio-Respiratory Arrest
 Influenza Like Illness
 Respiratory Disorder
 Vomiting

Ceftin (Cefuroxime
 Axetil) C
 Rocephin
 (Ceftriaxone Sodium) C
 Albuterol
 (Salbutamol) C
 Claritin
 (Loratadine) C
 Flovent (Fluticasone
 Propionate) C

Date:10/02/02ISR Number: 3986873-5Report Type:Expedited (15-DaCompany Report #NSADSS2002033023
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Dystonia | Health Professional Company Representative | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/03/02ISR Number: 3986336-7Report Type:Expedited (15-DaCompany Report #NSADSS2002031834
Age:6 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression Kidney Infection | Consumer | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 DAY (S), ORAL | | | | | | | |

Date:10/03/02ISR Number: 3988011-1Report Type:Expedited (15-DaCompany Report #PHNU2002DE01782
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Arrhythmia Blood Pressure Increased Bundle Branch Block Right | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride)Tablet | PS | | ORAL |
| Other | | Cardiac Murmur Electrocardiogram Abnormal Fatigue Heart Sounds Abnormal Pulmonary Hypertension Pulmonary Valve Incompetence Tricuspid Valve Incompetence Ventricular Hypertrophy | Other | | | | |
| ORAL | | | | | | | |

Date:10/03/02ISR Number: 3988013-5Report Type:Expedited (15-DaCompany Report #PHNU2002DE03133
Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Anorexia | Foreign Consumer Other | Ritaline(Methylpheni date Hydrochloride)Tablet | PS | | ORAL |
| 20 MG, BID, | | | | | | | |

ORAL

Date:10/04/02ISR Number: 3985759-XReport Type:Direct Company Report #CTU 177953
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|---------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Nausea Pharmaceutical Product Complaint Vomiting | | Ritalin | PS | | |

Date:10/04/02ISR Number: 3988233-XReport Type:Expedited (15-DaCompany Report #CEL-2002-01062-ROC (0)
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|------------------------|---|------|--------------|-------|
| Other | | Chest Pain Headache Hypertension Nausea | Health Professional | Metadate Er Tablets 20mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 40MG QAM, 20MG Q NOON, PO; 20MG QAM, 20MG Q NOON, PO | | Ventricular Extrasystoles Vomiting | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

0.2 MG (0.2
 MG, QHS),
 PO; . 0.5 MG
 (0.05 MG,QHS)
 PO

Clonidine
 (Clonidine) SS ORAL

Date:10/04/02ISR Number: 3988234-1Report Type:Expedited (15-DaCompany Report #CEL-2002-00571-ROC (1)
 Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Hallucination Medication Error Thrombocytopenic Purpura | Health Professional Company Representative | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG (20 MG, QAM), PO | | | | | | | |

Date:10/07/02ISR Number: 3984496-5Report Type:Expedited (15-DaCompany Report #WAES 0207SWE00008
 Age:76 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------|------------------------|--|-----------------------|------------------|--------------|
| Hospitalization - Initial or Prolonged | | Liver Disorder | Health Professional | Zocor Enalapril Maleate Methylphenidate Clindamycin Hydrochloride | PS SS SS SS | Merck & Co., Inc | ORAL ORAL |
| 36 DAY | | | | Bisacodyl Metformin Hydrochloride Furosemide Sodium Metoprolol Tartrate Aspirin Isosorbide | C C C C C | | |

Mononitrate

C

Date:10/07/02ISR Number: 3987398-3Report Type:Expedited (15-DaCompany Report #NSADSS2002034127
Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------------|---|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Caecitis | Health Professional | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 DAY(S), ORAL | | | Albuterol (Salbutamol) | C | | |

Date:10/07/02ISR Number: 3989871-0Report Type:Expedited (15-DaCompany Report #PHNU2002DE03005
Age:11 YR Gender:Male I/FU:F

| Outcome | PT |
|--|--|
| Hospitalization - Initial or Prolonged Other | Accident Angina Pectoris Blood Creatine Phosphokinase Increased Blood Creatine |

ORAL

Date:10/08/02ISR Number: 3989913-2Report Type:Expedited (15-DaCompany Report #CEL-2002-01111-ROC(0)

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chronic Hepatitis | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | |

Date:10/10/02ISR Number: 3991867-XReport Type:Expedited (15-DaCompany Report #NSADSS2002034861

Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Crying Depression Suicidal Ideation | Consumer | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

36 MG, 1 IN 1

DAY(S), ORAL

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/15/02ISR Number: 3993728-9Report Type:Expedited (15-DaCompany Report #PHEH2002US06619
 Age:20 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Lupus-Like Syndrome Polycythaemia Rheumatoid Arthritis | Consumer | Ritalin (Methylphenidate Hydrochloride) Tablet, 10 Mg | PS | | ORAL |
| 10 MG, BID, ORAL | | | | Minocin (Minocycline) | C | | |

Date:10/15/02ISR Number: 3994024-6Report Type:Direct Company Report #CTU 178615
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|---|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | | Concerta | PS | | ORAL |
| 18 MG PO | | | | Dexedrine | SS | | |
| 10 MG PO DEXEDRINE | | Drug Ineffective Educational Problem Fear Heart Rate Increased Panic Reaction | | | | | |

Date:10/15/02ISR Number: 3994093-3Report Type:Direct Company Report #CTU 178664
 Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|----------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased Pharmaceutical Product | | Generic Methylphenidate | PS | | ORAL |
| 10 PO TID | 2 MON | Complaint | | | | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|--|------|--------------|-------|
| Dose Other | | Depression Excitability Mood Swings | | Generic Ritalin (10mg) (Methylphenidate) | PS | | |
| RITALIN 15 MG | | Pharmaceutical Product | | | | | |
| BID (0) | | Complaint | | | | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|-------------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Dystonia Hyperhidrosis Medication Error | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| 30 MG/D; | | Muscle Contractions | Other | | | | |
| ORAL, SEE IMAGE | | Involuntary Tetanus Trismus | | Miradol (Sulpiride) Depas (Etizolam) | C C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/16/02ISR Number: 3993182-7Report Type:Expedited (15-DaCompany Report #A0381652A
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|------------------------|---|------------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety Hallucination, Auditory Insomnia Medication Error Psychotic Disorder | Literature Consumer | Paxil (Formulation Unknown) (Paroxetine Hydrochloride) Dexedrine (Formulation Unknown) (Dextroamphetamine Sulfate) | PS SS | | |
| ORAL | | | | Methylphenidate Hcl (Formulation Unknown) (Methylphenidate Hcl) | SS | | ORAL |
| ORAL | | | | | | | |

Date:10/16/02ISR Number: 3994948-XReport Type:Expedited (15-DaCompany Report #PHNU2002DE03393
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blindness | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | | | | |

Date:10/16/02ISR Number: 3994952-1Report Type:Expedited (15-DaCompany Report #PHBS2002NO12114
 Age:25 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------|------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Psychotic Disorder | Foreign Consumer Other | Ritaline (Methylphenidate Hydrochloride) Unknown | PS | | ORAL |
| ORAL | | | | Topimax (Topiramate) | C | | |

Date:10/17/02ISR Number: 3993793-9Report Type:Direct
 Age:65 YR Gender:Female I/FU:I

Company Report #CTU 178896

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---------------|----------------------|------|-------------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - | Asthenia | | D-Threo-Methylphenid | | | |
| Initial or Prolonged | Pain | | ate Hcl Celgene / | | | |
| | | | Biologics | PS | Celgene/Biologics | |
| 5 MG BID | | | Megace | C | | |
| | | | Decadron | C | | |
| | | | Arimidex | C | | |

Date:10/17/02ISR Number: 3997352-3Report Type:Expedited (15-DaCompany Report #HQ4590910OCT2002
 Age: Gender:Unknown I/FU:I

| Outcome | PT |
|---------|---|
| Other | Drug Exposure Via Breast Milk Drug Withdrawal Syndrome Neonatal Hypertonia Neonatal |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Maternal Drugs Affecting Foetus Somnolence Neonatal Tremor Neonatal | Report Source | Product | Role | Manufacturer | Route |
|----------------|----------|--|------------------------|---|------|--------------|-------|
| TRANSPLACENTAL | DAILY, | | Health Professional | Amoxan (Amoxapine, Capsule) | PS | | |
| TRANSPLACENTAL | DAILY, | | | Anafranil (Clomipramine Hydrochloride,) | SS | | |
| TRANSPLACENTAL | DAILY, | | | Amoxan (Amoxapine, Capsule) | SS | | |
| TRANSPLACENTAL | DAILY, | | | Anafranil (Clomipramine Hydrochloride,) | SS | | |
| TRANSPLACENTAL | DAILY, | | | Fluvoxamine Maleate (Fluvoxamine Maleate,) | SS | | |

UNTIL

DELIVERY

Fluvoxamine Maleate
(Fluvoxamine
Maleate,) SS

TRANSMAMMARY DAILY,

TRANSMAMMARY

Impromen
(Bromperidol,) SS

TRANSPLACENTAL DAILY,

TRANSPLACENTA

L; GESTATION

UNTIL

DELIVERY

Impromen
(Bromperidol,) SS

TRANSMAMMARY DAILY,

TRANSMAMMARY

Meilax (Ethyl
Loflazepate,) SS

TRANSPLACENTAL DAILY,

TRANSPLACENTA

L; GESTATION

UNTIL

DELIVERY

Meilax (Ethyl
Loflazepate,) SS

TRANSMAMMARY DAILY,

TRANSMAMMARY

Ritalin
(Methylphenidate
Hydrochloride,) SS

TRANSPLACENTAL DAILY,

TRANSPLACENTA

L; GESTATION

UNTIL

DELIVERY

Ritalin
(Methylphenidate)

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hydrochloride,) SS

TRANSMAMMARY DAILY,

TRANSMAMMARY

Date:10/18/02ISR Number: 3995635-4Report Type:Expedited (15-DaCompany Report #C2002-2994.01
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | Health | Metadate Er Tablets | | | |
| SEE IMAGE | | Headache | Professional | 20mg Celltech | PS | | ORAL |
| | | Heart Rate Irregular | Other | Clonidine | | | |
| | | Hypertension | | Hydrochloride | | | |
| SEE IMAGE | | Ventricular Extrasystoles | | Tablets 0.2 Mg Mylan | SS | | ORAL |
| | | Vomiting | | | | | |

Date:10/18/02ISR Number: 3996781-1Report Type:Expedited (15-DaCompany Report #PHBS2002CH12291
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | Foreign | Ritaline(Methylpheni | | | |
| 5 TO 10 | | Agitation | Health | date Hydrochloride) | PS | | |
| MG/DAY | | Confusional State | Professional | | | | |
| | | Screaming | Other | | | | |

Date:10/18/02ISR Number: 3998156-8Report Type:Expedited (15-DaCompany Report #PHEH2002US08968
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Dyskinesia | Other | Ritalin La | | | |
| Initial or Prolonged | | Hallucination | | (Methylphenidate | | | |
| | | Movement Disorder | | Hydrochloride) | | | |
| | | Muscle Contractions | | Extended Release | | | |
| 20 MG, | | Involuntary | | Capsules | PS | | ORAL |

Pain In Extremity

ONCE/SINGLE,

Tic

ORAL

Claritin
(Loratadine) C
Antibiotics C

Date:10/21/02ISR Number: 3998546-3Report Type:Expedited (15-DaCompany Report #NSADSS2002033025

Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Duodenal Ulcer | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

SEE IMAGE

Date:10/22/02ISR Number: 3996066-3Report Type:Direct Company Report #CTU 179178

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------|------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| 15MG BID PO | | Drug Effect Decreased Pharmaceutical Product Complaint | | Ritalin - Methylphenidate | PS | | ORAL |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/22/02ISR Number: 3997497-8Report Type:Expedited (15-DaCompany Report #NSADSS2002033565
Age:48 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|---------------|---------------------|---------------|----------|------|--------------|-------|
| Other | 36 MG, 1 IN 1 | Open Angle Glaucoma | Consumer | Concerta | PS | | ORAL |
| DAY(S), ORAL | | | | | | | |

| | |
|--|---|
| Amoxicillin (Amoxicillin) | C |
| Acidophyllus | C |
| Carafate (Sucralfate) | C |
| Tamoxifen(Tamoxifen) | C |
| Prilosec(Omeprazole) | C |
| Xanax (Alprazolam) | C |
| Flexeril (Cyclobenzaprine Hydrochloride) | C |
| Celexa (Citalopram Hydrobromide) | C |
| Ambien (Zolpidem Tartrate) | C |
| Multi -Vits | C |

Date:10/22/02ISR Number: 3997498-XReport Type:Expedited (15-DaCompany Report #NSADSS2002037454
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--------------------------------------|--|---------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | SEE IMAGE, 1 IN 1 DAY(S), ORAL | Abdominal Pain Chromaturia Decreased Appetite Haematochezia Vomiting Weight Decreased | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| Depakote(Valproate Semisodium) | | | | | | | |
| C | | | | | | | |

| | |
|-----------------------------------|---|
| Depakote(Valproate Semisodium) | C |
|-----------------------------------|---|

Date:10/22/02ISR Number: 3997822-8Report Type:Expedited (15-DaCompany Report #NSADSS2002032842
Age:42 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|------------------|---------------|----------------------|------|--------------|-------|
| Death | | Coma | Literature | Concerta (Sustained | | | |
| Required | | Convulsion | Health | Release Tablet) | | | |
| Intervention to | | Drug Ineffective | Professional | (Methylphenidate | | | |
| Prevent Permanent | | | | Hydrochloride) | PS | | |
| Impairment/Damage | | | | Bupropion Sr | | | |
| | | | | (Amfebutamone) | C | | |
| | | | | Chlordiazepoxide/Cli | | | |
| | | | | dinium (Nirvaxal) | C | | |
| | | | | Singulair | | | |
| | | | | (Montelukast Sodium) | C | | |
| | | | | Levothyroxine Sodium | | | |
| | | | | (Levothyroxine) | C | | |

Date:10/22/02ISR Number: 3997826-5Report Type:Expedited (15-DaCompany Report #NSADSS2002032843
Age:42 YR Gender:Male I/FU:F

Outcome
Death
Hospitalization -

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Initial or Prolonged Required Intervention to Prevent Permanent Dose Duration Impairment/Damage | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---|--------------------------------------|--|------|--------------|-------|
| ORAL | Brain Herniation Brain Oedema Cardiomegaly Cerebral Artery Occlusion | Literature Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| | Coma Completed Suicide Cyanosis Hepatosplenomegaly Loss Of Consciousness Moaning Pulmonary Congestion Renal Failure Respiratory Failure Retroperitoneal Haemorrhage Shock Ventricular Hypertrophy | | Bupropion (Amfebutamone) | SS | | |

Date:10/22/02ISR Number: 3998212-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE03132
Age:16 YR Gender:Male I/FU:F

| Outcome Dose Duration Hospitalization - Initial or Prolonged Other | PT | Report Source | Product | Role | Manufacturer | Route |
|--|---|--|---|------|--------------|-------|
| 20 MG/DAY, ORAL | Electrocardiogram Pq Interval Prolonged Hyperhidrosis Loss Of Consciousness Somnolence Ventricular Extrasystoles | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

Date:10/23/02ISR Number: 3999526-4Report Type:Expedited (15-DaCompany Report #PHEH2002US09000
Age:13 YR Gender:Female I/FU:I

| Outcome Dose Duration Other | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|-------------|---------------|---------|------|--------------|-------|
| | Nerve Block | Consumer | Focalin | | | |

Neuropathy Peripheral
Peroneal Nerve Palsy

(Dexamethylphenidate
Hydrochloride)
Tablet PS
Ritalin (La
(Methylphenidate
Hydrochloride)
Extended Release
Capsules SS

Date:10/23/02ISR Number: 3999617-8Report Type:Expedited (15-DaCompany Report #A0383130A
Age:42 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--------------------------------------|--|------|--------------|-------|
| Death | | Completed Suicide Intentional Misuse | Literature Health Professional | Wellbutrin Unspecified Tablet (Bupropion Hydrochloride) | PS | | ORAL |
| ORAL | | | | Methylphenidate (Formulation Unknown) (Methylphenidate) | SS | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/23/02ISR Number: 3999628-2Report Type:Expedited (15-DaCompany Report #A0383131A
 Age:42 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--------------------------------------|--|------|--------------|-------|
| Death | | Completed Suicide Intentional Misuse | Literature Health Professional | Wellbutrin Unspecified Tablet (Bupropion Hydrochloride) | PS | | ORAL |
| ORAL | | | | Methylphenidate (Formulation Unknown) (Methylphenidate) | SS | | |

Date:10/24/02ISR Number: 3996270-4Report Type:Direct Company Report #
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|--|------|--------------|-------|
| Dose | | Medication Error | | Metadate Cd (Methylphenidate Hcl, Usp) Extended-Release Capsules | PS | | |

Date:10/24/02ISR Number: 3997493-0Report Type:Direct Company Report #CTU 179404
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|--|------|--------------|-------|
| Dose | | Drug Effect Decreased Pharmaceutical Product Complaint | | Ritalin - Methylphenidate (Watson) | PS | Watson | ORAL |
| 15 MG BID PO | | | | | | | |

Date:10/24/02ISR Number: 4000753-0Report Type:Expedited (15-DaCompany Report #CEL-2002-01172-ROC(0)
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | |
|-----------|--------------------|--------------|------------------|----|
| Other | Anorexia | Foreign | Methylphenidate | |
| | Growth Retardation | Literature | Tablets | |
| | | Health | (Unspecified) | |
| | | Professional | (Methylphenidate | |
| | | | Hydrochloride | PS |
| SEE IMAGE | | | Fluticasone | |
| | | | (Fluticasone) | C |

Date:10/28/02ISR Number: 4001345-XReport Type:Expedited (15-DaCompany Report #NSADSS2002037679
 Age:32 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Coordination Abnormal | Health | Concerta | | | |
| | | Cyanosis | Professional | (Methylphenidate | | | |
| | | Oedema Peripheral | | Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 | | Sensory Loss | | | | | |
| DAY(S), ORAL | | Tremor | | Remeron | | | |
| | | | | (Mirtazapine) | SS | | |
| | | | | Effexor (Venlafaxine | | | |
| | | | | Hydrochloride) | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/29/02ISR Number: 4001638-6Report Type:Expedited (15-DaCompany Report #PHFR2002GB03393
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pallor Pancytopenia Weight Gain Poor | Foreign Health Professional Other | Methylphenidate (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 30 MG/DAY, ORAL | | | | | | | |

Date:10/29/02ISR Number: 4001702-1Report Type:Expedited (15-DaCompany Report #PHEH2002US09182
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Completed Suicide | Health Professional | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | PS | | |
| 30 MG, QD, | | | | | | | |

Date:10/29/02ISR Number: 4003196-9Report Type:Expedited (15-DaCompany Report #PHEH2002US09315
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---|---|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Coronary Artery Disease | Health Professional Company Representative | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | |

Date:10/29/02ISR Number: 4003458-5Report Type:Expedited (15-DaCompany Report #PHNU2002DE03483
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------------------|-------------------|--------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Crohn'S Disease Gastrointestinal | Foreign Health | Ritalin-Sr (Methylphenidate | | | |

| | | | | | |
|------|-------------|-----------------------|--|----|------|
| ORAL | Haemorrhage | Professional Other | Hydrochloride) Slow Release Tablet | PS | ORAL |
| | | | Ritaline (Methylphenidate Hydrochloride) Tablet | C | |

Date:10/30/02ISR Number: 4002281-5Report Type:Direct Company Report #CTU 179980
 Age:65 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|---------------|--|------|-------------------|-------|
| Death | | Malignant Neoplasm Progression Metastases To Central Nervous System | | D-Threo-Methylphenid ate Hcl Celgene / Biologics | PS | Celgene/Biologics | ORAL |
| 5MG BID PO | | | | Megace | C | | |
| | | | | Decadron | C | | |
| | | | | Toradal | C | | |
| | | | | Humalin 70/30 | C | | |
| | | | | Lortab | C | | |
| | | | | Arimidex | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/30/02ISR Number: 4004494-5Report Type:Expedited (15-DaCompany Report #NSADSS2002038373
Age:5 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------|---|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Psychotic Disorder | Health Professional Company Representative | Concerta (27 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 27 MG, 1 IN 1 | | | | | | | |
| DAY(S), ORAL | | | | | | | |
| | | | | Zoloft (Sertraline Hydrochloride) | SS | | ORAL |
| 25 MG, ORAL | | | | | | | |

Date:10/30/02ISR Number: 4004497-0Report Type:Expedited (15-DaCompany Report #NSADSS2002038321
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------------------|---------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hepatic Cirrhosis Joint Swelling | Consumer | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG , 1 IN | | | | | | | |
| 1 DAY(S) ORAL | | | | | | | |

Date:10/31/02ISR Number: 4004157-6Report Type:Expedited (15-DaCompany Report #PHEH2002US09142
Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---|------------------------|---|------|--------------|-------|
| Other | | Abdominal Pain Upper Dilatation Ventricular Gilbert'S Syndrome Oesophageal Disorder Syncope | Health Professional | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, TID, ORAL | | | | | | | |

Date:11/01/02ISR Number: 4005266-8Report Type:Expedited (15-DaCompany Report #NSADSS2002038971
Age:12 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---|---------------|---|------------------------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent 18 MG, 1 IN 1 Impairment/Damage DAY(S), ORAL | Drug Interaction Fall Formication Gait Disturbance Hallucination Movement Disorder Pelvic Pain Self Mutilation Tic Tourette'S Disorder | Consumer | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) Risperdal (Risperidone) Clonidine (Clonidine) | PS SS SS | | ORAL |

Date:11/01/02ISR Number: 4005285-1Report Type:Expedited (15-DaCompany Report #NSADSS2002038993
Age:15 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--------------|------------------------|---|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged 36 MG, 1 IN 1 | Pancreatitis | Health Professional | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

DAY(S), ORAL 18 MON

Date:11/04/02ISR Number: 4003448-2Report Type:Direct Company Report #CTU 180282
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin | PS | | ORAL |
| ORAL | | Pharmaceutical Product Complaint | | | | | |

Date:11/04/02ISR Number: 4003509-8Report Type:Direct Company Report #CTU 180264
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression | | Cylert | PS | | |
| | | Suicidal Ideation | | Ritalin | SS | | |

Date:11/04/02ISR Number: 4003673-0Report Type:Direct Company Report #CTU 180304
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| | | Medication Error | | Metadate Cd (Methylphenidate Hcl, Usp) Extended-Release Capsules 20mg | PS | | |
| 20 MG | | | | Metadate Er 20mg | SS | | |

Date:11/04/02ISR Number: 4003677-8Report Type:Direct Company Report #CTU 180301
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Metadate Cd | | | |

20MG

(Methylphenidate
Hcl,Usp)
Extended-Release
Capsules 20mg PS
Metadate Er 10mg SS

Date:11/04/02ISR Number: 4003680-8Report Type:Direct
Age: Gender: I/FU:I

Company Report #CTU 180302

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Metadate Cd | PS | | |
| 20 MG | | | | Metadate Er | SS | | |

Date:11/04/02ISR Number: 4003682-1Report Type:Direct
Age: Gender: I/FU:I

Company Report #CTU 180303

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Metadate Er Tablets (Methylphenidate Hydrochloride Extended-Release Tablets, Usp) 20 Mg | PS | | |
| 20MG | | | | Metadate Tid 20 | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/04/02ISR Number: 4006027-6Report Type:Expedited (15-DaCompany Report #NSADSS2002038539
Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|---|------|--------------|-------|
| Dose Other | | Abnormal Behaviour Learning Disorder Sleep Disorder | Consumer | Concerta (54 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54 MG, 1 IN 1 | | | | | | | |
| DAY(S), ORAL; | | | | | | | |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY(S, ORAL | | | | | | | |

Seroquel (Seroquel) C
Ddavn (Desmopressin) C
Clonidine
(Clonidine) C

Date:11/04/02ISR Number: 4006032-XReport Type:Expedited (15-DaCompany Report #NSADSS2002038804
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Psychotic Disorder | Health Professional Company Representative | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | | | | |

Date:11/04/02ISR Number: 4006036-7Report Type:Expedited (15-DaCompany Report #NSADSS2002038977
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Psychotic Disorder | Health Professional Company Representative | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | | | | |

Date:11/04/02ISR Number: 4006041-0Report Type:Expedited (15-DaCompany Report #NSADSS2002038971
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Required | | Drug Interaction Fall Formication | Consumer | Risperdal (Risperidone) | PS | | ORAL |
| Intervention to Prevent Permanent Impairment/Damage 18 MG, 1 IN 1 DAY(S), ORAL | | Gait Disturbance Hallucination Intentional Self-Injury Paralysis | | Concerta (18 Mg Sustained Release Tablet)(Methylphenid ate Hydrochloride) | SS | | ORAL |
| | | Pelvic Pain Tourette'S Disorder | | Clonidine (Clonidine) | SS | | |

Date:11/05/02ISR Number: 4004000-5Report Type:Direct Company Report #CTU 180356
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|--|----------|--------------|-------|
| Other ORAL | | Abnormal Behaviour | | Ritalin Generic | PS | | ORAL |
| | | Educational Problem Pharmaceutical Product Complaint | | Methylphenidate 10mg Apothecon Methylphenidate 20mg Generic | SS SS | Apothecon | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/05/02ISR Number: 4006198-1Report Type:Expedited (15-DaCompany Report #CEL-2002-01236-ROC(0)
Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Pyrexia | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | |
| UNKNOWN | | | | | | | |

Date:11/05/02ISR Number: 4006938-1Report Type:Expedited (15-DaCompany Report #PHNU2002DE03165
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Diabetes Mellitus Non-Insulin-Dependent | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, BID, ORAL | | | | | | | |
| 10 MG, QD, ORAL | | | | | | | |
| | | | | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | SS | | ORAL |

Date:11/06/02ISR Number: 4007848-6Report Type:Expedited (15-DaCompany Report #NSADSS2002037724
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|------------------------|--|------|--------------|-------|
| Other | | Idiopathic Thrombocytopenic Purpura | Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | | | | |

Date:11/06/02ISR Number: 4008530-1Report Type:Expedited (15-DaCompany Report #PHBS2002NZ12666
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------|------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Drug Abuser | Foreign Consumer Other | Ritaline (Methylphenidate Hydrochloride) | PS | | |

Date:11/07/02ISR Number: 4005531-4Report Type:Direct Company Report #CTU 180526
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------|--------------------------------------|------|--------------|-------|
| Death | | Completed Suicide Injury Asphyxiation | | Methylphenidate 10mg Tab At Lunch | PS | | |
| 10 | | | | Methylphenidate 20 Mg Er Morning | SS | | |
| 20 MG ER/QD | | | | | | | |

Date:11/07/02ISR Number: 4005809-4Report Type:Direct Company Report #CTU 180569
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|---------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased Pharmaceutical Product | | Methylphenydate Concerta Alza Corp | PS | Alza Corp | |
| BUCCAL | 54 MG | 1/DAY | | | | | |
| BUCCAL | | Complaint | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/07/02ISR Number: 4007593-7Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 180580

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------------|---------------|--------------|------|--------------|-------|
| Dose Required 1 1/2 TB Q Intervention to Prevent Permanent Impairment/Damage | | Drug Effect Decreased | | Ritalin 5 Mg | PS | | |
| | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |

Date:11/07/02ISR Number: 4009219-5Report Type:Expedited (15-DaCompany Report #CEL-2002-01227-ROC (0)
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|--------------------------------------|---|------------------|--------------|-------|
| Death | | Medication Error | Literature Health Professional | Methylphenidate Tablets (Unspecified) (Methylphenidate Hydrochloride) Methadone (Methadone) | PS SS | | |

Date:11/07/02ISR Number: 4009221-3Report Type:Expedited (15-DaCompany Report #CEL-2002-01240-ROC (0)
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Anger Crying Feeling Abnormal | Consumer | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | Hyperhidrosis | | Prozac (Fluoxetine Hydrochloride) | C | | |

Date:11/07/02ISR Number: 4009295-XReport Type:Expedited (15-DaCompany Report #PHEH2002US09394
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Memory Impairment | Consumer | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | |
| 2555 DAY | | | | | | | |

Date:11/07/02ISR Number: 4009322-XReport Type:Expedited (15-DaCompany Report #NSADSS2002039317
 Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Petit Mal Epilepsy | Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | | | | |

Date:11/08/02ISR Number: 4009760-5Report Type:Expedited (15-DaCompany Report #PHEH2002US09518
 Age:13 YR Gender:Male I/FU:I

| | |
|---------|--|
| Outcome | PT |
| Other | Diabetes Mellitus Non-Insulin-Dependent Increased Appetite |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | |
|--------------------|----------|------------------------------------|------------------------|---|------|--------------|
| | | Renal Disorder Weight Increased | | | | |
| Dose | Duration | | Report Source | Product | Role | Manufacturer |
| | | | Health Professional | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | |
| 20 MG, QD, ORAL | | | | | | ORAL |

Date:11/08/02ISR Number: 4010140-7Report Type:Expedited (15-DaCompany Report #PHNU2002DE03018
Age:18 YR Gender:Male I/FU:F

| | | | | | | | |
|-------------------|----------|-------------------|--|---|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Diabetes Mellitus | Foreign Health Professional Other | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | PS | | ORAL |
| 20MG/DAY, ORAL | | | | | | | |
| | | | | Medikinet (Methylphenidate Hydrochloride) | SS | | ORAL |
| 10MG/DAY, ORAL | | | | | | | |

Date:11/12/02ISR Number: 4011629-7Report Type:Expedited (15-DaCompany Report #NSADSS2002039773
Age:6 YR Gender:Male I/FU:I

| | | | | | | | |
|---------------|----------|--|---------------|---|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Anorexia Crying Emotional Disorder Insomnia Weight Decreased | Consumer | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |

DAILY, ORAL

Date:11/13/02ISR Number: 4012101-0Report Type:Expedited (15-DaCompany Report #NSADSS2002039317
Age:19 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated Feeling Abnormal Generalised Non-Convulsive Epilepsy | Health Professional | Concerta(Sustained Release Tablet)(Methylphenid ate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | Zoloft (Sertraline Hydrochloride) | C | | |

Date:11/15/02ISR Number: 4011265-2Report Type:Direct Company Report #CTU 181003
Age:10.5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Generic Ritalin | PS | | |
| 5MG BID BRAND | | Pharmaceutical Product | | | | | |
| NAME | | Complaint | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/15/02ISR Number: 4014029-9Report Type:Expedited (15-DaCompany Report #PHBS2002US13526
Age:41 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------|----------------------|------|--------------|-------|
| Death | | Acute Respiratory | Literature | Methylphenidate | | | |
| Hospitalization - | | Distress Syndrome | Health | (Methylphenidate | | | |
| Initial or Prolonged | | Agitation | Professional | Hydrochloride)Unknow | | | |
| | | Coma | | n | PS | | |
| | | Pulmonary Oedema | | Methadone | | | |
| | | Respiratory Disorder | | (Methadone) | SS | | |
| | | Snoring | | Cocaine(Cocaine) | SS | | |
| | | Somnolence | | | | | |
| | | Stupor | | | | | |

Date:11/15/02ISR Number: 4014069-XReport Type:Expedited (15-DaCompany Report #PHBS2002CA13562
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------|---------------|----------------------|------|--------------|-------|
| Other | | Syncope | Foreign | Ritaline(Methylpheni | | | |
| | | | Health | date Hydrochloride) | | | |
| | | | Professional | Tablet | PS | | ORAL |
| 20 MG/DAY, | | | | | | | |
| ORAL | | | | | | | |

Date:11/15/02ISR Number: 4014249-3Report Type:Expedited (15-DaCompany Report #PHNU2002DE03067
Age:6 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------------|---------------|----------------------|------|--------------|-------|
| Other | | Activated Partial | Foreign | Ritalin | | | |
| | | Thromboplastin Time | Health | (Methylphenidate | | | |
| | | Prolonged | Professional | Hydrochloride) | | | |
| | | Coagulation Factor Ix | Other | Tablet, 10 Mg | PS | | ORAL |
| 5 MG, BID, | | Level Decreased | | | | | |
| ORAL | | Coagulation Factor Viii | | Goldgeist (Pyrethrum | | | |
| | | Level Decreased | | Extract, Piperonyl | | | |
| | | Haematoma | | Butoxide, Diethylene | | | |
| | | Haemoglobin Decreased | | Glycol, | | | |

International Normalised
Ratio Decreased
Platelet Count Increased
Streptococcal Serology
Positive
Weight Decreased

Chlorocresol) C
Infectopedicul
(Permethrin)
Solution C

Date:11/18/02ISR Number: 4011305-0Report Type:Direct
Age:4.5 YR Gender:Female I/FU:I

Company Report #CTU 181079

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin Generic | PS | | |
| 5MG TABS PO | 1 MON | Pharmaceutical Product Complaint | | | | | |

Date:11/18/02ISR Number: 4013164-9Report Type:Expedited (15-DaCompany Report #NSADSS2002041230
Age:14 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hepatitis Migraine | Consumer | Concerta (18 Mg Sustained Release Tablet) | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

18 MG, 1 IN 1
 DAY(S), ORAL

(Methylphenidate Hydrochloride) PS ORAL

Acetaminophen/Codeine
 (Acetaminophen/Codeine)
 Sudafed
 (Pseudoephedrine Hydrochloride) C C

Date:11/18/02ISR Number: 4014524-2Report Type:Expedited (15-DaCompany Report #PHNU2002DE03706
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-----------------------------|--|---|------|--------------|-------|
| Dose Other | | Dyskinesia Hypoglycaemia | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 25 MG/DAY, ORAL | | | | | | | |

Date:11/19/02ISR Number: 4011732-1Report Type:Direct Company Report #CTU 181184
 Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|------------------|---------------|-----------------------|------|--------------|-------|
| Dose Other ONCE DAILY PO | | Drug Ineffective | | Metadate Cd 20 Mg | PS | | ORAL |
| TWICE DAILY PO | | Dyspepsia | | Methyplenicidate 5 Mg | SS | | ORAL |

Date:11/19/02ISR Number: 4012816-4Report Type:Direct Company Report #CTU 181278
 Age:4.5 YR Gender:Female I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|------|----------|-------------------------------------|---------------|---|------|--------------|-------|
| | | | Pharmaceutical Product Complaint | | Methalphenadate 5 Mg Tabs. = Major Pharmaceutical 009042768-80 | PS | | ORAL |
| 1/2 TAB PO | | | | | | | | |
| QAM AT 1200 + | | | | | | | | |
| 1600 | | 1 | MON | | | | | |

Date:11/20/02ISR Number: 4012678-5Report Type:Direct Company Report #CTU 181399
Age: Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------|----------|---|---------------|----------------------|------|--------------|-------|
| | | | Blood Pressure Increased Headache Pharmaceutical Product Complaint | | Generic Ritalin 5 Mg | PS | | |

Date:11/20/02ISR Number: 4015262-2Report Type:Expedited (15-DaCompany Report #PHNU2002DE03748
Age:12 YR Gender:Male I/FU:I

| Outcome | Other | PT |
|---------|---|----|
| | Activated Partial Thromboplastin Time Prolonged Autoimmune Thyroiditis | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|---------------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Dose | Duration | Blood Creatinine Increased Blood Urea Increased Weight Increased | Report Source | Product | Role | Manufacturer | Route |
| 10 MG, BID, ORAL | | | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

Date:11/20/02ISR Number: 4015472-4Report Type:Expedited (15-DaCompany Report #PHBS2002CA13834
Age: Gender:Male I/FU:I

| | | | | | | | |
|---------------|----------|--------------------|------------------------|--|----------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose Other | | Psychotic Disorder | Foreign Consumer Other | Ritaline (Methylphenidate Hydrochloride) Tablet Ritalin-Sr (Methylphenidate Hydrochloride) Tablet | PS SS | | |

Date:11/20/02ISR Number: 4015682-6Report Type:Expedited (15-DaCompany Report #PHBS2002JP13750
Age:19 YR Gender:Female I/FU:I

| | | | | | | | |
|----------------------------------|----------|---|-----------------------------------|--|----------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose Life-Threatening ORAL | | Cardiac Arrest Hyperpyrexia Loss Of Consciousness Overdose | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet Unknown Anafranil (Clomipramine Hydrochloride) Tablet | PS SS | | ORAL |

Date:11/21/02ISR Number: 4016888-2Report Type:Expedited (15-DaCompany Report #2002-101654-NL
Age:32 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|------------------------|---------------------|----------|--------------|-------|
| Dose | | | | | | | |
| Other | | Coordination Abnormal Cyanosis | Health Professional | Remeron Concerta | PS SS | | ORAL |
| 36 MG DAILY | | Faecal Incontinence | | | | | |
| ORAL | | Oedema Peripheral Sensory Loss Tremor Urinary Incontinence | | Effexor | SS | | |

Date:11/22/02ISR Number: 4014506-0Report Type:Direct Company Report #CTU 181577
Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------------------|---------------|------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Dyspepsia | | Metadate Cd 20mg Celltech | PS | Celltech | ORAL |
| ONCE DAILY PO | | Pharmaceutical Product Complaint | | Methyphenidate 5mg Geneva | SS | Geneva | ORAL |
| TWICE DAILY | | | | | | | |
| PO | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/25/02ISR Number: 4017279-0Report Type:Expedited (15-DaCompany Report #CEL-2002-01391-ROC(0)
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|----------------------|---|---|------|--------------|-------|
| Dose Other | | Grand Mal Convulsion | Foreign Literature Health Professional | Methylphenidate Tablets (Unspecified) (Methylphenidate Hydrochloride) | PS | | |
| 60 MG (UNK, DAILY) | | | | Bupropion (Bupropion) | SS | | |
| SEE IMAGE | 4 WK | | | | | | |

Date:11/25/02ISR Number: 4017426-0Report Type:Expedited (15-DaCompany Report #MK200211-0156-1
 Age:19 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|---|---------------|-----------|------|--------------|-------|
| Hospitalization - ONE TIME | | Cardiac Arrest | Foreign | Anafranil | PS | | |
| Initial or Prolonged | | Hyperpyrexia Loss Of Consciousness Overdose | | Ritalin | SS | | |

Date:11/26/02ISR Number: 4015461-XReport Type:Direct Company Report #CTU 181674
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|------------|------|--------------|-------|
| Required 20MG PO QAM | | Anorexia | | Ritalin Er | PS | | ORAL |
| Intervention to Prevent Permanent Impairment/Damage | | Attention Deficit/Hyperactivity Disorder Condition Aggravated | | | | | |

Date:11/26/02ISR Number: 4017452-1Report Type:Expedited (15-DaCompany Report #PHNU2002DE03759
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Thyroid Stimulating Hormone Increased Thyroxine Normal Tri-Iodothyronine Normal | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | | | | |

Date:11/26/02ISR Number: 4017889-0Report Type:Expedited (15-DaCompany Report #PHFR2002GB03612
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged Disability | | Drug Interaction Erectile Dysfunction Priapism | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 30 MG/DAY, | | | | | | | |
| ORAL | | | | | | | |
| | | | | Risperidone (Risperidone) | SS | | ORAL |
| ONCE/SINGLE, | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/26/02ISR Number: 4017891-9Report Type:Expedited (15-DaCompany Report #PHFR2002GB03782
Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Systemic Lupus Erythematosus | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Unknown | | | |
| | | | | | PS | | |

Date:11/26/02ISR Number: 4017924-XReport Type:Expedited (15-DaCompany Report #PHBS2002CA13562
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blindness Orthostatic Hypotension Syncope | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | | | |
| 20 MG/DAY, ORAL | | Visual Disturbance | Other | | PS | | ORAL |

Date:11/26/02ISR Number: 4018147-0Report Type:Expedited (15-DaCompany Report #HQ5434520NOV2002
Age:50 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Confusional State Feeling Abnormal Memory Impairment Road Traffic Accident | Health Professional | Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release) | | | |
| 600 MG 1X PER 2 DAY, ORAL | | | | | PS | | ORAL |
| "TWICE DAILY" | | | | Allegra-D (Fexofenadine Hydrochloride/Pseudo ephedrine Hydrochloride,) | SS | | |
| | | | | Ambien (Zolpidem | | | |

10 MG 1X PER

Tartrate,)

SS

ORAL

1 DAY, ORAL

Ritalin
(Methylphenidate
Hydrochloride,)

SS

ORAL

20 MG DAILY,

INTERMITTENTL

Y, ORAL

Date:11/26/02ISR Number: 4018172-XReport Type:Expedited (15-DaCompany Report #PHBS2002US13526
Age:41 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------|-------------------|------|--------------|-------|
| Death | | Acute Respiratory | Literature | Methylphenidate | | | |
| Hospitalization - | | Distress Syndrome | Health | (Methylphenidate | | | |
| Initial or Prolonged | | Agitation | Professional | Hydrochloride) | | | |
| | | Coma | | Unknown | PS | | |
| | | Oxygen Saturation | | Methadone | | | |
| | | Decreased | | (Methadone) | SS | | |
| | | Pulmonary Oedema | | Cocaine (Cocaine) | SS | | |
| | | Respiration Abnormal | | | | | |
| | | Snoring | | | | | |
| | | Somnolence | | | | | |
| | | Stupor | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/27/02ISR Number: 4015700-5Report Type:Direct
 Age:12 YR Gender:Female I/FU:I

Company Report #USP 55367

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Concerta (Methlphenidate Hydrochloride) | PS | Alza | |
| | | | | Concerta (Methlphenidate Hydrochloride) | SS | A;Za | |

Date:11/29/02ISR Number: 4019720-6Report Type:Expedited (15-DaCompany Report #CEL-2002-01441-ROC (0)
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia | Health | Metadate Cd Capsules | | | |
| | | Blindness Transient | Professional | 20 | | | |
| | | Blindness Unilateral | | Mg (Methylphenidate | | | |
| | | Hypoaesthesia | | Hydrochloride) | PS | | |
| 60 MG(60 MG, DAILY)/ SEVERAL MONTHS AGO- | | Muscle Disorder | | | | | |
| | | Vision Blurred | | | | | |
| | | | | Geodon (Ziprasidone Hydrochloride) | SS | | |
| LOW DOSE (DAILY)/ SEVERAL MONTHS AGO- | | | | Effexor (Venlafaxine Hydrochloride) | C | | |
| | | | | Wellbutrin - Slow Release (Bupropion Hydrochloride) | C | | |

Date:11/29/02ISR Number: 4027447-XReport Type:Periodic Company Report #NSADSS2002039219
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Weight Decreased | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

SEE IMAGE

Date:11/29/02ISR Number: 4027448-1Report Type:Periodic Company Report #NSADSS2002038359
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation Weight Gain Poor | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

ORAL

Date:11/29/02ISR Number: 4027450-XReport Type:Periodic Company Report #NSADSS2002037041
Age:9 YR Gender:Male I/FU:I

| Outcome | PT |
|---------|--|
| Other | Aggression Emotional Disorder Personality Disorder |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Weight Decreased

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|---------------|--|------|--------------|-------|
| 18 MG, 2 IN 1 DAY(S), ORAL | | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:11/29/02ISR Number: 4027452-3Report Type:Periodic Company Report #NSADSS2002034260
Age:6 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|---------------|--|------|--------------|-------|
| Dose Other SEE IMAGE | | Anorexia Insomnia Weight Gain Poor | Consumer | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Ritalin (Methylphenidate Hydrochloride) | C | | |
| | | | | Imipramine (Imipramine) | C | | |

Date:11/29/02ISR Number: 4027454-7Report Type:Periodic Company Report #NSADSS2002030960
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--|---------------|--|------|--------------|-------|
| Dose Other ORAL | | Convulsion Epileptic Aura Headache | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Proventil (Salbutamol) | C | | |
| | | | | Rhinocort (Budesonide) | C | | |

Date:11/29/02ISR Number: 4027459-6Report Type:Periodic
Age:10 YR Gender:Female I/FU:I

Company Report #NSADSS2002038799

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia Muscular Weakness Weight Decreased | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY(S), ORAL | | | | | | | |

Date:11/29/02ISR Number: 4027501-2Report Type:Periodic
Age:7 YR Gender:Male I/FU:I

Company Report #NSADSS2002029232

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Anorexia Weight Decreased | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/03/02ISR Number: 4021755-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE01782
 Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|-----------|--|--|--|------|--------------|-------|
| Life-Threatening Hospitalization - Initial or Prolonged | 10 MG, QD | Arrhythmia Blood Pressure Increased Bundle Branch Block Right Cardiac Murmur Ejection Fraction Decreased Electrocardiogram Abnormal Electrocardiogram T Wave Amplitude Decreased Fatigue Heart Sounds Abnormal Pulmonary Hypertension Pulmonary Valve Incompetence Thrombosis Tricuspid Valve Incompetence Ventricular Hypertrophy | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

Date:12/04/02ISR Number: 4019552-9Report Type:Direct Company Report #CTU 182123
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--------------|--|---------------|------------|------|--------------|-------|
| Required Intervention to Prevent Permanent Impairment/Damage | 20 MG PO QAM | Anorexia Attention Deficit/Hyperactivity Disorder Disease Recurrence | | Ritalin Er | PS | | ORAL |

Date:12/04/02ISR Number: 4022327-8Report Type:Expedited (15-DaCompany Report #PHNU2002DE03908
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--|--|--|------|--------------|-------|
| Dose Other | | Disturbance In Attention Fatigue Visual Acuity Reduced | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 15MG/DAY, ORAL | | | | | | | |

Date:12/05/02ISR Number: 4021652-4Report Type:Expedited (15-DaCompany Report #NSADSS2002043428
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Delusion Emotional Disorder Psychotic Disorder | Foreign Study Health Professional | Concerta(18 Mg Sustained Release Tablet)(Methylphenid ate Hydrochloride) | PS | | ORAL |
| 18 MG 1 IN 1 DAY(S), ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/05/02ISR Number: 4025837-2Report Type:Periodic
 Age:51 YR Gender:Female I/FU:I

Company Report #HQ1166204MAR2002

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------|------------------------|---|--------|--------------|-------|
| Dose Other | | Hypertension Vision Blurred | Health Professional | Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release) | PS | | ORAL |
| 3.75 MG ; 112.5 MG :1X PER 1 DAY, ORAL | | | | | | | |
| | | | | Methylphenidate-Slow Release (Methylphenidate Hydrochloride,) | SS | | ORAL |
| 20 MG 1X PER 1 DAY, ORAL | | | | | | | |
| | | | | Unspecified Hormone Replacement Therapy Agent (Unspecified Hormone Replacement Therapy Agent) .. | C C | | |

Date:12/06/02ISR Number: 4020328-7Report Type:Direct
 Age:10.5 YR Gender:Male I/FU:I

Company Report #CTU 182296

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|---|----------|--------------|--------------|
| Dose Other | | Abdominal Discomfort Abnormal Behaviour | | Generic Ritalin 5 Mg Tab | PS | | ORAL |
| 5 MG PO BID 10 MG PO QD 18 MG PO QD | | Aggression Decreased Appetite | | Adderall 10mg Tab Concerta 18 Mg Tab | SS SS | | ORAL ORAL |
| | | Drug Ineffective Educational Problem | | | | | |

Headache
 Hostility
 Insomnia
 Irritability
 Pharmaceutical Product
 Complaint
 Psychomotor Hyperactivity
 Pyromania
 Vomiting

Date:12/06/02ISR Number: 4022696-9Report Type:Expedited (15-DaCompany Report #MK200212-0087-1
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|--|------|--------------|----------------------------------|
| Hospitalization - Initial or Prolonged | | Drug Withdrawal Syndrome Neonatal Maternal Drugs Affecting Foetus | Foreign | Anafranil 25 Mg Capsules 100 Ritalin Impromen Meilax Depromel Amoxan | | | PS SS SS SS SS SS |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/06/02ISR Number: 4022807-5Report Type:Expedited (15-DaCompany Report #NSADSS2002038373
 Age:4 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Formication Hallucination, Tactile Psychotic Disorder Screaming | Health Professional Company Representative | Concerta (27 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 27 MG, 1 IN 1 | | | | | | | |
| DAY(S), ORAL | | | | | | | |
| 25 MG, ORAL | | | | Zoloft (Sertraline Hydrochloride) | SS | | ORAL |
| | | | | Clonidine | C | | |

Date:12/09/02ISR Number: 4023099-3Report Type:Expedited (15-DaCompany Report #PHBS2002JP14252
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------|-----------|---|-------------------|--|------|--------------|-------|
| Other | | Drug Exposure Via Breast Milk | Foreign Health | Anafranil(Clomiprami ne) Unknown | PS | | |
| TRANSPLACENTAL | UNK, UNK, | Drug Withdrawal Syndrome | Professional | | | | |
| TRANSPLACENTA | | Neonatal | Other | | | | |
| L | | Maternal Drugs Affecting Foetus Pregnancy | | Ritaline(Methylpheni date Hydrochloride) Unknown | SS | | |
| TRANSPLACENTAL | UNK, UNK, | | | | | | |
| TRANSPLACENTA | | | | | | | |
| L | | | | | | | |
| TRANSPLACENTAL | UNK, UNK, | | | Depromel(Fluvoxamine) | SS | | |
| TRANSPLACENTA | | | | | | | |
| L | | | | | | | |

Meilax(Ethyl Loflazepate) SS

TRANSPLACENTAL UNK, UNK,
 TRANSPLACENTA
 L

Amoxan(Amoxapine) SS

TRANSPLACENTAL UNK, UNK,
 TRANSPLACENTA
 L

Impromen(Bromperidol) SS

TRANSPLACENTAL UNK, UNK,
 TRANSPLACENTA
 L

Date:12/09/02ISR Number: 4023107-XReport Type:Expedited (15-DaCompany Report #PHBS2002NO14330
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Diabetes Mellitus Insulin-Dependent | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, TID, ORAL | | | Other | Dexamin (Amfetamine Sulfate) | C | | |
| | | | | Dexidrine (Dexamfetamine Sulfate) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/09/02ISR Number: 4023108-1Report Type:Expedited (15-DaCompany Report #PHBS2002NO14329
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Diabetes Mellitus Insulin-Dependent | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE, ORAL | | | Other | | | | |

Date:12/09/02ISR Number: 4023111-1Report Type:Expedited (15-DaCompany Report #PHRM2002FR02903
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Arthralgia Rash Rash Macular | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| SEE IMAGE ORAL | | Systemic Inflammatory Response Syndrome Urinary Tract Infection Vomiting Weight Decreased | | | | | |

Date:12/09/02ISR Number: 4023119-6Report Type:Expedited (15-DaCompany Report #PHBS2002NO14341
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Disability 10 MG, TID, ORAL | | Diabetes Mellitus Insulin-Dependent | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blindness Transient | Health | Geodon (Ziprasidone) | PS | | |
| DAILY | | Blindness Unilateral | Professional | Methylphenidate | | | |
| | | Multiple Sclerosis | | Hydrochloride | SS | | |
| 60 MG (DAILY) | | Vision Blurred | | Venlafaxine | | | |
| | | | | Hydrochloride | C | | |
| | | | | Bupropion | | | |
| | | | | Hydrochloride | C | | |

Age:47 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-----------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Hepatitis | | Methylphenidate | PS | | |
| 400MG DAILY | | | | Ethanol | SS | | ORAL |
| Initial or Prolonged | | | | Cocaine | SS | | |
| PO [CHRONIC] | | | | Barbiturates | SS | | |
| CHRONIC | | | | Opiates | SS | | |
| CHRONIC | | | | | | | |
| CHRONIC | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/10/02ISR Number: 4024989-8Report Type:Expedited (15-DaCompany Report #PHBS2002JP13750
Age:19 YR Gender:Female I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--|--|--|----------|--------------|-------|
| Dose Life-Threatening 20 MG/DAY, ORAL | Blood Creatine Phosphokinase Increased Convulsion Depression | Foreign Health Professional Other | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| Dose 10 MG, TID, ORAL | Hallucination, Auditory Hepatic Function Abnormal Hyperpyrexia Insomnia | | Anafranil (Clomipramine Hydrochloride)Tablet | SS | | ORAL |
| Dose 2 MG, TID, UNK | Memory Impairment Overdose | | Condition (Diazepam) | SS | | |
| Dose 15 MG, TID, UNK | Respiratory Arrest Vomiting | | Toledomin (Milnacipran Hydrochloride) | SS | | |
| Dose 200 MG/DAY UNK, UNK, UNK | | | Imidiol Normaln (Amitriptyline Hydrochloride) | SS SS | | |

Date:12/12/02ISR Number: 4026382-0Report Type:Expedited (15-DaCompany Report #PHEH2002US08968
Age:6 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|---------------|------------|------|--------------|-------|
| Dose Hospitalization - 20 MG, Initial or Prolonged ONCE/SINGLE/ ORAL | Dyskinesia Hallucination Muscle Contractions | Other | Ritalin La | PS | | ORAL |

Involuntary
Pain In Extremity
Tic

Claritin
(Loratadine) C
Antibiotics C

Date:12/12/02ISR Number: 4026394-7Report Type:Expedited (15-DaCompany Report #PHEH2002US09000
Age:13 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | C-Reactive Protein Increased Neuropathy Peripheral Peroneal Nerve Palsy | Consumer | Focalin (Dexamethylphine Hydrochloride) Tablet | PS | | |
| 10 MG, BID, | | | | Ritalin La (Methylphenidate Hydrochloride) Extended Release Capsules | SS | | |
| 20 MG, QD | | | | | | | |

Date:12/16/02ISR Number: 4026771-4Report Type:Expedited (15-DaCompany Report #MK200211-0156-2
Age:19 YR Gender:Female I/FU:F

| Outcome | PT |
|---|--|
| Hospitalization - Initial or Prolonged | Blood Creatine Phosphokinase Increased Convulsion Drug Ineffective Hallucination, Auditory Hepatic Function Abnormal Hyperphagia |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|---|---------------|---------------------------------|----------------|--------------|-------|
| 60MG DAILY | | Hyperpyrexia Insomnia Lethargy | Foreign | Anafranil | PS | | |
| 40MG/DAY | | Loss Of Consciousness | | Milnacipran Hydrochloride | SS | | |
| ONE TIME DOSE | | Memory Impairment Overdose Respiratory Arrest | | Ritalin | SS | | |
| 30 TABLETS | | Suicidal Ideation | | Ritalin | SS | | |
| FOR SUICIDE ATTEMPT | | Vomiting | | Condition Normaln Imidiol | SS SS SS | | |

Date:12/16/02ISR Number: 4027547-4Report Type:Expedited (15-DaCompany Report #PHNU2002DE04059
Age: Gender:Male I/FU:I

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---|--|---|------|--------------|-------|
| Death | | Sudden Cardiac Death Ventricular Extrasystoles | Foreign Health Professional Other | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | PS | | ORAL |
| 60MG/DAY, ORAL | | | | Zoloft (Sertraline Hydrochloride) | SS | | ORAL |
| 100 MG/DAY, ORAL | | | | | | | |

Date:12/16/02ISR Number: 4028166-6Report Type:Expedited (15-DaCompany Report #PHFR2002GB04019
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------------------|-----------------------|----------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Allergic Granulomatous Angiitis | Foreign Health | Methylphenidate Hydrochloride | PS | | ORAL |
| ORAL | | | Professional Other | | | | |

Date:12/18/02ISR Number: 4025741-XReport Type:Direct Company Report #CTU 182899
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|---------------|------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased Pharmaceutical Product | | Ritalin - Methylphenidate | PS | | ORAL |
| 5MG - PO AM | | Complaint | | | | | |

Date:12/18/02ISR Number: 4029125-XReport Type:Expedited (15-DaCompany Report #NSADSS2002045737
 Age:14 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------------------|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Confusional State Hypertension | Health Professional | Concerta (Sustained Release Tablet)(Methylphenid ate Hydrochloride) | PS | | |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY(S), ORAL; | | | | | | | |
| SEE IMAGE | | | | Celexa (Citalopram Hydrobromide) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/18/02ISR Number: 4029213-8Report Type:Expedited (15-DaCompany Report #CEL-2002-01509-SLO(0)
 Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|-----------------------------------|---|------|--------------|-------|
| Life-Threatening | | Eosinophilia Neutrophil Count Decreased Shift To The Left | Foreign Health Professional | Equasym (Strength Unspecified) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 30 MG (10 MG, THREE TIMES DAILY), PO | | White Blood Cell Count Decreased | | | | | |

Date:12/18/02ISR Number: 4029418-6Report Type:Expedited (15-DaCompany Report #A0387790A
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---|--|------|--------------|-------|
| Other | | Confusional State Drug Interaction Grand Mal Convulsion Somnolence | Foreign Literature Health Professional | Wellbutrin Unspecified Tablet (Bupropion Hydrochloride) | PS | | ORAL |
| PER DAY/ORAL | | | | Methylphenidate (Formulation Unknown) (Methylphenidate) | SS | | |
| 60 MG/PER DAY | | | | | | | |

Date:12/19/02ISR Number: 4029731-2Report Type:Expedited (15-DaCompany Report #PHBS2002US15140
 Age:45 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|--------------------------------------|---|--------|--------------|-------|
| Other | | Abnormal Behaviour Depression Drug Dependence Drug Withdrawal Syndrome | Literature Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | Hypertension Paranoia Personality Disorder | | Marijuana (Cannabis) Vicodin Amfetamine | C C | | |

(Amfetamine) C
 Opiates C
 Bupropion
 (Bupropion) C

Date:12/19/02ISR Number: 4030288-0Report Type:Expedited (15-DaCompany Report #PHFR2002GB04081
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------|-----------------------------------|---|------|--------------|-------|
| Death | | Circulatory Collapse Shock | Foreign Health Professional Other | Ritalin-Sr(Methylphenidate Hydrochloride) Slow Release Tablet | PS | | ORAL |
| ORAL | | | | | | | |

Date:12/20/02ISR Number: 4028717-1Report Type:Direct Company Report #CTU 183140
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|-------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged 30MG DAILY | | Bone Marrow Depression Laboratory Test Abnormal | | Remeron 30mg Organon | PS | Organon | ORAL |
| ORAL | | Pyrexia | | | | | |
| 54MG DAILY | | White Blood Cell Count Decreased | | Concerta Er 54mg Mcneil | SS | Mcneil | ORAL |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/20/02 ISR Number: 4030477-5 Report Type:Expedited (15-DaCompany Report #NSADSS2002043428
 Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Delusion Emotional Disorder Psychotic Disorder | Foreign Study Health Professional | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 DAY (S), ORAL | | | | | | | |

Date:12/23/02 ISR Number: 4032832-6 Report Type:Expedited (15-DaCompany Report #ALZ-13483
 Age:38 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|---|------------------------|--|------|--------------|-------|
| Other | | Iron Deficiency Anaemia Serum Sickness | Health Professional | Concerta (54 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54 MG, 1 IN 1 DAYS (S), ORAL | | | | | | | |
| | | | | Ortho Tri-Cyclen Tablets (Tablet (Acne)) (Norgestimate/Ethinyl lestradiol) | SS | | |
| 1 IN 1 DAY (S) | | | | | | | |
| | | | | Celexa (Citalopram Hydrobromide) | C | | |
| | | | | Seroquel (Seroquel) | C | | |
| | | | | Nexium (Esomeprazole Magnesium) | C | | |
| | | | | Singulair (Montelukast Sodium) | C | | |
| | | | | Advair | C | | |

Nasonex (Mometasone
Furoate) C
Albuterol
(Salbutamol) C

Date:12/23/02ISR Number: 4032893-4Report Type:Expedited (15-DaCompany Report #NSADSS2002046188
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Congenital Cardiovascular | Health | Concerta | PS | | ORAL |
| ORAL | | Anomaly Electrocardiogram Qt Prolonged Sudden Cardiac Death | Professional | | | | |

Date:12/26/02ISR Number: 4034273-4Report Type:Expedited (15-DaCompany Report #PHEH2002US09315
Age: Gender: I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---|---|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Coronary Artery Disease | Health Professional Company Representative | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/26/02ISR Number: 4035002-0Report Type:Expedited (15-DaCompany Report #PHEH2001US10491
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------|---------------------|--|------|--------------|-------|
| Death | | Death | Health Professional | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | |

Date:12/26/02ISR Number: 4035236-5Report Type:Expedited (15-DaCompany Report #PHBS2002JP13750
 Age:19 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Life-Threatening | | Blood Creatine Phosphokinase Increased Convulsion Hallucination, Auditory | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| SEE IMAGE | | Hyperphagia Hyperpyrexia Insomnia Lethargy | | Anafranil (Clomipramine Hydrochloride) Tablet | SS | | ORAL |
| SEE IMAGE | | Liver Function Test | | Condition (Diazepam) | SS | | |
| 2 MG, TID; 25 MG/DAY | | Abnormal | | | | | |
| | | Loss Of Consciousness Memory Impairment Overdose | | Toledomin (Milnacipran Hydrochloride) | SS | | |
| 15 MG, TID 150 MG/DAY | | Respiratory Arrest | | Imidiol() | SS | | |
| SEE IMAGE | | Suicidal Ideation Vomiting | | Normaln (Amitriptyline Hydrochloride) | SS | | |
| 15 MG/DAY | | | | Diazepam (Diazepam) | SS | | |

Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia | Health | Geodon (Ziprasidone) | PS | | ORAL |
| 40 MG (BID), | | Blindness Transient | Professional | | | | |
| ORAL | | Feeling Abnormal | | Methylphenidate | | | |
| | | Hypoaesthesia | | Hydrochloride | SS | | ORAL |
| 60 MG | | Multiple Sclerosis | | | | | |
| (DAILY), ORAL | | Vision Blurred | | Venlafaxine | | | |
| | | | | Hydrochloride | C | | |
| | | | | Bupropion | | | |
| | | | | Hydrochloride | C | | |

Age:12 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation | Foreign | Ritalin | | | |
| | | | Health | (Methylphenidate | | | |
| | | | Professional | Hydrochloride) | PS | | ORAL |
| ORAL | | | Other | Depromel | | | |
| | | | | (Fluvoxamine) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/30/02ISR Number: 4035868-4Report Type:Expedited (15-DaCompany Report #00HQ-10193
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--------------------------------------|---|------|--------------|-------|
| Death | | Coronary Artery Disease Coronary Artery Insufficiency Myocardial Ischaemia Sudden Cardiac Death | Literature Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | |

Date:12/30/02ISR Number: 4035935-5Report Type:Expedited (15-DaCompany Report #PHEH2002US10433
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---|---------------|---|------|--------------|-------|
| Other | | Leukocytoclastic Vasculitis Pharmaceutical Product Complaint | Consumer | Methylphenidate (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, TID, ORAL | | | | | | | |

Date:12/30/02ISR Number: 4036065-9Report Type:Expedited (15-DaCompany Report #EMADSS2002007059
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged Disability | | Drug Interaction Erectile Dysfunction Post Procedural Complication | Foreign Health Professional | Risperdal (Unspecified) (Risperidone) | PS | | ORAL |
| 1 MG, 1 IN 1 Required TIME (S), Intervention to ORAL | | | | | | | |
| Prevent Permanent Impairment/Damage 30 MG, DAILY, ORAL | | | | | | | |
| | | | | Methylphenidate (Methylphenidate) | SS | | ORAL |
| | | | | Clonidine | | | |

Date:12/30/02ISR Number: 4036106-9Report Type:Expedited (15-DaCompany Report #PHBS2002JP15313
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | Other | Depromel (Fluvoxamine) | SS | | |

Date:12/30/02ISR Number: 4036185-9Report Type:Expedited (15-DaCompany Report #PHNU2002DE03748
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Activated Partial Thromboplastin Time Prolonged | Foreign Health Professional | Ritaline(Methylphenidat Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, BID, | | Autoimmune Thyroiditis | Other | | | | |
| ORAL | | Blood Creatinine Increased Blood Urea Increased Hypothyroidism Weight Increased | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/30/02ISR Number: 4036540-7Report Type:Expedited (15-DaCompany Report #PHFR2002GB04247
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Photosensitivity Reaction Systemic Lupus Erythematosis | Foreign Health Professional Other | Ritaline(Methylpheni date Hydrochloride) | PS | | |

Date:01/02/03ISR Number: 4038472-7Report Type:Expedited (15-DaCompany Report #NSADSS2002045734
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|---------------|---------------|--|--------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypoglycaemia | Consumer | Concerta (18 Mg Sustained Release Tablet)(Methylphenid ate | PS | | ORAL |
| 18 MG, 1 IN 1 DAY(S), ORAL | | | | | | | |
| | | | | Effexor (Venlafaxine Hydrochloride) Ultralente (Insulin Zinc Suspension) Humalog (Insulin Lispro) | SS C C | | |

Date:01/06/03ISR Number: 4036893-XReport Type:Direct Company Report #CTU 183819
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------|---------------|---------|------|--------------|-------|
| Life-Threatening Disability Required Intervention to Prevent Permanent Impairment/Damage | | Tourette'S Disorder | | Ritalin | PS | | |

Date:01/06/03ISR Number: 4039988-XReport Type:Expedited (15-DaCompany Report #NSADSS2002047632
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Weight Decreased | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY(S), ORAL; | | | | | | | |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY(S), ORAL | | | | | | | |
| | | | | Zoloft (Sertraline Hydrochloride) | C | | |

Date:01/07/03ISR Number: 4040233-XReport Type:Expedited (15-DaCompany Report #NSADSS2002046654
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia Leukopenia | Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

SEE IMAGE

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

36 MG, 1 IN 1
 DAY(S); ORAL,
 18 MG, 1 IN 1
 DAY(S); ORAL;
 27 MG, 1 IN 1

Concerta (Sustained Release Tablet)
 (Methylphenidate Hydrochloride) SS ORAL

Date:01/08/03ISR Number: 4040543-6Report Type:Expedited (15-DaCompany Report #NSADSS2003000409
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Dysarthria Dyskinesia Oral Intake Reduced Pharyngitis Torticollis | Health Professional | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | | | ORAL |
| 36 MG, 1 IN 1 | | | | | PS | | ORAL |
| DAY (S), ORAL | | | | | | | |

| | | | | | | | |
|--|--|--|--|--|---|--|--|
| | | | | Evening Primrose Oil (Evening Primrose Oil) | C | | |
| | | | | Fish Oil (Fish Oil) | C | | |

Date:01/09/03ISR Number: 4039789-2Report Type:Direct Company Report #CTU 184177
 Age:19 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------------|---|---------------|---------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | 60MG DAILY | Blood Creatine Phosphokinase Increased Convulsion Depression | | Anafranil | PS | | |
| 40MG /DAY | | | | Milnacipran Hydrochloride | SS | | |
| | | | | Ritalin | SS | | |

| | | | |
|---------------|---------------------------|-----------|----|
| ONE TIME DOSE | Hallucination, Auditory | Ritalin | SS |
| 30 TABLETS | Hepatic Function Abnormal | | |
| FOR SUICIDE | Hyperphagia | | |
| ATTEMPT | Hyperpyrexia | | |
| | Hypersomnia | Condition | SS |
| | Insomnia | Normaln | SS |
| | Lethargy | Imidol | SS |
| | Loss Of Consciousness | | |
| | Memory Impairment | | |
| | Overdose | | |
| | Respiratory Arrest | | |
| | Suicidal Ideation | | |
| | Vomiting | | |

Date:01/10/03ISR Number: 4041128-8Report Type:Expedited (15-DaCompany Report #NSADSS2002034127
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Lower Anorexia Blood Pressure Increased Caecitis Vomiting | Health Professional | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 DAY (S), ORAL | | | | Albuterol (Salbutamol) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Prevacid
(Lansoprazole) C

Date:01/10/03ISR Number: 4041278-6Report Type:Expedited (15-DaCompany Report #PHNU2002DE04262
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Impaired Healing Peripheral Coldness Peripheral Vascular | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | Disorder | Other | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | SS | | ORAL |
| 1 DF, QD, | | | | | | | |
| ORAL | | | | | | | |

Date:01/10/03ISR Number: 4041329-9Report Type:Expedited (15-DaCompany Report #PHBS2002JP15313
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG/D, ORAL | | | Other | Depromel (Fluvoxamine) | SS | | ORAL |
| 25 MG/D, ORAL | | | | Pydoxal (Pyridoxal Phosphate) | C | | |

Date:01/13/03ISR Number: 4041694-2Report Type:Expedited (15-DaCompany Report #NSADSS2003000619
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|----------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Abdominal Pain Upper | Consumer | Concerta (Sustained | | | |

| | | | | |
|----------------------|-----------------------|------------------|----|------|
| Initial or Prolonged | Convulsion | Release Tablet) | | |
| | Hallucination | (Methylphenidate | | |
| SEE IMAGE | Loss Of Consciousness | Hydrochloride) | PS | ORAL |
| | Nausea | Clonidine | | |
| | Vomiting | (Clonidine) | C | |

Date:01/13/03ISR Number: 4041852-7Report Type:Expedited (15-DaCompany Report #PHFR2002GB03612
Age:13 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--|--|--|------|--------------|-------|
| Dose Duration Hospitalization - Initial or Prolonged Disability | Drug Interaction Erectile Dysfunction Priapism | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 30 MG/DAY, ORAL | | | Risperidone (Risperid one) | SS | | ORAL |
| ONCE/SINGLE, ORAL | | | Clonidine (Clonidine) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/13/03ISR Number: 4041859-XReport Type:Expedited (15-DaCompany Report #PHFR2002GB03782
Age:16 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Systemic Lupus Erythematosus | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) | PS | | |

Date:01/13/03ISR Number: 4041910-7Report Type:Expedited (15-DaCompany Report #PHBS2002NL15740
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agranulocytosis Stomatitis Vomiting | Foreign Health Professional Other | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | | | | |

Date:01/14/03ISR Number: 4042683-4Report Type:Expedited (15-DaCompany Report #2002-101654-NL
Age:32 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|------------------------|---------------------|----------|--------------|-------|
| Dose | | | | | | | |
| Other | | Coordination Abnormal Cyanosis | Health Professional | Remeron Concerta | PS SS | | ORAL |
| 36 MG DAILY | | | | | | | |
| ORAL | | Faecal Incontinence | | | | | |
| | | Muscle Spasms Oedema Peripheral Sensory Loss Tremor Urinary Incontinence | | Effexor | SS | | |

Date:01/16/03ISR Number: 4042958-9Report Type:Direct Company Report #CTU 184758
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|-----------------------------|------|--------------|-------|
| | | Medication Error | | Methylphenidate Hcl, Usp | PS | | |
| 20MG CAPSULES | | | | | | | |
| IN DOSE PACKS | | | | | | | |
| CONTAINING 30 | | | | | | | |
| CAPSULES EACH | | | | | | | |

Date:01/17/03ISR Number: 4044305-5Report Type:Expedited (15-DaCompany Report #NSADSS2003002020
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------|---------------|--|------|--------------|-------|
| Dose Other | | Syncope | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY (S), | | | | | | | |
| ORAL; 36 MG, | | | | | | | |
| 1 IN 1 | | | | | | | |
| DAY(S), ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/03ISR Number: 4045483-4Report Type:Expedited (15-DaCompany Report #PHEH2002US09142
Age:17 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dilatation Ventricular Gilbert'S Syndrome Oesophageal Disorder Syncope | Health Professional | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, TID, ORAL | | Ventricular Arrhythmia | | | | | |

Date:01/21/03ISR Number: 4048140-3Report Type:Expedited (15-DaCompany Report #EMADSS2002007793
Age:21 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Pressure Increased Emotional Disorder Overdose | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 DAY(S) , ORAL; 5 TABLE, 1 IN 1 TIME(S), ORAL | | Suicide Attempt | | | | | |

Date:01/23/03ISR Number: 4045531-1Report Type:Direct Company Report #CTU 185092
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased Pharmaceutical Product Complaint | | Ritalin - Methylphenidate Geneva | PS | Geneva | ORAL |
| 5 MG PO A.M. | | | | | | | |

Date:01/23/03ISR Number: 4046107-2Report Type:Expedited (15-DaCompany Report #CEL-2002-01236-ROC(1)
Age:16 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Meningitis | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | |

Date:01/27/03ISR Number: 4048706-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE00485
Age:47 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|------------------------------|--|------|--------------|-------|
| Other | | Endometrial Hyperplasia Psychotic Disorder Speech Disorder Uterine Leiomyoma | Foreign Consumer Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

Date:01/27/03ISR Number: 4048811-9Report Type:Expedited (15-DaCompany Report #PHNU2003DE00479
Age:21 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|------------------------------|---|------|--------------|-------|
| Other | | Persecutory Delusion | Foreign Consumer Other | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/27/03ISR Number: 4048813-2Report Type:Expedited (15-DaCompany Report #PHBS2003JP00907
 Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------|---------------|--|----------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Congenital Hydronephrosis Haemangioma | Foreign Health | Ritalin(Methylphenidate Hydrochloride) | PS | | |
| TRANSPLACENTAL | TRANSPLACENTA | Maternal Drugs Affecting | Professional | | | | |
| L | | Foetus Spina Bifida | Other | | | | |

Date:01/28/03ISR Number: 4049370-7Report Type:Expedited (15-DaCompany Report #HQ5434520NOV2002
 Age:50 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Confusional State Feeling Abnormal Memory Impairment Road Traffic Accident | Health Professional | Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release) | PS | | ORAL |
| 300 MG 2X PER | | | | | | | |
| 1 DAY, ORAL | | | | | | | |
| | | | | Allegra-D (Fexofenadine Hydrochloride/ Pseudoephedrine Hydrochloride,) | SS | | ORAL |
| 1 TABLET 2X | | | | | | | |
| PER 1 DAY, | | | | | | | |
| ORAL | 6 | MON | | Ambien (Zolpidem Tartrate,) | SS | | ORAL |
| 5 MG 1X PER 1 | | | | | | | |
| DAY, ORAL | 6 | MON | | | | | |
| | | | | Ritalin (Methylphenidate Hydrochloride,) | SS | | ORAL |
| 20 MG DAILY, | | | | | | | |

INTERMITTENTL

Y, ORAL

Date:01/28/03ISR Number: 4049822-XReport Type:Expedited (15-DaCompany Report #NSADSS2003000409
Age:11 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | |
| Hospitalization - | Dysarthria | Health | Concerta (36 Mg | | | |
| Initial or Prolonged | Movement Disorder | Professional | Sustained Release | | | |
| | Oligodipsia | | Tablet) | | | |
| | Oral Intake Reduced | | (Methylphenidate | | | |
| | Parapharyngeal Abscess | | Hydrochloride) | PS | | |
| | Pharyngitis | | Evening Primrose Oil | | | |
| | Torticollis | | (Evening Primrose | | | |
| | | | Oil) | C | | |
| | | | Fish Oil (Fish Oil) | C | | |

Date:01/29/03ISR Number: 4049815-2Report Type:Expedited (15-DaCompany Report #PHBS2003NL00948
Age:19 YR Gender:Male I/FU:I

| Outcome | PT |
|---------|--------------------------|
| Other | Abdominal Distension |
| | Blood Pressure Increased |
| | Blood Urine Present |
| | Fungal Infection |
| | Lymphadenopathy |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | |
|------|----------|-------------------|------------------------------|--|------|---------------|
| | | Pyrexia Stress | | | | |
| Dose | Duration | | Report Source | Product | Role | Manufacturer |
| | | | Foreign Consumer Other | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | |
| ORAL | | | | | | Route ORAL |

Date:01/30/03ISR Number: 4049563-9Report Type:Direct Company Report #CTU 185648
Age:10 YR Gender:Male I/FU:I

| | | | | | | | |
|---------------|----------|--|---------------|---------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Condition Aggravated | | Ritalin La 30 | PS | Novartis | |
| RITALIN LA 30 | | Disturbance In Attention | | | | | |
| MG 1 Q AM | | Impulsive Behaviour Psychomotor Hyperactivity | | | | | |

Date:01/31/03ISR Number: 4050776-0Report Type:Periodic Company Report #CEL-2002-01433-ROC (0)
Age: Gender:Male I/FU:I

| | | | | | | | |
|-------------------------|----------|-------|------------------------|--|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Death | | Death | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | |
| 20 MG (20 MG, DAILY) | | | | | | | |

Date:01/31/03ISR Number: 4051164-3Report Type:Expedited (15-DaCompany Report #CEL-2002-01441-ROC (1)
Age:37 YR Gender:Female I/FU:F

| | | | | | | | |
|---------|----------|---------------------------------|------------------------|-------------------------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Asthenia Blindness Transient | Health Professional | Metadate Cd Capsules 20 Mg | | | |

| | | | | |
|---------------------------|---|--|----|------|
| 60 MG (20 MG, TID), PO | Hypoaesthesia Muscle Disorder | (Methylphenidate Hydrochloride) | PS | ORAL |
| LOW DOSE (DAILY) | Paraesthesia Viral Infection Vision Blurred | Geodon (Ziprasidone Hydrochloride) | SS | |
| | | Effexor (Venlafaxine Hydrochloride) | C | |
| | | Wellbutrin- Slow Release (Bupropion Hydrochloride) | C | |

Date:01/31/03ISR Number: 4051188-6Report Type:Expedited (15-DaCompany Report #PHNU2002DE03023
Age:11 YR Gender:Male I/FU:F

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| 20MG/DAY, ORAL | | Blood Fibrinogen Decreased Coagulation Factor Decreased Coagulopathy Prothrombin Time Abnormal Prothrombin Time Shortened | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/31/03ISR Number: 4051693-2Report Type:Expedited (15-DaCompany Report #EMADSS2003000688
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hypoglycaemia | Foreign Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate) | PS | | ORAL |

TABLE, ORAL

Date:02/03/03ISR Number: 4050301-4Report Type:Direct Company Report #CTU 185808
Age:49 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|----------|--|---------------|--------------------------|------|--------------|-------|
| Other 20 MG 2X A DAY ORAL | | Depression Drug Effect Decreased Fatigue | | Ritalin 20mg Novartis | PS | Novartis | ORAL |

Pharmaceutical Product
Complaint

Date:02/05/03ISR Number: 4052103-1Report Type:Direct Company Report #CTU 186007
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--|---------------|-----------------|------|--------------|-------|
| 20 MG AM NOON 4 PM | | Abnormal Behaviour Drug Ineffective | | Methylphenidate | PS | | |

Pharmaceutical Product
Complaint

Date:02/07/03ISR Number: 4054405-1Report Type:Expedited (15-DaCompany Report #03-00182
Age:42 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|-----------------|------|--------------|-------|
| Death | | Completed Suicide | Literature | Methylphenidate | PS | | |

Intentional Misuse

Health
Professional
Other

Bupropion

C

Date:02/07/03ISR Number: 4054409-9Report Type:Expedited (15-DaCompany Report #03-00181
Age:42 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|---|------------------------------|---------|--------------|-------|
| Death | | Overdose | Literature Health Professional Other | Methylphenidate Bupropion | PS C | | |

Date:02/07/03ISR Number: 4054470-1Report Type:Expedited (15-DaCompany Report #03-00120
Age:41 YR Gender:Female I/FU:I

| Outcome | PT |
|---------|--|
| Death | Agitation Coma Condition Aggravated Drug Abuser Intentional Misuse Oxygen Saturation Decreased Pulmonary Oedema |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Respiratory Disorder
Snoring

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|------|----------|---------------|-----------------|------|--------------|-------|
| | | Literature | Methylphenidate | PS | | |
| | | Health | Methadone | C | | |
| | | Professional | Cocaine (Crack) | C | | |
| | | Other | | | | |

Date:02/10/03ISR Number: 4054838-3Report Type:Direct Company Report #CTU 186336
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination, Visual | | Concerta (Ritalin) | PS | | ORAL |
| 18-36MGM ORAL | 5 DAY | Insomnia | | | | | |
| | | Sleep Disorder | | | | | |

Date:02/10/03ISR Number: 4054843-7Report Type:Expedited (15-DaCompany Report #PHNR2003AU00498
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety | Foreign | Ritalin La | | | |
| | | Bronchospasm | Consumer | (Methylphenidate | | | |
| | | | Other | Hydrochloride) | | | |
| | | | | Extended Release | | | |
| 40 MG, QD, | | | | Capsules | PS | | ORAL |
| ORAL | | | | Lomotil | | | |
| | | | | (Diphenoxylate | | | |
| | | | | Hydrochloride) | C | | |

Date:02/11/03ISR Number: 4055961-XReport Type:Expedited (15-DaCompany Report #PHEH2003US00938
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Hospitalization -
Initial or Prolonged

Duodenal Ulcer
Gastric Ulcer
Gastroesophageal Reflux
Disease

Health
Professional

Ritalin
(Methylphenidate
Hydrochloride)
Tablet

PS

40 MG, QD

Hiatus Hernia
Oesophageal Ulcer
Oesophagitis

Date:02/11/03ISR Number: 4056196-7Report Type:Expedited (15-DaCompany Report #2003004699

Age: Gender:Male I/FU:I

| Outcome Dose Other 100 MG (DAILY) , ORAL 20 MG (DAILY) , ORAL | Duration | PT Convulsion Drug Interaction Dysphonia Eye Pain Keratoconjunctivitis Sicca Sleep Apnoea Syndrome Somnolence Visual Disturbance | Report Source Consumer | Product Zoloft (Sertraline) Methylphenidate Hydrochloride | Role PS SS | Manufacturer | Route ORAL ORAL |
|--|----------|---|-------------------------------|--|----------------------------------|--------------|---------------------------------------|
|--|----------|---|-------------------------------|--|----------------------------------|--------------|---------------------------------------|

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/11/03ISR Number: 4056724-1Report Type:Expedited (15-DaCompany Report #PHNU2003DE00644
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|----------------------------------|--|--|------|--------------|-------|
| Dose Other | | Nodal Arrhythmia Palpitations | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 15 MG/DAY, ORAL | | | | | | | |

Date:02/12/03ISR Number: 4057752-2Report Type:Expedited (15-DaCompany Report #NSADSS2003005851
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|------------------------|---|------|--------------|-------|
| Dose Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to 54 MG, 1 IN 1 Prevent Permanent DAY (S), ORAL Impairment/Damage | | Cardiac Arrest Ventricular Arrhythmia | Health Professional | Concerta (54 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Remeron (Mirtazapine) | C | | |

Date:02/12/03ISR Number: 4057753-4Report Type:Expedited (15-DaCompany Report #NSADSS2003005850
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------|---------------|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | | Lymphatic System Neoplasm | Consumer | Concerta (54 Mg Sustained Frelease Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54 MG, 1 IN 1 DAY (S), ORAL | | | | | | | |
| | | | | Celexa (Citalopram) | | | |

Hydrobromide) C

Date:02/13/03ISR Number: 4057528-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE00479
Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Intolerance Persecutory Delusion | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | Zoloft (Sertraline Hydrochloride) Film-Coated Tablet | C | | |

Date:02/13/03ISR Number: 4057935-1Report Type:Expedited (15-DaCompany Report #NSADSS2003006196
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------|---|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Dystonia | Health Professional Company Representative | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | Risperdal (Risperidone) | C | | |

Freedom Of Information (FOI) Report

Depakote (Valproate
Semisodium) C
Celexa (Citalopram
Hydrobromide) C
Buspar (Buspirone
Hydrochloride) C
Benadryl
(Diphenhydramine
Hydrochloride) C

Date:02/13/03ISR Number: 4057936-3Report Type:Expedited (15-DaCompany Report #NSADSS2003006182
Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------------|---------------|-----------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Agitation | Consumer | Concerta (Methylphenidate) | PS | | ORAL |
| 108 MG, 1 IN | | | | | | | |
| 1 DAY (S), | | | | | | | |
| ORAL; SEE IMAGE | | | | | | | |

Prozac
(Fluoxetine
Hydrochloride) C

Date:02/13/03ISR Number: 4057967-3Report Type:Expedited (15-DaCompany Report #PHEH2003US00938
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Duodenal Ulcer Gastric Ulcer Gastrooesophageal Reflux | Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | |
| 40 MG, QD | | Disease Hiatus Hernia Oesophageal Ulcer Oesophagitis | | | | | |

Date:02/13/03ISR Number: 4058100-4Report Type:Expedited (15-DaCompany Report #PHEH2002US09142
Age:17 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper Cardiac Disorder Dilatation Ventricular Gilbert'S Syndrome | Health Professional | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 10 MG, TID, ORAL | | Oesophageal Disorder Syncope Ventricular Arrhythmia | | | | | |

Date:02/14/03ISR Number: 4056667-3Report Type:Direct Company Report #CTU 186752
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|----------|----------------------------------|---------------|----------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Irritability | | Generic Methylphenidate | PS | | |
| PRIOR TO ESTABLISH WITH ME | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/19/03ISR Number: 4059710-0Report Type:Expedited (15-DaCompany Report #EMADSS2003001178
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Body Temperature Increased Confusional State Hyperhidrosis | Foreign Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54 MG, DAILY, ORAL | | Mydriasis Overdose Tachycardia | | | | | |

Date:02/19/03ISR Number: 4059781-1Report Type:Expedited (15-DaCompany Report #NSADSS2003005978
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---|---------------|---|------|--------------|-------|
| Other | | Elevated Mood Hallucination Headache Pyrexia Rash | Consumer | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36, ORAL | | | | | | | |

Date:02/20/03ISR Number: 4058069-2Report Type:Direct Company Report #CTU 186996
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------|---------------|----------|------|--------------|-------|
| Other | | Tremor | | Concerta | PS | | ORAL |
| 18MG PO QD | | | | | | | |

Date:02/20/03ISR Number: 4058202-2Report Type:Direct Company Report #USP 55449
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------|------|--------------------|-------|
| Other | | Medication Error | | Methylin | PS | Mallinckrodt Pharm | |

Date:02/20/03ISR Number: 4058601-9Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 186908

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Methylphenidate | PS | | |
| 10MG IN AM | | Pharmaceutical Product Complaint | | | | | |

Date:02/20/03ISR Number: 4060732-4Report Type:Expedited (15-DaCompany Report #2002069463
Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------------------------|---------------|--|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia | Consumer | Geodon (Ziprasidone) | PS | | ORAL |
| 40 MG (BID), | | Blindness Transient | Health | | | | |
| ORAL | | Blindness Unilateral Hypoaesthesia | Professional | Methylphenidate Hydrochloride | SS | | ORAL |
| 60 MG (TID), | | Sensory Disturbance | | | | | |
| ORAL | | Vision Blurred | | Venlafaxine Hydrochloride Bupropion Hydrochloride | C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/21/03ISR Number: 4062207-5Report Type:Expedited (15-DaCompany Report #EMADSS2003000688
Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Emotional Disorder Hypoglycaemia | Foreign Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | | | | |

Date:02/24/03ISR Number: 4064903-2Report Type:Expedited (15-DaCompany Report #NSADSS2003007333
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------------------|------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hallucination Ill-Defined Disorder | Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | | | | |
| | | | | Promethazine With Codeine | C | | |

Date:02/25/03ISR Number: 4065360-2Report Type:Expedited (15-DaCompany Report #PHBS2003CA01572
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|----------------------------------|--|--|------|--------------|-------|
| Other | | Neurofibromatosis Skin Lesion | Foreign Health Professional Other | Ritalin-Sr (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| SEE IMAGE | | | | | | | |

Date:02/26/03ISR Number: 4066897-2Report Type:Expedited (15-DaCompany Report #PHFR2003IE00874
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|---------------|----------------------|------|--------------|-------|
| Other | | Epistaxis | Foreign | Ritaline(Methylpheni | | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---------------------------------|-----------------------------------|--|------|--------------|-------|
| 7.5 TID, 5MG/EVE, ORAL | | | Consumer Other | date Hydrochloride) Tablet | PS | | ORAL |
| Date:02/27/03ISR Number: 4066928-XReport Type:Expedited (15-DaCompany Report #PHFR2002GB04247 Age:8 YR Gender:Male I/FU:F | | | | | | | |
| Other | | Systemic Lupus Erythematosus | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Unknown | PS | | ORAL |
| ORAL | | | Other | Melatonin (Melatonin) | C | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged 54 MG TO 126 MG02 | | Drug Ineffective Drug Interaction Dystonia | Health Professional Company | Concerta (Methyphenidate Hydrochloride) | PS | | |
| | | Tic | Representative | Risperdal | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Risperidone) SS
 Celexa
 (Citalopram
 Hydrobromide) SS
 Strattera
 (Atomoxetine) SS
 Depakote
 (Valproate
 Semisodium) C
 Buspar
 (Buspirone
 Hydrochloride) C
 Benadryl
 (Diphenhydramine
 Hydrochloride) C

Date:02/27/03ISR Number: 4068352-2Report Type:Expedited (15-DaCompany Report #NSADSS2003006196
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|---|-------------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Drug Ineffective Drug Interaction Dystonia | Health Professional Company | Risperdal (Unspecified) (Risperidone) | PS | | |
| UNK | | Tic | Representative | Concerta *Sustained Release Tablet) (Methylphenidate Hydrochloride) | SS | | |
| 54 MG TO 126 MG | | | | Strattera (Atomoxetine) | SS | | |
| UNK | | | | Celexa (Citalopram Hydrobromide) | SS | | |
| UNK | | | | Depakote (Valproate Semisodium) Buspar (Buspirone Hydrochloride) Benadryl (Diphenhydramine Hydrochloride) | C C C | | |

Date:02/28/03ISR Number: 4067644-0Report Type:Expedited (15-DaCompany Report #EMADSS2003000793
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucinations, Mixed Vision Blurred | Foreign Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | Anaesthetics (Anaesthetics) | C | | |

Date:02/28/03ISR Number: 4068092-XReport Type:Expedited (15-DaCompany Report #HQWYE482319FEB03
Age:75 YR Gender:Female I/FU:I

| Outcome | PT |
|---|--|
| Hospitalization - Initial or Prolonged | Drug Interaction Flushing Hypotension Malaise |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Medication Error | Report Source | Product | Role | Manufacturer | Route |
|----------------------------------|----------|--|------------------------|--|------|--------------|-------|
| 37.5 MG 1X PER 1 DAY, ORAL | 1 DAY | Myalgia Nausea Serotonin Syndrome Vertigo Vomiting | Health Professional | Efexor (Venlafaxine Hydrochloride, Tablet) | PS | | ORAL |
| 450 MG 1X PER 1 DAY, ORAL | | | | Aurorix (Moclobemide) | SS | | ORAL |
| 20 MG 1X PER 1 DAY, ORAL | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |
| 20 ML 1X PER 1 DAY, ORAL | 1 DAY | | | Unspecified Herbal Product | SS | | ORAL |
| | | | | Tranxilium (Clorazepate Dipotassium) | C | | |

Date:03/03/03ISR Number: 4069057-4Report Type:Expedited (15-DaCompany Report #EMADSS2003001588
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|-----------------------|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Hallucination, Visual | Foreign Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 DAY(S), ORAL | | | | Ritalin | | | |

(Methylphenidate Hydrochloride) SS ORAL

10 MG, DAILY,

ORAL

Date:03/03/03ISR Number: 4069153-1Report Type:Expedited (15-DaCompany Report #NSADSS2003009091
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucinations, Mixed | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

SEE IMAGE

Date:03/03/03ISR Number: 4069810-7Report Type:Expedited (15-DaCompany Report #M01304-2002
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Biopsy Bone Marrow | Health | Remeron | PS | | |
| 30 MG DAILY | | | | | | | |
| Initial or Prolonged | | Abnormal | Professional | Concerta | SS | | |
| 54 MG DAILY | | | | | | | |
| | | Pancytopenia | | | | | |
| | | Pyrexia | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/03/03ISR Number: 4084931-0Report Type:Periodic Company Report #NSADSS2002041857
 Age:5 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Vomiting | Health Professional Company Representative | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate) | PS | | ORAL |
| 18 MG, ORAL | | | | | | | |

Date:03/03/03ISR Number: 4084933-4Report Type:Periodic Company Report #NSADSS2003002006
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|--------------------|---------------|--|------|--------------|-------|
| Other | | Growth Retardation | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54 MG, 1 IN 1 DAY (S), ORAL | | | | | | | |

Date:03/04/03ISR Number: 4066219-7Report Type:Direct Company Report #USP 55554
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|------------------|---------------|-------------|------|--------------|-------|
| EXTENDED RELEASE | | Medication Error | | Metadate Er | PS | Celltech | |
| EXTENDED RELEASE | | | | Metadate Cd | SS | Celltech | |

Date:03/04/03ISR Number: 4071093-9Report Type:Expedited (15-DaCompany Report #PHBS2003CH02114
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--|--|--|--------------|-------|
| Hospitalization - Initial or Prolonged | | Flushing Hypotension Malaise Myalgia Nausea Vomiting | Foreign Health Professional Other | Ritalin (Methylphenidate Hydrochloride) Efexor (Venlafaxine Hydrochloride) Elisir Roborans Pm (Magnesium-, Calcium- , Natriumglycerophosp horicum; Strychnin Nitrate) Aurorix (Moclobemide) Tranxilium (Clorazepate Dipotassium) | PS SS SS C C | | |

Date: 03/04/03
 Age: 18 YR
 Gender: Female
 I/FU: I

ISR Number: 4071095-2
 Report Type: Expedited (15-DaCompany Report #PHBS2003SE02090

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|--|--|------|--------------|-------|
| Other | | Angioneurotic Oedema | Foreign Health Professional Other | Ritalin (Methlphenidate Hydrochloride) | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/05/03ISR Number: 4071224-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE01089
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypothyroidism Thyroid Atrophy | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| 10 | | | Other | | | | |
| MG-0-5MG/DAY, | | | | | | | |
| ORAL | | | | | | | |

Date:03/07/03ISR Number: 4072728-7Report Type:Expedited (15-DaCompany Report #PHEH2003US01685
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|--|--------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Obsessive-Compulsive Disorder Tourette'S Disorder | Consumer | Ritalin(Methylphenid ate Hydrochloride) Concerta (Methylphenidate Hydrochloride) | PS SS | | |

Date:03/10/03ISR Number: 4073121-3Report Type:Expedited (15-DaCompany Report #NSADSS2003010350
Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Anorexia Depression Self-Induced Vomiting | Consumer | Concerta (54 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54MG, 1 IN 1 | | | | | | | |
| DAY (S), ORAL | | | | | | | |

Date:03/10/03ISR Number: 4073522-3Report Type:Expedited (15-DaCompany Report #NSADSS2003009649
Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------------|---------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Depression Suicidal Ideation | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | |

Date:03/10/03ISR Number: 4073527-2Report Type:Expedited (15-DaCompany Report #NSADSS2003009651
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|--|------|--------------|-------|
| Other | | Idiopathic Thrombocytopenic Purpura | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

ORAL

Date:03/10/03ISR Number: 4074467-5Report Type:Expedited (15-DaCompany Report #EMADSS2003001829
Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------------|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Dehydration Haematemesis | Foreign Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/12/03ISR Number: 4072011-XReport Type:Direct
Age:73 YR Gender:Male I/FU:I

Company Report #CTU 188576

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----------------------------------|---------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged 15 MG BID | | Diarrhoea Febrile Neutropenia | | D-Methylphenidate 5 Mg Tabs Biologics | PS | | ORAL |
| ORAL | | Nausea Vomiting | | Placebo 5 Mg Tabs Biologics | SS | | |

Date:03/12/03ISR Number: 4072071-6Report Type:Direct
Age:11 YR Gender:Female I/FU:I

Company Report #USP 55494

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------------------|----------|--------------|-------|
| Other | | Medication Error | | Concerta Concerta | PS SS | Sandoz Alza | |

Date:03/13/03ISR Number: 4074031-8Report Type:Direct
Age:10 YR Gender:Female I/FU:I

Company Report #CTU 188661

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------|--------------------|------|--------------|-------|
| 20 1 QD | | Disturbance In Attention | | Ritalin Sr 20mg Qd | PS | | |

Date:03/13/03ISR Number: 4076034-6Report Type:Expedited (15-DaCompany Report #PHEH2002US10433
Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|--|---------------|---|------|--------------|-------|
| Other 10 MG, TID, ORAL | | Leukocytoclastic Vasculitis Petechiae Pharmaceutical Product Complaint | Consumer | Methylphenidate (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

Date:03/13/03ISR Number: 4076078-4Report Type:Expedited (15-DaCompany Report #PHBS2003NO02324
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------------|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination, Visual | Foreign Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG/DAY | | | Other | | | | |
| ORAL | | | | Concerta | C | | |

Date:03/13/03ISR Number: 4076079-6Report Type:Expedited (15-DaCompany Report #PHNR2003AU00606
Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination | Foreign Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | |
| 40 MG | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/13/03ISR Number: 4076128-5Report Type:Expedited (15-DaCompany Report #PHNU2002DE04262
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Impaired Healing Peripheral Coldness Peripheral Vascular Disorder | Foreign Health Professional Other | Ritalin-Sr(Methylphe nid Hydrochloride) Slow Release Tablet | PS | | ORAL |
| 20MG/DAY, ORAL | | | | | | | |

Date:03/14/03ISR Number: 4074119-1Report Type:Direct Company Report #CTU 188714
Age:48 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------|---------------|--|--------------|------------------|------------------|
| Dose | | | | | | | |
| Required Intervention to 1 TAB BID Prevent Permanent ORAL Impairment/Damage 1 TAB BID ORAL | | Blindness Cataract | | Trileptal 300 Mg Nova Ritalin 10 Mg Nova | PS SS | Nova Nova | ORAL ORAL |
| | | | | Synthroid Climara Paxil | C C C | | |

Date:03/17/03ISR Number: 4077432-7Report Type:Expedited (15-DaCompany Report #NSADSS2003011394
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------------------------|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged 54 MG, DAILY, ORAL | | Pancytopenia Pyrexia | Health Professional | Concerta (54 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

Remeron
(Mirtazapine) SS ORAL

30 MG, DAILY,

ORAL

Date:03/17/03ISR Number: 4077435-2Report Type:Expedited (15-DaCompany Report #NSADSS2002038813
Age:21 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------------------|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Libido Decreased Testis Cancer | Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

54 MG, 1 IN 1

DAY(S), ORAL

Date:03/17/03ISR Number: 4077569-2Report Type:Expedited (15-DaCompany Report #EMADSS2003002050
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cerebrovascular Accident | Foreign Health Professional | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

18 MG, 1 IN 1

DAILY, ORAL;

36 MG, 1 IN

1 DAILY, ORAL

18-Aug-2005 11:49 AM
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Methylphenidate It
(Methylphenidate) C

Date:03/17/03ISR Number: 4077575-8Report Type:Expedited (15-DaCompany Report #EMADSS2003001983
Age:5 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Blood Pressure Increased Gastrointestinal Infection Medication Error Pyrexia | Foreign Health Professional | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |
| DAILY, ORAL | | | | | | | |

Date:03/18/03ISR Number: 4078062-3Report Type:Expedited (15-DaCompany Report #NSADSS2003011185
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|--|------|--------------|-------|
| Other | | Cerebral Cyst Sinusitis Upper Respiratory Tract Infection | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAILY, ORAL | | | | | | | |

Clonidine
(Clonidine) C

Date:03/19/03ISR Number: 4078137-9Report Type:Direct Company Report #CTU 189122
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------|--|------|--------------|-------|
| Other | | Drug Effect Decreased Educational Problem Pharmaceutical Product | | Ritalin (Methlphenidate) 20mg Geneva | PS | Geneva | ORAL |
| 20MG TID PO | | | | | | | |

Complaint

Date:03/19/03ISR Number: 4078871-0Report Type:Expedited (15-DaCompany Report #NSADSS2003012338
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | Consumer | Concerta (Sustained | | | |
| | | Fall | | Release Tablet) | | | |
| | | Gait Disturbance | | (Methylphenidate | | | |
| | | Loss Of Consciousness | | Hydrochloride) | PS | | ORAL |
| 54 MG, 1 IN 1 | | | | | | | |
| | | Medication Error | | | | | |
| DAY(S), ORAL; | | | | | | | |
| | | | | | | | |
| 72 MG, 1 IN 1 | | | | | | | |
| TIME(S) | | | | Clonidine | C | | |

Date:03/20/03ISR Number: 4080450-6Report Type:Expedited (15-DaCompany Report #NSADSS2002038993
 Age:15 YR Gender:Male I/FU:F

| Outcome | PT |
|----------------------|--------------------------|
| Hospitalization - | Alanine Aminotransferase |
| Initial or Prolonged | Increased |
| | Aspartate |
| | Aminotransferase |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Increased
Pancreatitis

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------|--|------|--------------|-------|
| | | Health Professional | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | | | |

Date:03/20/03ISR Number: 4080739-0Report Type:Expedited (15-DaCompany Report #PHBS2003NL02778
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|------------------------|---------------------------|--|------|--------------|-------|
| Dose Other | | Chest Pain Dyspnoea | Foreign Consumer Other | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 30 MG/DAY, ORAL | | | | | | | |

Date:03/20/03ISR Number: 4080820-6Report Type:Expedited (15-DaCompany Report #EMADSS2003002190
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|---|-----------------------------|--|------|--------------|-------|
| Dose Other | | Apathy Depressed Mood Sedation Social Avoidant Behaviour | Foreign Health Professional | Concerta (54 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54 MG, DAILY, ORAL | | | | | | | |

Date:03/25/03ISR Number: 4080170-8Report Type:Direct Company Report #CTU 189407
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Face Oedema Feeling Hot Flushing | | Methylphenidate 5mg Geneva Ndc 00781-8841-01 | PS | Geneva | ORAL |
| 5MG PO Q AM | | Rash | | | | | |
| AND QHS | | Urticaria | | Tenex | C | | |

Date:03/26/03ISR Number: 4084114-4Report Type:Expedited (15-DaCompany Report #EMADSS2003002050
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Cerebrovascular Accident Haemorrhage Intracranial | Foreign Health Professional | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | Mehylphenidate Ir (Methylphenidate) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/28/03ISR Number: 4080241-6Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12217170
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alanine Aminotransferase | | Trazodone Hcl Tabs | PS | Apothecon | ORAL |
| 50-100 mg | | Increased | | Concerta Xl | SS | | ORAL |
| | | Aspartate | | Isotretinoin | C | | |
| | | Aminotransferase | | | | | |
| | | Increased | | | | | |
| | | Blood Triglycerides | | | | | |
| | | Abnormal | | | | | |
| | | Epistaxis | | | | | |
| | | Gamma-Glutamyltransferase | | | | | |
| | | Increased | | | | | |
| | | Lipids Increased | | | | | |

Date:03/28/03ISR Number: 4083381-0Report Type:Direct Company Report #CTU 189700
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Methylphenidate Hcl | PS | | |
| 5MG Q AM AND | | Pharmaceutical Product | | | | | |
| NOON | | Complaint | | Methylphenidate Hcl | SS | | |
| 20MG Q AM AND | | | | | | | |
| NOON | | | | | | | |

Date:03/28/03ISR Number: 4083568-7Report Type:Periodic Company Report #2002UW14531
Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Required | | Bradycardia | Distributor | Zestril | PS | | ORAL |
| 40 MG QD PO | | | | | | | |
| Intervention to | | Syncope | | Concerta | SS | | ORAL |
| 36 MG QD PO | | | | | | | |
| Prevent Permanent | | | | | | | |
| Impairment/Damage | | | | | | | |

Date:03/28/03ISR Number: 4083684-XReport Type:Direct
Age:7 YR Gender:Male I/FU:I

Company Report #CTU 189715

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---------------------|---------------|--------------------|------|--------------|-------|
| Life-Threatening | | Abnormal Behaviour | | Depakote 250 Mg X6 | PS | | |
| Hospitalization - | | Crying | | Ritilan 20mg X3 | SS | | |
| Initial or Prolonged | | Physical Assault | | | | | |
| | | Psychiatric Symptom | | | | | |
| | | Skin Discolouration | | | | | |
| | | Weight Decreased | | | | | |

Date:03/28/03ISR Number: 4086792-2Report Type:Expedited (15-DaCompany Report #EMADSS2003001829
Age:7 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------|---------------|-------------------|------|--------------|-------|
| Hospitalization - | | Dehydration | Foreign | Concerta(18 Mg | | | |
| Initial or Prolonged | | Dyspraxia | Health | Sustained Release | | | |
| | | Haematemesis | Professional | Tablet) | | | |
| | | Insomnia | | (Methylphenidate | PS | | ORAL |
| | | Learning Disorder | | Hydrochloride) | | | |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY(S), ORAL | | | | Melatonin | | | |
| | | | | (Melatonin) | C | | |
| | | | | Vallergen | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Alimemazine
Tartrate) C

Date:03/31/03ISR Number: 4083947-8Report Type:Direct Company Report #CTU 189823
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Methylphenidate 20mg | PS | | ORAL |
| PO TID | | Pharmaceutical Product | | | | | |
| [SEVERAL | | Complaint | | | | | |
| MONTHS] | | | | | | | |

Date:03/31/03ISR Number: 4087342-7Report Type:Expedited (15-DaCompany Report #EMADSS2003002413
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Body Temperature Increased | Foreign Health Professional | Concerta (Sustained Release Tablets) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54 MG , ORAL | | Dysarthria | | | | | |
| | | Facial Paresis | | Clonidine (Clonidine) | C | | |
| | | Headache | | | | | |

Date:03/31/03ISR Number: 4087520-7Report Type:Expedited (15-DaCompany Report #PHBS2003CA01572
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Neurofibromatosis | Foreign Health Professional | Ritalin-Sr (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 20; 40 MG, | | | Other | | | | |
| QD, ORAL | | | | | | | |

Date:03/31/03ISR Number: 4087553-0Report Type:Expedited (15-DaCompany Report #PHNU2002DE03759
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Thyroid Stimulating Hormone Increased Thyroid Adenoma | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |
| 20 MG, QD, | | | Other | | | | |
| ORAL | | | | | | | |

Date:03/31/03ISR Number: 4087609-2Report Type:Expedited (15-DaCompany Report #PHNU2003DE01337
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Activated Partial Thromboplastin Time Prolonged | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | |
| 365 DAY | | Antiphospholipid Antibodies Positive Von Willebrand'S Disease | Other | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/02/03ISR Number: 4088103-5Report Type:Expedited (15-DaCompany Report #CEL-2003-00606-ROC
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|---|--------|--------------|-------|
| Hospitalization - Initial or Prolonged | | General Physical Health Deterioration Tic | Health Professional | Metadate Cd (Methylphenidate Hydrochloride) | PS | | |
| 20 MG (20 MG, QD), UNK | | | | Depakote (Valproate Semisodium) Ssri (Ssri) | C C | | |

Date:04/04/03ISR Number: 4089913-0Report Type:Expedited (15-DaCompany Report #PHEH2003US02507
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------|---|------|--------------|-------|
| Other | | Cardiac Arrest | Consumer | Ritalin (Methylphenidate Hydrochloride) | PS | | |

Date:04/04/03ISR Number: 4090090-0Report Type:Expedited (15-DaCompany Report #PHBS2003UY03435
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Oral Infection Oral Soft Tissue Disorder Viral Infection | Foreign Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | ORAL |
| 1 MG/KG/DAY, ORAL | | | Other | | | | |

Date:04/04/03ISR Number: 4090124-3Report Type:Expedited (15-DaCompany Report #CEL-2003-00586-ROC (0)
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|-------|----------|--|--|----|------|
| Other | Epilepsy | Health Professional Company Representative | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | ORAL |
|-------|----------|--|--|----|------|

40 MG (40 MG,
Q AM), PO

Date:04/04/03ISR Number: 4090814-2Report Type:Expedited (15-DaCompany Report #PHNU2003DE00892
Age:12 YR Gender:Female I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|--------------------------------------|--|------|--------------|-------|
| | | Electrocardiogram Qt Corrected Interval Prolonged | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

30 MG/DAY,
ORAL

Date:04/04/03ISR Number: 4091005-1Report Type:Expedited (15-DaCompany Report #PHFR2003GB01311
Age:14 YR Gender:Male I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|-------------------------------------|--------------------------------------|---|------|--------------|-------|
| | | Raynaud'S Phenomenon Tachycardia | Foreign Health Professional Other | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | PS | | ORAL |

20MG/DAY;

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Date:04/11/03ISR Number: 4094191-2Report Type:Expedited (15-DaCompany Report #NSADSS2003016574
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------|---|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anger | Health Professional Company Representative | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 72 MG, 1 IN 1 | | | | | | | |
| DAILY; ORAL; | | | | | | | |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY(S); ORAL | | | | | | | |

Strattera/Atomoxetine
C

Date:04/15/03ISR Number: 4095884-3Report Type:Expedited (15-DaCompany Report #PHNU2003DE01527
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cerebral Haemorrhage Coagulopathy Haemorrhage | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 0.5 DF QD | | | | | | | |
| ORAL | | | | | | | |

Ritalin-Sr
(Methylphenidate

Freedom Of Information (FOI) Report

1 DF QD ORAL
 Hydrochloride) Slow
 Release Tablet SS ORAL

Date:04/15/03ISR Number: 4096014-4Report Type:Expedited (15-DaCompany Report #PHBS2003JP03691
 Age:36 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Overdose Renal Failure Acute Rhabdomyolysis | Foreign Health Professional Other | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

50 TABLETS,
 ONCE/SINGLE,
 ORAL

Date:04/18/03ISR Number: 4098819-2Report Type:Expedited (15-DaCompany Report #NSADSS2003008050
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Headache Pyrexia Thrombocythaemia | Health Professional Company Representative | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

18, 1 IN 1
 DAY(S), ORAL

Date:04/18/03ISR Number: 4098846-5Report Type:Expedited (15-DaCompany Report #PHRM2003FR01240
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Adrenal Insufficiency Headache Hearing Impaired | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |

ORAL

| | | | | | |
|--------------|-----------------------|-------|----------------------|----|--|
| | Intracranial Pressure | Other | Viraferon(Interferon | | |
| | Increased | | Alfa-2b) Solution | | |
| | Vision Blurred | | For Injection | SS | |
| SUBCUTANEOUS | SUBCUTANEOUS | | | | |

Date:04/21/03ISR Number: 4093998-5Report Type:Expedited (15-DaCompany Report #CH-ROCHE-335934
Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-----------------------|---------------|---------------|------|--------------|-------|
| Dose Duration | | | | | | |
| Life-Threatening | Condition Aggravated | Consumer | Valium | PS | Roche | ORAL |
| Hospitalization - | Electrocardiogram Qt | | Ketalgine | | | |
| Initial or Prolonged | Prolonged | | (Switzerland) | SS | | ORAL |
| | Hypomagnesaemia | | Ketalgine | | | |
| | Loss Of Consciousness | | (Switzerland) | SS | | ORAL |
| DOSAGE | | | | | | |
| | Syncope | | | | | |
| DECREASED IN | | | | | | |
| | Torsade De Pointes | | | | | |
| RESPONSE TO | | | | | | |
| EVENTS. | | | | | | |
| | | | Risperdal | SS | | ORAL |
| | | | Ritalin | SS | | |
| UNKNOWN | | | | | | |
| | | | Ritalin | SS | | |
| UNKNOWN | | | | | | |
| | | | Cocaine | SS | | |
| UNKNOWN | | | | | | |
| | | | Ilomedin | SS | | |
| INTRAVENOUS | 30 DAY | | | | | |
| | | | Mst | C | | ORAL |
| | | | Seresta | C | | ORAL |
| | | | Liquemin | C | | |
| INTRAVENOUS | STRENGTH: 5000 | | | | | |
| AND 25000 U. | 29 DAY | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/21/03ISR Number: 4099224-5Report Type:Expedited (15-DaCompany Report #EMADSS2003003151
 Age:37 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---------------|--|-----------------------------|--|-------------|--------------|-------|
| Life-Threatening Hospitalization - Initial or Prolonged | 2 MG, DAILY, | Drug Abuser | Foreign Health Professional | Risperdal (2 Mg Tablet) (Risperidone) | PS | | ORAL |
| ORAL | | Medication Error | | | | | |
| 160 MG, | | Peripheral Ischaemia Torsade De Pointes | | Ketalgin (Methadone Hydrochloride) | SS | | ORAL |
| DAILY, ORAL | | Ventricular Tachycardia | | | | | |
| | | | | Kokain (Cocaine) Ritalin (Methylphenidate Hydrochloride) | SS | | |
| INTRA-ARTERIAL | ARTER | | | | | | |
| 20 MG, DAILY, | | | | Valium (Diazepam) | SS | | ORAL |
| ORAL | | | | | | | |
| INTRAVENOUS | 50 MG, DAILY, | | | Ilomedin (Iloprost) | SS | | |
| IV | | | | | | | |
| | | | | Seresta (Oxazepam) Mst (Morphine Sulfate) Liquemin (Heparin) | C C C | | |

Date:04/21/03ISR Number: 4099606-1Report Type:Expedited (15-DaCompany Report #PHRM2003FR01253
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------|-----------------------------|---|------|--------------|-------|
| Other | | Conduction Disorder | Foreign Health Professional | Ritaline(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | Other | | | | |

Date:04/22/03ISR Number: 4099931-4Report Type:Expedited (15-DaCompany Report #EMADSS2003003300
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------------------|-----------------------------------|---|------|--------------|-------|
| Dose Other | | Pseudo Lymphoma Skin Disorder | Foreign Health Professional | Concerta Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | 10 WK | | | | | | |

Date:04/22/03ISR Number: 4100751-2Report Type:Expedited (15-DaCompany Report #CEL-2003-00606-ROC
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-----|------------------------|---|--------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Tic | Health Professional | Metadate Cd (Methylphenidate Hydrochloride) | PS | | |
| 20 MG (20 MG, QD); 40 MG (20 MG, QD) | | | | Depakote (Valproate Semisodium) Ssri | C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/23/03ISR Number: 4101649-6Report Type:Expedited (15-DaCompany Report #CEL-2003-00919-ROC
Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------------|------------------------|---|---------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Headache Petit Mal Epilepsy | Health Professional | Metadate (Formulation Unspecified) Methylphenidate Hydrochloride) Strattera Celexa (Citalopram Hydrobromide) | PS SS C | | |

Date:04/23/03ISR Number: 4101676-9Report Type:Expedited (15-DaCompany Report #CEL-2003-00606-ROC(2)
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------|------------------------|---|--------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Anxiety Tic | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | |
| SEE IMAGE | | | | Depakote (Valproate Semisodium) Ssri (Ssri) | C C | | |

Date:04/24/03ISR Number: 4102312-8Report Type:Expedited (15-DaCompany Report #NSADSS2003018777
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|------------|--|---------------|--|------|--------------|-------|
| Death | | Brain Oedema Drug Abuser | Other | Duragesic (100 Mcg/ Hr Patch) (Fentanyl) | PS | | |
| TRANSDERMAL | 100 MCG/H, | Endocardial Disease | | | | | |
| TRANSD | | Haemorrhage Overdose Petechiae Pleural Disorder Pulmonary Congestion | | Darvon (Dextropropoxyphene Hydrochloride) Ritalin (Methylphenidate | SS | | |

Pulmonary Oedema
Respiratory Arrest
Toxicologic Test Abnormal

Hydrochloride) SS
Marijuana (Cannabis) SS

Date:04/24/03ISR Number: 4102482-1Report Type:Expedited (15-DaCompany Report #PHEH2003US03056
Age:19 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|----------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Glaucoma | Consumer | Ritalin(Methylphenidate Hydrochloride) Unknown | PS | | ORAL |
| 20 MG, QD, ORAL | | | | | | | |

Date:04/25/03ISR Number: 4097931-1Report Type:Direct Company Report #USP 51470
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------------------|----------|--------------|-------|
| Dose | | | | | | | |
| | | Medication Error | | Ritalin Sr Ritalin | PS SS | Ciba Ciba | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/25/03ISR Number: 4103211-8Report Type:Expedited (15-DaCompany Report #2003016398
Age:16 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--------------------------------------|--|------|--------------|-------|
| Death | | Completed Suicide Drug Level Increased | Literature Health Professional | Hydroxyzine Hydrochloride (Tablet) (Hydroxyzine Hydrochloride) | PS | | ORAL |
| ORAL | | | | Amitriptyline (Amitriptyline) | SS | | ORAL |
| ORAL | | | | Methylphenidate (Methylphenidate) | SS | | ORAL |
| ORAL | | | | Nortriptyline (Nortriptyline) | SS | | ORAL |

Date:04/28/03ISR Number: 4104145-5Report Type:Expedited (15-DaCompany Report #NSADSS2003018691
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------------|---|--|------|--------------|-------|
| Other | | Dizziness Syncope Vomiting | Health Professional Company Representative | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | | | | |

Date:04/28/03ISR Number: 4104199-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE01648
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Circulatory Collapse Ventricular Extrasystoles | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| 25MG/DAY, | | | | | | | |

ORAL

Date:04/28/03ISR Number: 4104233-3Report Type:Expedited (15-DaCompany Report #PHFR2002GB04019

Age: Gender: I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------------------|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Allergic Granulomatous Angiitis | Foreign Health Professional Other | Methylphenidate Hydrochloride (Methylphenidate Hydrochloride) Unknown | | | |
| | | | | | PS | | ORAL |

ORAL

Date:04/28/03ISR Number: 4104488-5Report Type:Expedited (15-DaCompany Report #PHBS2003JP03109

Age:46 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Erythema Ichthyosis Acquired Pigmentation Disorder | Other | Anafranil(Clomiprami ne Hydrochloride) Tablet | | | |
| 10 MG/DAY, | | Rash Papular | | | PS | | ORAL |
| ORAL | | Xerosis | | Ritalin(Methylphenid ate Hydrochloride) | SS | | ORAL |
| 20 MG/DAY, | | | | | | | |
| ORAL | | | | Rohypnol (Flunitrazepam) | C | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Serenzin C
 Reslin (Trazodone
 Hydrochloride) C
 Ethyl Loflazepate
 (Ethyl Loflazepate) C
 Miradol (Sulpiride) C

Date:04/30/03ISR Number: 4104588-XReport Type:Expedited (15-DaCompany Report #US010793
 Age:32 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------|---------------------|------------------|----------|--------------|-------|
| Other | | Convulsion | Health Professional | Actiq Methadone | PS SS | | ORAL |
| 100 MG TID | | | | | | | |
| ORAL | | | | | | | |
| 60 MG PRN | | | | Morphine Sulfate | SS | | ORAL |
| ORAL | | | | | | | |
| 25 MG TID | | | | Ritalin | SS | | ORAL |
| ORAL | | | | | | | |

Date:04/30/03ISR Number: 4104590-8Report Type:Expedited (15-DaCompany Report #US010793
 Age:33 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------------|---------------------|----------------|----------|--------------|-------|
| Other | | Convulsion Depression | Health Professional | Actiq Provigil | PS SS | | ORAL |
| 200 MG QAM | | | | | | | |
| ORAL | | Somnolence | | | | | |
| 100 MG QPM | | | | Provigil | SS | | ORAL |
| ORAL | | | | | | | |
| 100 MG TID | | | | Methadone | SS | | ORAL |

| | | | | | |
|------------|--|--|------------------|----|------|
| ORAL | | | | | |
| 60 MG PRN | | | Morphine Sulfate | SS | ORAL |
| ORAL | | | | | |
| 25 MG TID | | | Ritalin | SS | ORAL |
| ORAL | | | | | |
| 150 MG QHS | | | Effexor | SS | ORAL |
| ORAL | | | | | |
| 225 MG QHS | | | Effexor | SS | ORAL |
| ORAL | | | | | |

Date:04/30/03ISR Number: 4105121-9Report Type:Expedited (15-DaCompany Report #A001-002-005498
Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|------------------------|---------------|---------------------|------|--------------|-------|
| Required | | Asthenia | Health | Aricept (Donepezil) | | | |
| Intervention to | | Nausea | Professional | (Donepezil | | | |
| Prevent Permanent | | Vomiting | | Hydrochloride) | PS | | ORAL |
| 10 MG, 1 IN 1 | | | | | | | |
| Impairment/Damage | | White Blood Cell Count | | | | | |
| D, PER ORAL | | Decreased | | Ritalin Sr | | | |
| | | | | (Methylphenidate | | | |
| 20 MG, ORAL; | | | | Hydrochloride) | SS | | ORAL |
| 40 MG, ORAL | | | | | | | |
| | | | | Albuterol | | | |
| | | | | (Salbutamol) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/30/03ISR Number: 4105775-7Report Type:Expedited (15-DaCompany Report #CEL-2003-00925-ROC(0)
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine Phosphokinase Monoplegia Pain In Extremity | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG (20 MG, QAM SCHOOL DAYS); PO/ APROXI. 1 1/2 WEEKS | | | | | | | |

Date:05/01/03ISR Number: 4106368-8Report Type:Expedited (15-DaCompany Report #NSADSS2003020304
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression Anxiety Hallucination | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | Nightmare | | Paxil (Parozetine Hydrochloride) | C | | |

Date:05/01/03ISR Number: 4106370-6Report Type:Expedited (15-DaCompany Report #NSADSS2003020199
 Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Accident Drowning Treatment Noncompliance | Consumer | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | | | | | |

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--|--|---|-------------|--------------|-------|
| Dose Duration Hospitalization - Initial or Prolonged Disability | Arthralgia Blood Magnesium Decreased Drug Abuser Electrocardiogram Qt | Foreign Health Professional Other | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | |
| 10 MG/DAY, INJECTION NOS | Prolonged | | | | | |
| 160 MG/DAY | Extremity Necrosis Finger Amputation | | Ketalgin(Methadone Hydrochloride) | SS | | |
| 2 MG/DAY | Gangrene Intentional Misuse | | Risperdal (Risperidon e) | SS | | |
| 20 MG/DAY | Loss Of Consciousness | | Valium(Diazepam) | SS | | |
| INTRAVENOUS 5000 IU, INTRAVENOUS | Medication Error Necrosis Ischaemic | | Urokinase(Urokinase) | SS | | |
| INTRAVENOUS 50 MG, INTRAVENOUS | Peripheral Ischaemia Syncope | | Ilomedin(Iloprost) | SS | | |
| | Torsade De Pointes Ventricular Tachycardia | | Mst (Morphine Sulfate) Seresta (Oxazepam) Liquemin (Heparin) | C C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/07/03ISR Number: 4109224-4Report Type:Expedited (15-DaCompany Report #PHBS2003BE04237
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Increased Appetite Weight Increased | Foreign Health Professional Other | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | | | | | | |

Date:05/07/03ISR Number: 4109247-5Report Type:Expedited (15-DaCompany Report #PHFR2003GB01785
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Activated Partial Thromboplastin Time Prolonged | Foreign Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | Contusion | Other | | | | |

Date:05/07/03ISR Number: 4109719-3Report Type:Expedited (15-DaCompany Report #NSADSS2003021341
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|--|--------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Headache Loss Of Consciousness Ventricular Extrasystoles | Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | Motrin (Ibuprofen) Tylenol (Paracetamol) | C C | | |

Date:05/09/03ISR Number: 4110831-3Report Type:Direct Company Report #
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Date:05/12/03ISR Number: 4110935-5Report Type:Direct
Age:8.5 YR Gender:Male I/FU:I

Company Report #CTU 192758

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------------------------------|---------------|-------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression | | Ritalin 10mg Methaphildate | PS | | ORAL |
| 10MG 3X ORAL | | Depression Emotional Disorder | | | | | |

Date:05/13/03ISR Number: 4111930-2Report Type:Expedited (15-DaCompany Report #NSADSS2003017198
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Crying Emotional Disorder Hallucination, Tactile Hallucination, Visual | Health Professional | Concerta (36 Mg Sustained Release Tablet) (Methyphenidate Hydrochloride) | PS | | ORAL |
| 72 MG, 1 IN 1 DAY (S), ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/15/03ISR Number: 4112929-2Report Type:Expedited (15-DaCompany Report #PHEH2003US03697
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|-------------|--|---------------|--|----------|--------------|-------|
| Death | | Brain Oedema Endocardial Disease Haemorrhage Intentional Misuse Medication Tampering | Other | Ritalin (Methylphenidate Hydrochloride) Tablet Fentanyl (Fentanyl) | PS SS | | |
| TRANSDERMAL | 100 MCG/HR, | Petechiae | | | | | |
| TRANSDERMAL | | Pleural Haemorrhage Pulmonary Congestion Pulmonary Oedema Respiratory Arrest Toxicologic Test Abnormal | | Dextropropoxyphene (D extropropoxyphene) Marijuana (Cannabis) | SS SS | | |

Date:05/15/03ISR Number: 4112974-7Report Type:Expedited (15-DaCompany Report #PHRM2003FR01240
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|--------------|---|--|--|----------|--------------|-------|
| Life-Threatening | | Adrenal Insufficiency Hearing Impaired Intracranial Pressure Increased | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet Viraferon (Interferon Alfa-2b) Solution For Injection | PS SS | | ORAL |
| ORAL | | | | | | | |
| SUBCUTANEOUS | SUBCUTANEOUS | | | | | | |

Date:05/15/03ISR Number: 4113342-4Report Type:Expedited (15-DaCompany Report #PHFR2003GB01831
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------------|--|------|--------------|-------|
| Death | | Cardiac Arrest Cardiac Disorder Circulatory Collapse | Foreign Health Professional | Methylphenidate (Meth ylphenidate Hydrochloride) | | | |

| | | | | | |
|-----------|--|-------|--|----|------|
| ORAL | Electrocardiogram | Other | Unknown | PS | ORAL |
| | Abnormal Electrocardiogram Repolarisation Abnormality | | Ritalin-Sr (Methylphenidate Hydrochloride) Unknown | SS | |
| 20 MG/DAY | Myocardial Infarction Ventricular Tachycardia | | | | |

Date: 05/19/03
 ISR Number: 4113174-7
 Report Type: Expedited (15-DaCompany Report #PHBS2003US04722
 Age: 48 YR Gender: Female I/FU: I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|--------------------------------------|---|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Back Pain Confusional State Disorientation Drug Interaction | Literature Health Professional | Methylphenidate (Methylphenidate Hydrochloride) Unknown | PS | | |
| 10 MG, TID, | Drug Withdrawal Syndrome Grand Mal Convulsion | | Venlafaxine (Venlafaxine) Unknown | SS | | |
| SEE IMAGE | Insomnia | | Zolpidem (Zolpidem) Unknown | SS | | |
| 10 MG, QHS, | Muscle Spasms Nausea Serotonin Syndrome Somnolence | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/19/03ISR Number: 4113272-8Report Type:Expedited (15-DaCompany Report #PHEH2003US03667
Age:22 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | |
| | | | | Effexor (Venlafaxine Hydrochloride) | SS | | |

Date:05/19/03ISR Number: 4115106-4Report Type:Expedited (15-DaCompany Report #PHNU2003DE01648
Age:17 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------------|---------------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Syncope | Foreign Health Professional | Ritaline(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| Other | 25 MG/DAY, | Ventricular Extrasystoles | Other | | | | ORAL |

Date:05/19/03ISR Number: 4115292-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE00993
Age:19 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Henoch-Schonlein Purpura | Foreign Health Professional | Ritaline(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| | | Leukopenia | | | | | |
| | | Lymphopenia | | | | | |
| SEE IMAGE | | | Other | Cipramil Film-Coated Tablet | C | | |
| | | | | Fenistil | C | | |

Date:05/20/03ISR Number: 4115319-1Report Type:Expedited (15-DaCompany Report #NSADSS2003022622
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|-------------|-----------------------|------------------------|---|----|------|
| Other | Delirium Mydriasis | Health Professional | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | ORAL |
| 36 MG, 1 IN | | | | | |
| 12 DAY(S), | | | | | |
| ORAL | | | | | |

Date:05/20/03ISR Number: 4115320-8Report Type:Expedited (15-DaCompany Report #NSADSS2003022997
Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|------------------------|---|------|--------------|-------|
| Other | | Agitation Hallucination, Visual Screaming | Health Professional | Concerta (27 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 27 MG, 1 IN 1 | | | | | | | |
| DAY(S), ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/20/03ISR Number: 4115322-1Report Type:Expedited (15-DaCompany Report #NSADSS2003007333
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------|------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hallucination Malaise | Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | Promethazine With Codeine | C | | |

Date:05/20/03ISR Number: 4115324-5Report Type:Expedited (15-DaCompany Report #NSADSS2002046188
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|------------------------|---|------|--------------|-------|
| Death | | Sudden Cardiac Death Ventricular Tachycardia | Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate) | PS | | ORAL |
| SEE IMAGE | | | | | | | |

Date:05/21/03ISR Number: 4115891-1Report Type:Expedited (15-DaCompany Report #PHFR2003GB01961
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Leukaemia Monocytic | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) | PS | | |

Date:05/21/03ISR Number: 4118082-3Report Type:Direct Company Report #CTU 193534
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------|---------------|---------|------|--------------|-------|
| Other 20MG AM, 15 | | Abnormal Behaviour | | Ritalin | PS | | |

Crying
AT NOON, 5 AT
Pharmaceutical Product
3PM
Complaint

Date:05/21/03ISR Number: 4118088-4Report Type:Direct Company Report #CTU 193536
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | | | | | |
| 18MG ORAL | | Disturbance In Attention | | Concerta 18mg Mcneil | PS | Mcneil | ORAL |
| | | Educational Problem | | | | | |
| | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |

Date:05/22/03ISR Number: 4116744-5Report Type:Expedited (15-DaCompany Report #PHNR2003AU00498
Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| | | Anxiety | Foreign | Ritalin La | | | |
| | | Bronchospasm | Other | (Methylphenidate | | | |
| | | | | Hydrochloride) | | | |
| | | | | Extended Release | | | |
| 40 MG, | | | | Capsules | PS | | ORAL |
| QD,ORAL | | | | | | | |
| | | | | Lomotil | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Diphenoxylate
Hydrochloride) C

Date:05/23/03ISR Number: 4116815-3Report Type:Expedited (15-DaCompany Report #EMADSS2003004081
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Eosinophilia | Foreign Health Professional | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY (S), ORAL | | | | | | | |

Date:05/23/03ISR Number: 4117123-7Report Type:Expedited (15-DaCompany Report #DSA_70099_2003
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|---------------|---|---------------|----------------------|----------|--------------|-------|
| Death | | Brain Oedema Haemorrhage | | Darvon Fentanyl | PS SS | | |
| TRANSDERMAL | 100 MCG/HR TD | Medication Error Nervous System Disorder | | Ritalin Marijuana | SS SS | | |
| VAR | | | | | | | |
| Petechiae Pleural Haemorrhage Pulmonary Congestion Pulmonary Oedema Respiratory Arrest | | | | | | | |

Date:05/23/03ISR Number: 4117169-9Report Type:Expedited (15-DaCompany Report #NSADSS2003023571
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------|---------------------|-------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Neutrophil Count Decreased | Health Professional | Risperdal (Unspecified) | | | |

| | | | | |
|---------------|------------------------|--|----|------|
| 1.5 MG, | White Blood Cell Count | (Risperidone) | PS | ORAL |
| DAILY, ORAL | Decreased | | | |
| | | Concerta (Methylphenidate Hydrochloride) | SS | ORAL |
| 36 MG, 1 IN 1 | | | | |
| DAY(S), ORAL | | | | |

Date:05/27/03ISR Number: 4119141-1Report Type:Direct Company Report #CTU 193931
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------------------|---------------|--|------|--------------|-------|
| | | Dysphemia Painful Erection | | Concerta 36 Mg And 54 Mg Separately | PS | | ORAL |
| 1 X DAY PO | | Priapism | | | | | |

Date:05/28/03ISR Number: 4117845-8Report Type:Direct Company Report #CTU 194075
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--------------------------|---------------|------------------|------|--------------|-------|
| Other 27MG Q D | | Arthritis Infective | | Concerta 27mg Qd | PS | | |
| EXISTING | | Hallucination | | | | | |
| 150MG TWO BID | | Headache | | Rifamipin | SS | | |
| | | Staphylococcal Infection | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/28/03ISR Number: 4122691-5Report Type:Periodic Company Report #NSADSS2003016575
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|----------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Psychotic Disorder | Health | Concerta | | | |
| | | Therapeutic Response | Professional | (Methylphenidate | | | |
| | | Increased | Company | Hydrochloride) | PS | | ORAL |
| 54 MG DAILY, | | | Representative | | | | |
| 2 IN 1 DAILY, | | | | | | | |
| ORAL | | | | | | | |

Date:05/28/03ISR Number: 4122769-6Report Type:Expedited (15-DaCompany Report #2003-03-2595
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|--------------|-----------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Intracranial Pressure | Foreign | Viraferon | | | |
| | | Increased | Health | (Interferon Alfa-2b) | PS | | |
| SUBCUTANEOUS | SUBCUTANEOUS | | Professional | Ritalin Tablets | SS | | ORAL |
| ORAL | | | Other | | | | |

Date:05/29/03ISR Number: 4120090-3Report Type:Expedited (15-DaCompany Report #PHBS2003JP03691
 Age:36 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Haemodialysis | Foreign | Ritalin | | | |
| Hospitalization - | | Overdose | Health | (Methylphenidate | | | |
| Initial or Prolonged | | Renal Failure Acute | Professional | Hydrochloride) | | | |
| Disability | | Rhabdomyolysis | Other | Tablet | PS | | ORAL |
| 50 TO 100 | | | | | | | |

TABLETS/DAY;

ORAL; REGIMEN

2, 40 MG/DAY;

ORAL

| | |
|----------------------|---|
| Depromel | |
| (Fluvoxamine) | C |
| Depas (Etizolam) | C |
| Halcion (Triazolam) | C |
| Rohypnol | |
| (Flunitrazepam) | C |
| Constan (Alprazolam) | C |

Date:05/29/03ISR Number: 4124828-0Report Type:Expedited (15-DaCompany Report #PHEH2003US04330
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------------------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain Cough Dyspnoea | Consumer | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | PS | | ORAL |
| 20 MG, QD, | | | | | | | |

ORAL

Date:05/30/03ISR Number: 4119520-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0409464A
 Age:44 YR Gender:Male I/FU:I

| | |
|---------|---|
| Outcome | PT |
| Other | Abdominal Distension Condition Aggravated Constipation Dizziness Drug Withdrawal Syndrome |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------|----------|--|---------------|---------------------|---------|-----------------|--------------|
| 1 | YR | Flatulence Heart Rate Irregular Hypersomnia Nausea | | Paxil | PS | Glaxosmithkline | ORAL |
| | | Oliguria Paraesthesia Paralysis Performance Status Decreased | | Ritalin Adderall | SS C | | ORAL ORAL |

Date:05/30/03ISR Number: 4120597-9Report Type:Expedited (15-DaCompany Report #NSADSS2003022356
Age:12 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|--------------|--|------------------------|---|------|--------------|-------|
| Other | 18 MG, 1 IN 1 | DAY(S), ORAL | Condition Aggravated Juvenile Arthritis Tremor | Health Professional | Concerta (18 Mg Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:05/30/03ISR Number: 4121513-6Report Type:Expedited (15-DaCompany Report #2003-05-3818
Age:36 YR Gender:Female I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | 5 X 5 MG ORAL | | Fatigue Overdose Suicide Attempt | Foreign Health Professional | Aerius (Desloratadine) Tablets Like Clarinet | PS | | ORAL |
| | 20 X 10 MG | | | | Loratadine Tablets | SS | | ORAL |
| ORAL | | | | | Ritalin Tablets | SS | | ORAL |
| | 40 X 10 MG | | | | | | | |

| | | | | | | |
|--------------|--|--|--|--------------------|----|------|
| ORAL | | | | | | |
| 7 X 10 MG | | | | Cetirizine Tablets | SS | ORAL |
| ORAL | | | | | | |
| 12 X 250 MG | | | | Cefuroxime Tablets | SS | ORAL |
| ORAL | | | | | | |
| 9600 MG ORAL | | | | Kepinol Tablets | SS | ORAL |
| 26 X 40 MG | | | | Furosemid Tablets | SS | ORAL |
| ORAL | | | | | | |

Date:06/02/03ISR Number: 4121836-0Report Type:Expedited (15-DaCompany Report #PHFR2002GB04081
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|-----------------------------------|--|------|--------------|-------|
| Death | | Cardiac Arrest Circulatory Collapse Electrocardiogram | Foreign Health Professional | Ritalin-Sr(Methylphenidate Hydrochloride) Slow Release Tablet | PS | | ORAL |
| 20MG/DAY, | | Abnormal | Other | | | | |
| ORAL | | Myocardial Infarction Sudden Death Ventricular Tachycardia | | Methylphenidate(Methylphenidate Hydrochloride) | SS | | ORAL |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/03ISR Number: 4121941-9Report Type:Expedited (15-DaCompany Report #PHFR2003GB01831
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|-----------------------------------|---|------|--------------|-------|
| Death | | Cardiac Arrest Echocardiogram Abnormal Electrocardiogram Qt | Foreign Health Professional | Methylphenidate(Meth ylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | Prolonged Myocardial Infarction Sudden Death | Other | Ritalin-Sr (Methylphenidate Hydrochloride) | SS | | |
| 20 MG/DAY | | Ventricular Tachycardia | | | | | |

Date:06/02/03ISR Number: 4121985-7Report Type:Expedited (15-DaCompany Report #PHBS2003JP03109
 Age:46 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|-----------------------------------|--|------|--------------|-------|
| Other | | Erythema Flushing Ichthyosis Acquired | Foreign Health Professional | Anafranil(Clomiprami ne Hydrochloride)Tablet | PS | | ORAL |
| 10 MG/DAY, | | Pigmentation Disorder | Other | | | | |
| ORAL | | Rash Papular Xerosis | | Ritalin(Methylphenid ate Hydrochloride) | SS | | ORAL |
| 20 MG/DAY, | | | | | | | |
| ORAL | | | | Rohypnol(Flunitrazep am) | SS | | ORAL |
| 2 MG/DAY, | | | | | | | |
| ORAL | | | | Serenzin(Diazepam) | SS | | ORAL |
| 5 MG/DAY, | | | | | | | |
| ORAL | | | | Reslin(Trazodone Hydrochloride) | SS | | ORAL |
| 75 MG/DAY, | | | | | | | |
| ORAL | | | | | | | |

300 MG/DAY,

Miradol (Sulpiride) SS

ORAL

ORAL

Ethyl Loflazepate
(Ethyl Loflazepate) C

Date:06/05/03ISR Number: 4123732-1Report Type:Direct
Age:43 YR Gender:Female I/FU:I

Company Report #CTU 195062

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|----------|---------------|-------------|------|--------------|-------|
| Hospitalization - 5 MG BID ORAL | | Nausea | | Ritalin 5mg | PS | | ORAL |
| Initial or Prolonged | | Vomiting | | Placebo | SS | | |

Date:06/05/03ISR Number: 4125233-3Report Type:Expedited (15-DaCompany Report #CEL-2003-01087-SLO(0)
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-----------|-----------------------------------|---|------|--------------|-------|
| Life-Threatening | | Epistaxis | Foreign Health Professional | Equasym (Strength Unspecified) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | Antibiotics (Antibiotics) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/05/03ISR Number: 4125604-5Report Type:Expedited (15-DaCompany Report #NSADSS2003024815
Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Upper Condition Aggravated Dyspnoea Electrocardiogram Qt | Health Professional Company Representative | Concerta (36 Mg Sustained Release Tablet) (Methylphenidate) | PS | | ORAL |
| 36 MG, 1 IN 1 DAILY, ORAL | | Prolonged Nausea | | | | | |

Date:06/09/03ISR Number: 4126414-5Report Type:Expedited (15-DaCompany Report #EMADSS2003004553
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------------|-----------------------------------|--|------|--------------|-------|
| Other | | Hallucination Insomnia | Foreign Health Professional | Concerta (Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| SEE IMAGE | | | | | | | |

Date:06/09/03ISR Number: 4126416-9Report Type:Expedited (15-DaCompany Report #EMADSS2003004554
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Other | | Facial Palsy Hemiplegia Iiird Nerve Paralysis | Foreign Health Professional | Concerta(Sustained Release Tablet) (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAILY, ORAL | | | | | | | |

Date:06/09/03ISR Number: 4126444-3Report Type:Expedited (15-DaCompany Report #EMADSS2003004226
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|---------------|----------------------|--------------|---------------------|----|------|
| Disability | Chest Pain | Foreign | Concerta (Sustained | | |
| | Musculoskeletal Pain | Health | Release Tablet) | | |
| | Viral Infection | Professional | (Methylphenidate | | |
| | | | Hydrochloride) | PS | ORAL |
| 36 MG, 1 IN 1 | | | | | |
| TIME(S), ORAL | | | | | |
| | | | Melatonin | | |
| | | | (Melatonin) | C | |
| | | | Ritalin | | |
| | | | (Methylphenidate | | |
| | | | Hydrochloride) | C | |
| | | | .. | C | |

Date:06/13/03ISR Number: 4128430-6Report Type:Direct Company Report #CTU 195703
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------|---------------|---------|------|--------------|-------|
| Disability | | Bedridden | | Ritalin | PS | | |
| | | Fatigue | | Zoloft | SS | | |
| | | Rhinorrhoea | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/16/03ISR Number: 4129396-5Report Type:Direct
 Age:30 YR Gender:Female I/FU:I

Company Report #CTU 195803

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Ear Pain | | Adderall | PS | | ORAL |
| 30MG BID | | Facial Pain | | | | | |
| DAILY ORAL | | Gingival Disorder | | Ritalin | SS | | ORAL |
| 70MG DAILY | | Hyperacusis | | | | | |
| ORAL | | Hypoaesthesia | | | | | |
| | | Mastication Disorder | | | | | |
| | | Mobility Decreased | | | | | |
| | | Muscle Spasms | | | | | |
| | | Myalgia | | | | | |
| | | Pain In Jaw | | | | | |
| | | Paraesthesia | | | | | |
| | | Trismus | | | | | |

Date:06/16/03ISR Number: 4130471-XReport Type:Expedited (15-DaCompany Report #PHBS2003CH05877
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Appendicectomy | Foreign | Ritalin | | | |
| Initial or Prolonged | | Pancreatitis Acute | Health | (Methylphenidate | PS | | |
| 10 MG/DAY | | | Professional | Hydrochloride) | | | |
| | | | Other | | | | |

Date:06/16/03ISR Number: 4130472-1Report Type:Expedited (15-DaCompany Report #PHNU2003DE02168
 Age:37 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Blood Creatine | Foreign | Ritaline | | | |
| Initial or Prolonged | | Phosphokinase Increased | Consumer | (Methylphenidate | | | |
| | | Blood Creatine | Other | Hydrochloride) | | | |
| | | Phosphokinase Mb | | Tablet | PS | | ORAL |
| 30MG/DAY, | | | | | | | |

ORAL
Increased
Chest Pain

Date:06/17/03ISR Number: 4131597-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030600089
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained | PS | | ORAL |

ORAL

Date:06/17/03ISR Number: 4131873-8Report Type:Expedited (15-DaCompany Report #EMADSS2003004554
Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Cerebral Artery Occlusion | Foreign Health | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| Other | | Facial Palsy Hemiplegia Iiird Nerve Paralysis | Professional | | | | |

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/17/03ISR Number: 4131901-XReport Type:Expedited (15-DaCompany Report #EMADSS2003001241
 Age:10 YR Gender: I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Decreased Appetite Gilbert'S Syndrome Headache Jaundice Nausea | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

36 MG, 1 IN 1

DAY; ORAL

Equasym
(Unspecified)
Methylphenidate
Hydrochloride C
Melatonin
(Unspecified)
Melatonin C

Date:06/18/03ISR Number: 4131168-2Report Type:Direct Company Report #CTU 196121
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------|---------------|---------------------------------|------|-------------------|-------|
| Hospitalization - Initial or Prolonged 54 MG PO Required QAM Intervention to Prevent Permanent Impairment/Damage | | Hallucination, Visual | | Concerta (Johnson & Johnson) | PS | Johnson & Johnson | ORAL |
| | | | | Risperdal | C | | |
| | | | | Zoloft | C | | |
| | | | | Tenez | C | | |
| | | | | Depakote | C | | |
| | | | | Dexadrine | C | | |

Date:06/18/03ISR Number: 4131169-4Report Type:Direct Company Report #CTU 196122
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|-----------------------|---------------|--------------------|------|--------------|-------|
| Hospitalization - | | Hallucinations, Mixed | | Concerta Johnson & | | | |

| | | | | | |
|--|-----------------|---------------|----|-------------------|------|
| Initial or Prolonged 54 MG PO Q AM Required Intervention to Prevent Permanent Impairment/Damage | Suicide Attempt | Johnson | PS | Johnson & Johnson | ORAL |
| | | Wellbutrin Se | C | | |
| | | Zyprexa | C | | |
| | | Colace | C | | |
| | | Maalox | C | | |

Date:06/18/03ISR Number: 4131170-0Report Type:Direct Company Report #CTU 196123
Age:6 YR Gender:Female I/FU:I

| Outcome Dose Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|-----------------------|---------------|--------------------------------|------|-------------------|-------|
| Hospitalization - Initial or Prolonged 36 MG PO QAM Required Intervention to Prevent Permanent Impairment/Damage | Hallucinations, Mixed | | Concerta, Johnson & Johnson | PS | Johnson & Johnson | ORAL |
| | | | Dexadrine | C | | |
| | | | Prozac | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/18/03ISR Number: 4131171-2Report Type:Direct
Age:8 YR Gender:Male I/FU:I

Company Report #CTU 196124

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------------|---------------|---|-----------------------|-------------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Disorientation | | Concerta, Johnson & Johnson | PS | Johnson & Johnson | ORAL |
| 36 MG PO QAM Required Intervention to Prevent Permanent Impairment/Damage | | Excitability Mania | | Lithium Zyprexa Clonidine Paxil Ritalin | C C C C C | | |

Date:06/18/03ISR Number: 4132138-0Report Type:Expedited (15-DaCompany Report #PHBS2003JP05996
Age:20 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------|-----------------------------------|---|------|--------------|-------|
| Death | | Death | Foreign Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | Other | | | | |

Date:06/19/03ISR Number: 4133059-XReport Type:Expedited (15-DaCompany Report #HQWYE536110JUN03
Age:48 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Anorexia Back Pain Confusional State | Literature | Effexor (Venlafaxine Hydrochloride, Unspec) | PS | | ORAL |
| SEE IMAGE | | Depressed Level Of Consciousness | | Methylphenidate (Methylphenidate,) | SS | | |
| 10 MG 3X PER 1 DAY | 7 YR | Depressed Mood | | | | | |
| 10 MG 1X PER 1 DAY | | Disorientation Drug Interaction | | Zolpidem (Zolpidem,) | SS | | |

Drug Withdrawal Syndrome
 Electrolyte Imbalance
 Grand Mal Convulsion
 Insomnia
 Intentional Misuse
 Metabolic Disorder
 Mood Altered
 Muscle Spasms
 Nausea
 Somnolence

Date:06/20/03ISR Number: 4133714-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030600095
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Confusional State | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/20/03ISR Number: 4133715-3Report Type:Expedited (15-DaCompany Report #NSADSS2003011394
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Biopsy Bone Marrow Abnormal Pancytopenia Pyrexia | Health Professional | Concerta (Methylphenidate Hydrochloride)Sustai ned | PS | | ORAL |
| 54 MG, 1 IN 1 DAY, ORAL | | | | Remeron (Mirtazapine) | SS | | ORAL |
| 30 MG, 1 IN 1 DAY, ORAL | | | | | | | |

Date:06/20/03ISR Number: 4133717-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030600600
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Other | | Chills Cough Fatigue Listless | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 18 MG, 1 IN 1 DAY, ORAL | | Pallor | | Tegretol (Carbamazepine) | C | | |

Date:06/20/03ISR Number: 4133722-0Report Type:Expedited (15-DaCompany Report #NSADSS2003024815
Age:13 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Upper Dyspnoea Electrocardiogram Qt Prolonged | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release | | | |

36 MG, 1 IN 1 Nausea Tablets PS ORAL

DAY, ORAL

Date:06/20/03ISR Number: 4134188-7Report Type:Expedited (15-DaCompany Report #PHFR2003GB02326
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Agitation Mydriasis | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |
| ORAL | | | Other | Methylenedioxyamphet amine | C | | |

Date:06/25/03ISR Number: 4135688-6Report Type:Direct Company Report #CTU 196638
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|---------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| | | Drug Hypersensitivity Pharmaceutical Product Complaint | | Ritalin 30mg At 800am, 20mg At 200 | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/25/03ISR Number: 4136208-2Report Type:Expedited (15-DaCompany Report #NSADSS2003012338
 Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------------|---------------|---------------------|------|--------------|-------|
| Dose | | Chest Pain | Consumer | Concerta | | | |
| Other | | Fall | Health | (Methylphenidate | | | |
| | | Gait Disturbance | Professional | Hydrochloride) | | | |
| | | Heart Rate Decreased | | Sustained Release | | | |
| | | Lethargy | | Tablets | PS | | ORAL |
| SEE IMAGE | | Loss Of Consciousness | | Clonidine (Tablets) | | | |
| | | Medication Error | | Clonidine | C | | |

Date:06/25/03ISR Number: 4163033-9Report Type:Periodic Company Report #USA030229857
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|----------------------|---------------|----------------------|------|--------------|-------|
| Dose | | Cough | Consumer | Strattera | | | |
| | | Feeling Cold | | (Atomoxetine | | | |
| 25 MG/DAY | | Malaise | | Hydrochloride) | PS | | |
| | | Pulmonary Congestion | | Prozac-Oral | | | |
| | | | | (Fluoxetine) | | | |
| | | | | (Fluoxetine | | | |
| 60 MG/DAY | | | | Hydrochloride) | SS | | |
| | | | | Concerta | | | |
| | | | | Methylphenidate | | | |
| | | | | Hydrochloride) | SS | | |
| | | | | Provigi; (Modafinil) | C | | |
| | | | | Wellbutrin | | | |
| | | | | (Bupropion | | | |
| | | | | Hydrochloride) | C | | |

Date:06/25/03ISR Number: 4163415-5Report Type:Periodic Company Report #USA030229650
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|--------------|------|--------------|-------|
| Dose | | Abdominal Pain Upper | Consumer | Strattera | | | |
| | | Abnormal Behaviour | | (Atomoxetine | | | |

18 MG/DAY

Crying

Hydrochloride)

PS

Decreased Appetite

Dizziness

Eye Disorder

Flushing

Concerta

(Methylphenidate

Hydrochloride)

SS

Date:06/27/03ISR Number: 4138233-4Report Type:Expedited (15-DaCompany Report #PHFR2002GB04081

Age:13 YR Gender:Male I/FU:F

Outcome

PT

Death

Arrhythmia

Cardiac Arrest

Chromosome Abnormality

Circulatory Collapse

Echocardiogram Abnormal

Electrocardiogram

Repolarisation

Abnormality

Medication Error

Mineral Metabolism

Disorder

Myocardial Infarction

18-Aug-2005 11:49 AM

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Pupil Fixed Sudden Death Ventricular Tachycardia | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--|--|--|------|--------------|-------|
| 20MG/DAY, ORAL | | | Foreign Health Professional Other | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | PS | | ORAL |
| UNK, UNK, ORAL | | | | Methylphenidate (Methylphenidate Hydrochloride) Unknown | SS | | ORAL |

Date: 06/27/03
 ISR Number: 4138241-3
 Report Type: Expedited (15-DaCompany Report #2003-05-3818)
 Age: 36 YR
 Gender: Female
 I/FU: F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Excitability Fatigue Intentional Misuse Suicide Attempt | Foreign Health Professional | Aerius (Desloratadine) Tablets "Like Clarinet" | PS | | ORAL |
| 5 X 5 MG ORAL | | Tachycardia | | Loratadine Tablets | SS | | ORAL |
| 20 X 10 MG ORAL | | | | Ritalin Tablets | SS | | ORAL |
| 40 X 10 MG ORAL | | | | Cetirizine Tablets | SS | | ORAL |
| 7 X 10 MG ORAL | | | | Cefuroxime Tablets | SS | | ORAL |
| 12 X 250 MG ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/27/03ISR Number: 4139357-8Report Type:Expedited (15-DaCompany Report #PHEH2003US04978
Age:49 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Dependence | Consumer | Ritalin(Methylphenidate Hydrochloride) | | | |
| | | | | Unknown | PS | | |

2190 DAY

Date:06/27/03ISR Number: 4139366-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030603190
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Residue Pharmaceutical Product Complaint | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained | | | |
| | | | | | PS | | ORAL |

ORAL

Date:06/27/03ISR Number: 4195954-5Report Type:Periodic Company Report #PHEH2003US01390
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | Health Professional | Ritalin La(Methylphenidate Hydrochloride) Extended Release Capsules | | | |
| | | | | | PS | | ORAL |

40 MG, QD

ORAL

| | | | | | | | |
|--|--|--|--|--|----|--|------|
| | | | | Ritalin(Methylphenidate Hydrochloride) Tablet | SS | | ORAL |
|--|--|--|--|--|----|--|------|

10 MG. Q4PM,

ORAL

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--------------------|-----------------------------------|---|------|--------------|-------|
| Dose Disability | | Abnormal Behaviour | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Ritalin
(Methylphenidate
Hydrochloride) C

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Dose Disability | | Abnormal Behaviour Drug Ineffective | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 18 MG, 2 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Ritalin
(Methylphenidate
Hydrochloride)
Unknown C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/03ISR Number: 4140775-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030602880
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Attention Deficit/Hyperactivity Disorder Condition Aggravated | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| | | | | Melatonin (Melatonin) Unknown | C | | |

Date:07/02/03ISR Number: 4141677-8Report Type:Expedited (15-DaCompany Report #NSADSS2003024795
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper Anorexia Weight Decreased | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG 1 IN 1 | | | | | | | |
| DAY ORAL | | | | | | | |

Qvar ()
Beclometasone Dipropionate C
Albuterol ()
Salbutamol C
Motrin () Ibuprofen C
Claritin (Loratadine) C

Date:07/02/03ISR Number: 4141691-2Report Type:Expedited (15-DaCompany Report #NL-JNJFOC-20030602514
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Amnesia | Foreign | Concerta | | | |

| | | | | | |
|---------------|--|------------------------|---|----|------|
| 36 MG, 1 IN 1 | Confusional State Depressed Level Of Consciousness | Health Professional | (Methylphenidate Hydrochloride) Sustained | PS | ORAL |
| DAY, ORAL | Hallucination, Visual | | | | |
| | Myalgia Restlessness Retrograde Amnesia Self Mutilation | | | | |

Date:07/02/03ISR Number: 4141696-1Report Type:Expedited (15-DaCompany Report #PHFR2003GB02426
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Platelet Count Increased Red Blood Cell Count Increased White Blood Cell Count Increased | Foreign Health Professional Other | Ritaline(Methylpheni date Hydrochloride) Unknown | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/07/03ISR Number: 4142846-3Report Type:Direct
Age:9 YR Gender:Male I/FU:I

Company Report #CTU 197281

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--|---------------|----------------------------|------|--------------|-------|
| Dose Other | | Drug Ineffective Pharmaceutical Product | | Generic Methylphenidate | PS | | |
| 15 MGM BID (0) | 7 YR | Complaint | | | | | |

Date:07/07/03ISR Number: 4144100-2Report Type:Expedited (15-DaCompany Report #NSADSS2003022997
Age:8 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|------------------------|---|------|--------------|-------|
| Dose Other | | Agitation Hallucination Medication Error | Health Professional | Conerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 27 MG, 1 IN 1 DAY, ORAL | | | | | | | |

Date:07/07/03ISR Number: 4144103-8Report Type:Expedited (15-DaCompany Report #NSADSS2002038804
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hallucinations, Mixed Psychotic Disorder Suicide Attempt | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 54 MG, 1 IN 1 DAY, ORAL | | | | Wellbutrin (Bupropion Hydrochloride) Tablets Zyprexa (Olanzapine) | C | | |

Tablets C
Colace (Docusate Sodium) Capsules C

Date:07/07/03ISR Number: 4144628-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030603419
Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------------------|---------------------|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged Other | Thrombocytopenia | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| 1 TABLET, DAILY. | | | Medikinet (Methylphenidate Hydrochloride) Tablets | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/08/03ISR Number: 4143391-1Report Type:Direct
Age:13 YR Gender:Female I/FU:I

Company Report #CTU 197475

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------------|------|--------------|-------|
| Death | | Sinus Arrhythmia | | Concerta 36 Mg | PS | | |

Date:07/08/03ISR Number: 4144785-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE02168
Age:37 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Blood Creatine Phosphokinase Increased Blood Creatine | Foreign Health Professional | Ritaline(Methylpheni date Hydrochloride)Tablet | PS | | ORAL |
| 10 MG, TID, ORAL | | Phosphokinase Mb Increased Chest Discomfort Chest Pain | Other | Citalopram (Citalopram) | C | | |

Date:07/08/03ISR Number: 4144815-6Report Type:Expedited (15-DaCompany Report #CEL-2003-00916-ROC
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------------------|------------------------|-----------------|------|--------------|-------|
| Dose 20 MG | | Drug Ineffective | Health Professional | Methylphenidate | PS | | |
| | | Pharmaceutical Product Complaint | Other | | | | |

Date:07/08/03ISR Number: 4145198-8Report Type:Expedited (15-DaCompany Report #PHNU2003DE02444
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------------|--|------|--------------|-------|
| Other | | Blood Alkaline Phosphatase Increased Blood Glucose Decreased | Foreign Health Professional | Ritalin-Sr (Methylphenidate Hydrochloride) | | | |

ORAL Hypoglycaemia Other Tablet PS ORAL
Leukocytosis
Sinus Tachycardia

Date:07/08/03ISR Number: 4145274-XReport Type:Expedited (15-DaCompany Report #PHNU2003DE02428
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Erectile Dysfunction Prescribed Overdose | Foreign Consumer Other | Ritaline(Methylpheni date Hydrochloride) Tablet | PS | | ORAL |

UP TO

300MG/DAY,

ORAL

Date:07/08/03ISR Number: 4145289-1Report Type:Expedited (15-DaCompany Report #PHEH2003US05290
Age:81 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------------------|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Aortic Valve Disease Overdose | Health Professional | Ritalin (Methylphenidate Hydrochloride) Unknown | PS | | |

UNKNOWN 100 MG 5

TIMES A DAY

UNK

18-Aug-2005 11:49 AM

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | |
|---------|------------|---|----|
| UNKNOWN | 40 MG UNK | Ritalin-Sr (Methylphenidate Hydrochloride) Slow Release Tablet | SS |
| UNKNOWN | 1.2 G, QD, | Provigil (Modafinil) | SS |
| UNK | | | |

Date:07/08/03ISR Number: 4145302-1Report Type:Expedited (15-DaCompany Report #PHBS2003JP06699
Age:29 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------------|---------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Dependence | Foreign Literature Health | Ritalin(Methylphenidate Hydrochloride) | PS | Unknown | ORAL |
| 20 MG/DAY, | | | Professional | | | | |
| ORAL | | | Other | Anafranil | C | | |
| | | | | Sulpiride | C | | |
| | | | | Trazodone | | | |
| | | | | Hydrochloride | C | | |
| | | | | Fluvoxamine | C | | |
| | | | | Milnacipran | | | |
| | | | | Hydrochloride | C | | |
| | | | | Valproate Sodium | C | | |
| | | | | Amoxapine | C | | |

Date:07/09/03ISR Number: 4144411-0Report Type:Direct Company Report #USP 55957
Age:43 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dizziness | | Methylphenidate | PS | Mallinckrodt | |
| | | Feeling Abnormal | | Methadone | SS | Mallinckrodt | |
| | | Medication Error | | | | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hallucinations, Mixed Psychotic Disorder | Health Professional Company | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 | | | Representative | | | | |
| DAY, ORAL | | | | Prozac (Fluoxetine Hydrochloride) | C | | |
| | | | | Albuterol Mdi (Salbutamol) | C | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|--|------|--------------|-------|
| Other | | Anaemia Anorexia Inflammatory Bowel Disease Liver Function Test | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 | | Abnormal | | | | | |
| DAY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/10/03ISR Number: 4146893-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030701084
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cyanosis | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | |
| 54 MG | | | | | | | |

Date:07/11/03ISR Number: 4145267-2Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0302394A
 Age:20 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------|---------------|-------------------------------|------|-----------------|-------|
| Hospitalization - 20MG per day Initial or Prolonged | | Neuroleptic Malignant Syndrome | | Paroxetine | PS | Glaxosmithkline | ORAL |
| | | | | Methylphenidate Hydrochloride | SS | | ORAL |
| | | | | Milnacipran Hydrochloride | C | | ORAL |

Date:07/14/03ISR Number: 4146439-3Report Type:Direct Company Report #CTU 197846
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------|---------------|-------------------------------|------|--------------|-------|
| Life-Threatening | | Drug Ineffective | | Methylphenidate 20 Milligrams | PS | | |
| Other | | Drug Screen Negative | | | | | |
| 6 DAY | | | | | | | |
| Pharmaceutical Product Complaint Weight Increased | | | | | | | |

Date:07/14/03ISR Number: 4147962-8Report Type:Expedited (15-DaCompany Report #PHEH2003US05548
 Age:41 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--------------------|---------------|----------------------|------|--------------|-------|
| Hospitalization - | | Arterial Occlusive | Health | Ritalin(Methylphenid | | | |

| | | | | | |
|----------------------|-----------------------|--------------|--------------------|----|------|
| Initial or Prolonged | Disease | Professional | ate Hydrochloride) | | |
| 5 MG, QD, | Myocardial Infarction | | Tablet, 5mg | PS | ORAL |
| ORAL | | | | | |

| | |
|--------------------|---|
| Levothyroxine | |
| (Levothyroxine) | C |
| Prozac (Fluoxetine | |
| Hydrochloride) | C |

Date:07/14/03ISR Number: 4148288-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030702159
 Age: Gender: I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|---------------------------|---------------|------------------|------|--------------|-------|
| Dose Duration | | | | | | |
| Hospitalization - | Accidental Exposure | Health | Concerta | | | |
| Initial or Prolonged | Insomnia | Professional | (Methylphenidate | | | |
| 27MG, 1 OR 2 | Muscle Twitching | | Hydrochloride) | PS | | |
| CAPSULES | Psychomotor Hyperactivity | | | | | |

Date:07/16/03ISR Number: 4150419-1Report Type:Expedited (15-DaCompany Report #PHNU2003DE02480
 Age: Gender:Female I/FU:I

Outcome
 Hospitalization -
 Initial or Prolonged

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------|----------|---|------------------------------|--|------|--------------|-------|
| | | Arrhythmia Blood Potassium Decreased | Foreign Consumer Other | Ritaline(Methylpheni date Hydrochloride)Tablet | PS | | ORAL |
| ORAL | | | | Ritalin-Sr(Methylphe nidate Hydrochloride)Slow Release Tablet | SS | | ORAL |
| ORAL | | | | Trevilor (Venlafaxine Hydrochloride) | SS | | ORAL |
| 1 DF, ONCE/SINGLE, ORAL | | | | Lorzaar Plus (Losartan Potassium) | C | | |

Date:07/21/03ISR Number: 4150385-9Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0417271A
Age:33 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|---------------|------|-----------------|-------|
| Death | | Completed Suicide | | Bupropion | PS | Glaxosmithkline | |
| Other | | Intentional Misuse | | Benadryl | SS | Glaxosmithkline | |
| | | Oedema | | Ritalin | SS | | |
| | | Pulmonary Congestion | | Codeine | SS | | |
| | | | | Acetaminophen | SS | Glaxosmithkline | |

Date:07/21/03ISR Number: 4151192-3Report Type:Direct Company Report #CTU 198301
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|-----------------------------------|---------------|--------------------------------------|------|--------------|-------|
| Life-Threatening Required | | Anxiety Gastrointestinal Ulcer | | Concerta 38 Mcneil Pharmaceutical | PS | Mcneil | |

Intervention to Gastrooesophagitis
 1 CAPSU ONCE
 Prevent Permanent
 A DAY ORAL
 Impairment/Damage

Pharmaceutical ORAL

Date:07/21/03ISR Number: 4152910-0Report Type:Expedited (15-DaCompany Report #PHFR2003GB02426
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Platelet Count Increased Red Blood Cell Count Increased White Blood Cell Count Increased | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) | PS | | |

Date:07/21/03ISR Number: 4152943-4Report Type:Expedited (15-DaCompany Report #PHFR2003GB02326
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Agitation Drug Abuser | Foreign Health Professional | Ritaline(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| ORAL | | Mydriasis | Other | Methylenedioxyamphet amine(Methylenedioxy | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

amphetamine) SS

Date:07/21/03ISR Number: 4153194-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030703323

Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------------------------|-------------------------------------|-----------------------------------|---|------|--------------|-------|
| Disability | 18 MG, 1 IN 1 DAY, ORAL | Arthralgia Haematuria Pyrexia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Released Tablets | PS | | ORAL |
| | | | | Phenergan (Promethazine Hydrochloride) | C | | |

Date:07/22/03ISR Number: 4153693-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE02607

Age:15 YR Gender:I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------------|-----------------|--|--|------|--------------|-------|
| Other | 15 MG/DAY, ORAL | Amaurosis Fugax | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

Date:07/22/03ISR Number: 4154074-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE02679

Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | 15 TO 20 | Hydrocele Post Procedural Haemorrhage | Foreign Health Professional | Ritaline (Methylphenidate Hydrochloride) | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/24/03ISR Number: 4153418-9Report Type:Expedited (15-DaCompany Report #PHBS2003ES05736
 Age:47 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|--------------------------|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Cataplexy | | Methylphenidate | PS | Novartis Sector: Pharma | |
| UNKNOWN | 10 mg/day | Drug Withdrawal Syndrome | | | | | |
| | | Somnolence | | Clomipramine | SS | | |
| UNKNOWN | 75 mg/day | | | | | | |

Date:07/24/03ISR Number: 4153421-9Report Type:Expedited (15-DaCompany Report #PHBS2003ES05735
 Age:81 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|--------------------------|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia | | Methylphenidate | PS | Novartis Sector: Pharma | |
| | | Cataplexy | | | | | |
| UNKNOWN | 20 mg/day | Drug Withdrawal Syndrome | | Clomipramine | SS | | |
| UNKNOWN | 75 mg/day | Somnolence | | | | | |

Date:07/24/03ISR Number: 4156064-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030704561
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypersomnia | Consumer | Concerta | | | |
| | | Idiopathic | | (Methylphenidate | | | |
| | | Thrombocytopenic Purpura | | Hydrochloride) | | | |
| | | | | Sustained Release | | | |
| SEE IMAGE | | | | Tablets | PS | | ORAL |
| | | | | Risperidal | | | |
| | | | | (Risperidone) | | | |
| | | | | Tablets | C | | |

Date:07/24/03ISR Number: 4156369-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030701084
 Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|----------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cyanosis | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | |
| SEE IMAGE | | | | | | | |
| | | | | B-Calm (Herbal Preparation) Tablets | C | | |

Date:07/25/03ISR Number: 4156880-0Report Type:Expedited (15-DaCompany Report #PHFR2003GB02426
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--------------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Neutropenia Red Blood Cell Count Increased Thrombocythaemia White Blood Cell Count Increased | Foreign Health Professional Other | Ritaline(Methylphenidate Hydrochloride) Unknown | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/28/03ISR Number: 4155476-4Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12217170
 Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alanine Aminotransferase | | Trazodone Hcl Tabs | PS | | ORAL |
| 50-100 mg | | Increased | | Concerta Xl | SS | | ORAL |
| | | Aspartate | | Isotretinoin | C | | |
| | | Aminotransferase | | | | | |
| | | Increased | | | | | |
| | | Epistaxis | | | | | |
| | | Gamma-Glutamyltransferase | | | | | |
| | | Increased | | | | | |
| | | Lipids Increased | | | | | |
| | | Liver Function Test | | | | | |
| | | Abnormal | | | | | |

Date:07/28/03ISR Number: 4155863-4Report Type:Direct Company Report #USP 50341
 Age:7 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| TABLET | | Blood Glucose Decreased | | Ritalin | PS | Ciba | |
| TABLET | | Brain Damage | | Glynase | SS | Upjohn | |
| | | Coma | | | | | |
| | | Convulsion | | | | | |
| | | Medication Error | | | | | |
| | | Mental Retardation | | | | | |
| | | Severity Unspecified | | | | | |
| | | Overdose | | | | | |

Date:07/29/03ISR Number: 4159715-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030706353
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Serum Sickness | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release | | | |

ORAL

Tablets

PS

ORAL

Date:07/30/03ISR Number: 4158968-7Report Type:Expedited (15-DaCompany Report #PHBS2003NL07681

Age:37 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Affect Lability Apathy Chest Pain Dyspnoea Jaundice Pneumothorax Rash Vision Blurred | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:07/30/03ISR Number: 4158969-9Report Type:Expedited (15-DaCompany Report #PHBS2003JP06515

Age:88 YR Gender:Female I/FU:F

| Outcome | PT |
|---------|---------------|
| Death | Death |
| Other | Hallucination |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Nausea Tremor | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|-----------|------|----------------------------|-------|
| 10 mg/day | | | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 150 mg/day | | | | Symmetrel | SS | | ORAL |
| 100 mg/day | | | | Symmetrel | SS | | ORAL |
| 1 tablet/day | | | | Gramalil | C | | ORAL |

Date:07/30/03ISR Number: 4161019-1Report Type:Expedited (15-DaCompany Report #MK200307-0716-1
Age:81 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------|--|--------------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Anal Neoplasm Cataplexy Drug Withdrawal Syndrome Narcolepsy | Foreign Literature | Clomipramine 75mg (Mrf Unknown) Methylphenidate (Mfr Unknown) | PS SS | | |

Date:07/30/03ISR Number: 4162102-7Report Type:Expedited (15-DaCompany Report #PHBS2003ES05736
Age:47 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------------------------|---------------------------------|--|------|--------------|-------|
| Other | | Cataplexy Drug Withdrawal Syndrome | Foreign Literature Health | Clomipramine(Clomipr amine Hydrochloride) Unknown | PS | | |
| 75 MG/DAY | | | Professional Other | Methylphenidate (Methylphenidate Hydrochloride) Unknown | SS | | |
| 10 MG/DAY | | | | | | | |

Date:07/30/03ISR Number: 4162117-9Report Type:Expedited (15-DaCompany Report #PHBS2003ES05735
Age:81 YR Gender:Female I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|---------------------------------|--|------|--------------|-------|
| 75 MG/DAY | | Abnormal Dreams Anal Neoplasm Asthenia | Foreign Literature Health | Clomipramine (Clomipramin Hydrochloride) Unknown | PS | | |
| 20 MG/DAY | | Cataplexy Drug Withdrawal Syndrome Narcolepsy Somnolence | Professional Other | Methylphenidate (Methylphenidate Hydrochloride) Unknown | SS | | |

Date: 07/31/03
 ISR Number: 4162040-X
 Report Type: Expedited (15-DaCompany Report #GB-JNJFOC-20030602880)
 Age: 12 YR Gender: Female I/FU: I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| 36 MG, 1 IN 1 DAY, ORAL | | Attention Deficit/Hyperactivity Disorder Condition Aggravated | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| | | | | Melatonin (Melatonin) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/31/03ISR Number: 4162041-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030603416
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Disability | | Abnormal Behaviour Drug Ineffective | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 18 MG, 2 IN 1 DAY, ORAL | | | | | | | |

| | | | | | | | |
|--|--|--|--|--|---|--|--|
| | | | | Rtalin (Methylphenidate Hydrochloride) | C | | |
|--|--|--|--|--|---|--|--|

Date:07/31/03ISR Number: 4162042-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030602875
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Disability | | Abnormal Behaviour Condition Aggravated | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 18 MG, 1 IN 1 DAY, ORAL | | | | | | | |

| | | | | | | | |
|--|--|--|--|---|---|--|--|
| | | | | Ritalin (Methylphenidate Hydrochloride) | C | | |
|--|--|--|--|---|---|--|--|

Date:07/31/03ISR Number: 4162045-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030600095
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------------|-----------------------------------|--|------|--------------|-------|
| Other | | Confusional State | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, ORAL | | | | | | | |

Date:07/31/03ISR Number: 4162068-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20030600089
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

ORAL

Date:08/01/03ISR Number: 4206308-7Report Type:Periodic Company Report #CEL-2003-01115-ROC (0)
Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Convulsion Face Injury Fall Loss Of Consciousness | Consumer | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG (20 MG, Q AM), PO | | Streptococcal Infection | | Theraflu (Theraflu) | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/04/03ISR Number: 4160293-5Report Type:Expedited (15-DaCompany Report #PHFR2003GB02426
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Infection | | Ritaline | PS | Novartis Sector: | |
| UNKNOWN | | Neutrophilia | | | | Pharma | |
| | | Rash | | | | | |
| | | Red Blood Cell Count | | | | | |
| | | Increased | | | | | |
| | | Thrombocythaemia | | | | | |
| | | White Blood Cell Count | | | | | |
| | | Increased | | | | | |

Date:08/04/03ISR Number: 4160491-0Report Type:Expedited (15-DaCompany Report #PHBS2001NZ12212
Age:24 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------|---------|------|------------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Drug Abuser | | Ritalin | PS | Novartis Sector: | |
| Initial or Prolonged | | Medication Error | | | | Pharma | |
| | | Oedema Peripheral | | | | | |
| | | Peripheral Ischaemia | | | | | |
| | | Skin Discolouration | | | | | |

Date:08/04/03ISR Number: 4160577-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE02679
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-----------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Hydrocele | | Ritaline | PS | Novartis Sector: | |
| Initial or Prolonged | | Post Procedural | | | | Pharma | ORAL |
| 15 to 20 | | | | | | | |
| mg/day | | Haemorrhage | | | | | |
| | | Varicocele | | | | | |

Date:08/04/03ISR Number: 4161001-4Report Type:Direct Company Report #CTU 199127
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|------------------|------|--------------|-------|
| Dose | | Abnormal Behaviour | | Ritalin 30-10-10 | PS | | |
| | | Mood Altered | | Celexa 20 | SS | | |

Date:08/04/03ISR Number: 4161245-1Report Type:Direct Company Report #USP 50174
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|-----------|------|--------------|-------|
| Dose | | Developmental Delay | | Ritodrine | PS | | |
| Other | | Maternal Drugs Affecting Foetus Medication Error | | Ritalin | SS | Ciba | |

Date:08/04/03ISR Number: 4163841-4Report Type:Expedited (15-DaCompany Report #2003-BP-05192RO
 Age:41 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------|---------------|------------------------------------|------|--------------|-------|
| Death | | Agitation | Literature | Methadone | | | |
| Hospitalization - Initial or Prolonged | | Coma | Health | (Methadone) | PS | | |
| | | Oxygen Saturation Decreased | Professional | Methylphenidate | | | |
| | | Snoring | Other | (Methylphenidate) Crack Cocaine | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Cocaine) SS

Date:08/04/03ISR Number: 4163913-4Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030707098
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Oculogyration | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:08/04/03ISR Number: 4164217-6Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030706439
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Photosensitivity Reaction Systemic Lupus Erythematosus | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | |

Date:08/05/03ISR Number: 4165416-XReport Type:Expedited (15-DaCompany Report #CEL-2003-02764-ROC
 Age:41 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|--------------------------------|--|----------------|--------------|-------|
| Dose | | | | | | | |
| Death | | Agitation Coma Drug Abuser Oxygen Saturation Decreased Pulmonary Oedema Respiratory Disorder Snoring Somnolence Stupor | Literature Health Professional | Methylphenidate Tablets (Unspecified)(Methylphenidate Hydrochloride) Methadone (Methadone) Cocaine (Cocaine) | PS SS SS | | |

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|--------------------------------------|---|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Back Pain Blood Calcium Decreased Blood Potassium Decreased Blood Sodium Decreased Condition Aggravated | Literature Health Professional | Methylphenidate Tablets (Unspecified) (Methylphenidate Hydrochloride) | | | |
| 30 MG (10 MG, TID), PO | Drug Withdrawal Syndrome | | | PS | | ORAL |
| 600 MG (DAILY), PO | Grand Mal Convulsion Haematocrit Decreased Haemoglobin Decreased | | Venlafaxine (Venlafaxine) | SS | | ORAL |
| 10 MG (10 MG, HS), PO | Insomnia Muscle Spasms Nausea Platelet Count Red Blood Cell Count Decreased Self-Medication White Blood Cell Count Increased | | Zolpidem (Zolpidem) | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/06/03ISR Number: 4162496-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0383131A
 Age:42 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------|-----------------|------|-----------------|-------|
| Death | | Cerebral Infarction | | Bupropion | PS | Glaxosmithkline | ORAL |
| UNKNOWN | | Completed Suicide | | Methylphenidate | SS | | |
| | | Cyanosis | | | | | |
| | | Drug Level Increased | | | | | |
| | | Intentional Misuse | | | | | |
| | | Loss Of Consciousness | | | | | |
| | | Nervous System Disorder | | | | | |
| | | Renal Failure | | | | | |
| | | Respiratory Failure | | | | | |
| | | Shock | | | | | |

Date:08/06/03ISR Number: 4165420-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030603419
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Fall Haematoma Petechiae Skin Haemorrhage Thrombocytopenia | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) Sus Tained Release Tablets | PS | | |
| 1 | | | | Medikinet (Tablets(Methylphenidate Hydrochloride | C | | |
| TABLET/DAILY. | | | | | | | |

Date:08/07/03ISR Number: 4163239-9Report Type:Expedited (15-DaCompany Report #PHEH2003US06719
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-------------------------------------|---------------|------------|------|----------------------------|-------|
| Other | | Coordination Abnormal Dysarthria | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 20 mg, QD | | Musculoskeletal Stiffness | | Flonase | C | | |

Date:08/08/03ISR Number: 4163969-9Report Type:Expedited (15-DaCompany Report #PHBS2001NZ12213
 Age:42 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-------------------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | |
| Hospitalization - | Erythema | | Ritaline | PS | Novartis Sector: | |
| Initial or Prolonged | Groin Pain | | | | Pharma | |
| | Local Swelling | | | | | |
| | Mycotic Aneurysm | | | | | |
| | Oedema Peripheral | | | | | |
| | Pitting Oedema | | | | | |
| | Sepsis | | | | | |
| | Vascular Pseudoaneurysm | | | | | |
| | Wound Necrosis | | | | | |

Date:08/09/03ISR Number: 4167362-4Report Type:Expedited (15-DaCompany Report #HQWYE525831JUL03
 Age:18 YR Gender:Male I/FU:I

| Outcome | PT | Report Source |
|---------|----------------|---------------|
| Other | Gun Shot Wound | Consumer |
| | Murder | Company |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Representative

| Dose | Duration | Product | Role | Manufacturer | Route |
|------|----------|---|------|--------------|-------|
| ORAL | | Effexor (Venlafaxine Hydrochloride, Tablet) | PS | | ORAL |
| | | Ambien (Zolpidem Tartrate) | SS | | |
| | | Clonazepam (Clonazepam) | SS | | |
| | | Methylphenidate (Methylphenidate) | SS | | |
| | | Wellbutrin (Amfebutamone Hydrochloride) | SS | | |

Date:08/11/03ISR Number: 4164614-9Report Type:Expedited (15-DaCompany Report #PHEH2003US06788
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|---------|------|-------------------------|-------|
| Death | | Sudden Death | | Ritalin | PS | Novartis Sector: Pharma | |
| Unk/Unk | | | | | | | |

Date:08/11/03ISR Number: 4165371-2Report Type:Expedited (15-DaCompany Report #PHFR2003GB03027
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------|------|-------------------------|-------|
| Other | | Tachycardia Ventricular Hypertrophy | | Ritaline | PS | Novartis Sector: Pharma | |

Date:08/11/03ISR Number: 4165373-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE02428
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|----------|------|------------------|-------|
| Other | | Erectile Dysfunction | | Ritaline | PS | Novartis Sector: | |

Prescribed Overdose

Pharma

ORAL

up to

300mg/day

Date:08/12/03ISR Number: 4166035-1Report Type:Expedited (15-DaCompany Report #PHNU2003DE02965

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | 20mg/day | Ear Discomfort Hypoacusis Vertigo | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:08/12/03ISR Number: 4168814-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030603419

Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|---------------------|--|---------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | 1 TABLET, DAILY. | Fall Haematoma Petechiae Skin Haemorrhage Thrombocytopenia | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Medikinet
(Methylphenidate
Hydrochloride)
Tablets C

Date:08/13/03ISR Number: 4166789-4Report Type:Expedited (15-DaCompany Report #PHBS2003JP03691
Age:36 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|----------|------|----------------------------|-------|
| Life-Threatening Hospitalization - 50 to 100 Initial or Prolonged tablets/day | 2880 MIN | Depressed Mood Dialysis | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 40 mg/day | | Muscular Weakness Overdose Renal Failure Acute | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| 150 mg/day | | Rhabdomyolysis | | Depromel | C | | ORAL |
| 5 mg/day | | | | Depas | C | | ORAL |
| 0.25 mg/day | | | | Halcion | C | | ORAL |
| 1 mg/day | | | | Rohypnol | C | | ORAL |
| 1.2 mg/day | | | | Constan | C | | ORAL |

Date:08/13/03ISR Number: 4167012-7Report Type:Expedited (15-DaCompany Report #PHNU2003DE02967
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|----------|---------------|----------|------|----------------------------|-------|
| Other | | Morphoea | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 15mg/day | | | | | | | |

Date:08/13/03ISR Number: 4169430-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20030707380
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Akathisia Insomnia Logorrhoea Mania | Study Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | Psychomotor Hyperactivity | | | | | |

Date:08/15/03ISR Number: 4169436-0Report Type:Direct Company Report #USP 50592
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---|----------|------------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Methylphenidate 10mg Methadone 10 Mg | PS SS | Parmed Roxane | |

Date:08/15/03ISR Number: 4169469-4Report Type:Direct Company Report #USP 50803
 Age:61 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------------------|---------------|----------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error Nausea | | Methadone Hydrochloride | PS | Roxane | |
| TABLET 5MG | | | | | | | |
| TABLET 5MG | | Tremor Vomiting | | Methylphenidate Hydrochloride | SS | Apothecon | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/15/03ISR Number: 4170193-2Report Type:Direct
Age:7 YR Gender:Male I/FU:I

Company Report #USP 50139

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------|---------|------|----------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Glucose Decreased | | Ritalin | PS | Ciba | |
| TABLET | | | | | | | |
| | | Brain Damage | | Glynase | SS | Pharmacia And Upjohn | |
| TABLET | | | | | | | |
| | | Coma | | | | | |
| | | Convulsion | | | | | |
| | | Medication Error | | | | | |
| | | Mental Retardation | | | | | |
| | | Severity Unspecified | | | | | |

Date:08/18/03ISR Number: 4169310-XReport Type:Expedited (15-DaCompany Report #PHEH2003US06788
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---------------------------|---------------|-------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Death | | Cardiac Disorder | | Ritalin | PS | Novartis Sector: Pharma | |
| Hospitalization - | | Cardio-Respiratory Arrest | | | | | |
| 80 mg, UNK | | | | | | | |
| Initial or Prolonged | | Leg Amputation | | Ritalin | SS | Novartis Sector: Pharma | |
| | | Sudden Death | | | | | |
| 60 mg, UNK | | | | | | | |
| | | Wound Infection | | Mirtazapine | C | | |

Date:08/18/03ISR Number: 4173742-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030801274
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Attention | Foreign | Concerta Xl | | | |
| | | Deficit/Hyperactivity | Health | (Methylphenidate | | | |
| | | Disorder | Professional | Hydrochloride) | | | |
| | | Condition Aggravated | | Sustained Release | | | |
| | | Hypomania | | Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| | | | | Ritalin | | | |
| | | | | (Methylphenidate | | | |

Date:08/20/03ISR Number: 4171016-8Report Type:Expedited (15-DaCompany Report #PHNU2003DE03032
 Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | |
| Duration | | | | | | |
| Hospitalization - | Aggression | | Ritaline | PS | Novartis Sector: | |
| Initial or Prolonged | Blister | | | | Pharma | |
| Other | Dependence | | | | | |
| | Depression | | | | | |
| | Heart Rate Increased | | | | | |
| | Renal Pain | | | | | |

Date:08/20/03ISR Number: 4172195-9Report Type:Direct Company Report #CTU 200270E
 Age:13 YR Gender:Female I/FU:I

| Outcome | PT |
|----------------------|--------------------------|
| Hospitalization - | Anorexia |
| Initial or Prolonged | Asthenia |
| Required | Blood Creatinine |
| Intervention to | Increased |
| Prevent Permanent | Blood Urea Increased |
| Impairment/Damage | Cachexia |
| | Disturbance In Attention |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | |
|--------------|----------|----------------------------|---------------|-----------------|------|--------------|
| | | Stress Weight Decreased | | | | |
| Dose | Duration | | Report Source | Product | Role | Manufacturer |
| 36 MG ONCE A | | | | Concerta 36 Mg | PS | |
| DAY ORAL | | | | | | ORAL |
| 40 MG ONCE A | | | | Strattera 40 Mg | SS | |
| DAY ORAL | | | | | | ORAL |

Date:08/20/03ISR Number: 4172973-6Report Type:Direct Company Report #CTU 200336
 Age:12 YR Gender:Male I/FU:I

| | | | | | | | |
|-------------|----------|---------------------|---------------|-----------------------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Aggression Anger | | Metadate Cd - 20 Mg Tabs | PS | | ORAL |
| 3 TABS PO Q | | | | | | | |
| AM | | | | | | | |

Date:08/21/03ISR Number: 4173428-5Report Type:Direct Company Report #CTU 200455
 Age:11 YR Gender:Male I/FU:I

| | | | | | | | |
|---------------|----------|------------------------------------|---------------|-----------------------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| 20 MG PO AT 4 | | Aggression Drug Ineffective | | Methylphenidate Sr 20 Mg | PS | | ORAL |
| PM | | Impulse-Control Disorder | | | | | |
| | | Psychomotor Hyperactivity Theft | | | | | |

Date:08/25/03ISR Number: 4177638-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030803159
 Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Discomfort Agitation Disturbance In Attention | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, 1 IN 1 DAY, ORAL | | Miosis Restlessness Tachycardia | | Medikinet (Tablets) Methylphenidate Hydrochloride | C | | |

Date:08/26/03ISR Number: 4173418-2Report Type:Expedited (15-DaCompany Report #PHBS2003JP06515
Age:89 YR Gender:Female I/FU:F

| Outcome | PT |
|---------|--|
| Death | Asthenia |
| Other | Blood Pressure Decreased Body Temperature Increased C-Reactive Protein Eating Disorder Hallucination, Visual Mental Impairment Nausea Pneumonia Aspiration Po2 Decreased Respiratory Distress Somnolence Suicidal Ideation Tremor |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

White Blood Cell Count

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------|-----------|------|----------------------------|-------|
| 10 mg/day | 69120MIN | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 150 mg/day | 34560MIN | | Symmetrel | SS | | ORAL |
| 100 mg/day | 23040MIN | | Symmetrel | SS | | ORAL |
| 50 mg/day | 11520MIN | | Gramalil | C | | ORAL |
| 25 mg/day | 57600MIN | | Gramalil | C | | ORAL |
| 5 mg/day | 11520MIN | | Myslee | C | | ORAL |
| INTRAVENOUS | | | Vitaject | C | | |
| INTRAVENOUS | | | Hicaliq | C | | |
| INTRAVENOUS | | | Glucose | C | | |
| INTRAVENOUS | | | Mineralin | C | | |
| INTRAVENOUS | | | Amiparen | C | | |

Date:08/27/03ISR Number: 4180718-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030704702
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|-------------------------------|-----------------------------------|---|------|--------------|-------|
| Dose Other | | Cardiac Flutter Chest Pain | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 18 MG, 1 IN 1 DAY, ORAL | | | | Neoclarityn (Desloratadine) Unknown Salbutamol (Salbutamol) | C | | |

Inhalation

C

Date:08/27/03ISR Number: 4180725-6Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030704702
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cardiac Flutter Chest Pain | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | | | ORAL |

18 MG, 1 IN 1

DAY, ORAL

Neoclarityn
(Desloratadine)
Unknown
Salbutamol
(Salbutamol)
Inhalation

PS

C

C

Date:08/28/03ISR Number: 4175016-3Report Type:Expedited (15-DaCompany Report #PHNR2003AU01172
Age: Gender:Female I/FU:F

| Outcome | PT |
|---------|---|
| Other | Anaemia Anxiety Drug Interaction Fatigue Heart Rate Irregular Lethargy |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|------------------------------------|---------------|------------|------|----------------------------|-------|
| | | Nausea Palpitations Pruritus | | | | | |
| 40 mg, QD, mane | | Somnolence | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 2 capsules, 1 in am, 1 in pm | | | | Ritalin La | SS | Novartis Sector: Pharma | ORAL |
| 40 mg, QD, mane | | | | Ritalin La | SS | Novartis Sector: Pharma | ORAL |
| 200 mg | 2880 MIN | | | Tegretol | SS | | ORAL |

Date:08/28/03ISR Number: 4175021-7Report Type:Expedited (15-DaCompany Report #PHNR2003AU01176
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--|---------------|------------|------|----------------------------|-------|
| Dose Other | | Drug Ineffective Increased Appetite | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 30 mg, QD, mane | | | | Catapres | C | | |
| Unspecified | | | | Ventolin | C | | |
| Unspecified | | | | Flixotide | C | | |
| Unspecified | | | | | | | |

Date:08/28/03ISR Number: 4182101-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030804648
Age:7 YR Gender:Female I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|---------------|--|------|--------------|-------|
| | | Gastrooesophageal Reflux Disease Vomiting | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

ORAL

Date:08/29/03ISR Number: 4175821-3Report Type:Expedited (15-DaCompany Report #PHBS2003ZA09019
 Age:12 YR Gender:Unknown I/FU:I

| Outcome Dose Death | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--------------|---------------|---------|------|-------------------------|-------|
| | | Sudden Death | | Ritalin | PS | Novartis Sector: Pharma | |

UNKNOWN

Date:08/29/03ISR Number: 4182478-4Report Type:Expedited (15-DaCompany Report #2003UW10598
 Age:13 YR Gender:Male I/FU:I

| Outcome Dose Hospitalization - Initial or Prolonged | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------------|------------------------|----------|--------------|-------|
| | | Dysphagia Hallucination Respiratory Arrest | Health Professional | Iressa Iressa Baclofen | PS SS SS | | |

START DATE IS

PRIOR TO

02-AUG-2003

START DATE IS

PRIOR TO

02-AUG-2003

START DATE IS

PRIOR TO

18-Aug-2005 11:49 AM

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

02-AUG-2003

START DATE IS

Lorazepam

SS

PRIOR TO

02-AUG-2003

START DATE IS

Zoloft

SS

PRIOR TO

02-AUG-2003

START DATE IS

Benadryl

SS

PRIOR TO

02-AUG-2003

Date:08/29/03ISR Number: 4202553-5Report Type:Periodic
Age:8 YR Gender:Male I/FU:I

Company Report #NSADSS2003024795

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|---------------|---|------------------|--------------|-------|
| Dose Other | | Abdominal Pain Anorexia Weight Decreased | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 DAY, ORAL | | | | Qvar (Beclometasone Dipropionate) Albuterol (Salbutamol) Motrin (Ibuprofen) Claritin (Loratadine) | C C C C | | |

Date:08/29/03ISR Number: 4202554-7Report Type:Periodic
Age:12 YR Gender:Male I/FU:I

Company Report #US-JNJFOC-20030706262

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|--|------|--------------|-------|
| Dose Other | | Convulsion | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| 54 MG, 1 IN 1 | | | | | | | |
| DAY | | | | | | | |

Date:08/29/03ISR Number: 4202555-9Report Type:Periodic Company Report #US-JNJFOC-20030600089
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|--|------|--------------|-------|
| Dose Other | | Growth Retardation | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |

Date:09/02/03ISR Number: 4176974-3Report Type:Expedited (15-DaCompany Report #PHNR2003AU01199
 Age:16 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|------------------------|---------------|------------|------|----------------------------|-------|
| Dose Other | | Anxiety Tachycardia | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 30 mg, QD, mane 2880 MIN | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/02/03ISR Number: 4177207-4Report Type:Expedited (15-DaCompany Report #PHNU2003DE01527
 Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Cerebral Haemorrhage | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| .5 DF, QD | | Coagulopathy | | | | | |
| | | Disseminated | | Ritalin-Sr | SS | | ORAL |
| 1 DF, QD | | Intravascular Coagulation | | | | | |
| | | Haemorrhage | | | | | |
| | | Injury | | | | | |
| | | Nervous System Disorder | | | | | |
| | | Skin Haemorrhage | | | | | |

Date:09/02/03ISR Number: 4177208-6Report Type:Expedited (15-DaCompany Report #PHRM2002FR02903
 Age:9 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Abdominal Pain | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Initial or Prolonged | | Arthralgia | | | | | |
| 20 mg/day | | Inflammation | | Ritaline | SS | Novartis Sector: Pharma | ORAL |
| 30 mg/day | | Pyelonephritis Chronic | | | | | |
| | | Pyrexia | | Ritaline | SS | Novartis Sector: Pharma | ORAL |
| 20 mg/day | | Rash Macular | | | | | |
| | | Urinary Tract Infection | | | | | |
| | | Vomiting | | | | | |
| | | Weight Decreased | | | | | |

Date:09/02/03ISR Number: 4178575-XReport Type:Direct Company Report #CTU 201140
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Generic Ritalin 20 | PS | | ORAL |
| 1-1/2-1/2 | | Pharmaceutical Product | | Mg | | | |

| | | | | | | |
|------------|------------------|--|--|----------------------|----|------|
| ORAL | Complaint | | | | | |
| Q-1-1 ORAL | Weight Decreased | | | Generic Ritalin 5 Mg | SS | ORAL |
| | Weight Increased | | | | | |

Date:09/02/03ISR Number: 4183468-8Report Type:Expedited (15-DaCompany Report #NSADSS2003024795
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|----------------------|---------------|---------------------|------|--------------|-------|
| Dose | | Abdominal Pain Upper | Consumer | Concerta | | | |
| Other | | Anorexia | | (Methylphenidate | | | |
| | | Hyperphagia | | Hydrochloride) | | | |
| | | Weight Decreased | | Sustained Release | | | |
| | | | | Tablets | PS | | ORAL |
| SEE IMAGE | | | | Qvar (Beclometasone | | | |
| | | | | Dipropionate) | C | | |
| | | | | Albuterol | | | |
| | | | | (Salbutamol) | C | | |
| | | | | Motrin (Ibuprofen) | C | | |
| | | | | Claritin | | | |
| | | | | (Loratadine) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/02/03ISR Number: 4184810-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030603419
 Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Fall Skin Haemorrhage Thrombocytopenia | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| 1 | | | | Medikinet Tablets) Methylphenidate Hydrochloride | C | | |

Date:09/03/03ISR Number: 4184946-8Report Type:Expedited (15-DaCompany Report #CEL-2003-03092-ROC
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|---|----------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Cerebrovascular Accident Coma Medication Error Poisoning Somnolence | Consumer | Methylphenidate Tablets (Unspecified) (Methylphenidate Hydrochloride) Methadone (Methadone) | PS SS | | |

Date:09/04/03ISR Number: 4179809-8Report Type:Direct Company Report #CTU 201285
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|---------|------|--------------|-------|
| 10 MG #90 | | Drug Ineffective Pharmaceutical Product Complaint | | Ritalin | PS | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|----------------------|------|--------------|-------|
| Dose | | Agitation | | Methylphenidate 5 Mg | PS | | |
| | | Aphonia | | Metolazone | SS | | |
| | | Confusional State | | | | | |
| | | Disorientation | | | | | |
| | | Medication Error | | | | | |

Date:09/04/03ISR Number: 4183795-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030603419
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------|---------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Bleeding Time Prolonged | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) | | | |
| Other | | Haematoma | | Sustained Release Tablets | PS | | |
| 1 | | Petechiae | | | | | |
| | | Skin Haemorrhage | | | | | |
| | | Thrombocytopenia | | | | | |
| | | | | Medikinet (Tablets) | | | |
| | | | | Methylphenidate Hydrochloride | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/04/03ISR Number: 4185071-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030805307
 Age:2 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------------------------|------------------------------------|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | 18 MG, 1 IN 1 DAY, ORAL | Apathy Mydriasis Tachycardia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:09/05/03ISR Number: 4180647-0Report Type:Direct Company Report #CTU 201336
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|---------|------|--------------|-------|
| 10 MG #90 | | Drug Ineffective Pharmaceutical Product Complaint | | Ritalin | PS | | |

Date:09/08/03ISR Number: 4181062-6Report Type:Expedited (15-DaCompany Report #PHBS2003ZA09019
 Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-------------------|--------------------------------------|---------------|------------|------|----------------------------|-------|
| Death | 20 mg/d | Circulatory Collapse Sudden Death | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | 50 microgram/d | 90 DAY | | Budesonide | C | | |
| UNKNOWN | | | | Flixonase | C | | |
| UNKNOWN | | 73 DAY | | Inflammid | C | | |

Date:09/08/03ISR Number: 4186487-0Report Type:Expedited (15-DaCompany Report #NSADSS2002033023
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Conversion Disorder Dystonia Tonic Clonic Movements | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |

18 MG, 1 IN 1

DAY, ORAL

| | | |
|--|---|--|
| Singulair (Montelukast Sodium) | C | |
| Phenergan (Promethazine Hydrochloride) | C | |

Date:09/08/03ISR Number: 4186488-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030604709
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Dyskinesia Flushing Muscle Twitching Nausea | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |

54 MG, 1 IN 1

DAY, ORAL

Tic

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/09/03ISR Number: 4181251-0Report Type:Expedited (15-DaCompany Report #PHNR2003AU01252

Age:14 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------|---------------|-------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Androgens Increased | | Ritalin | PS | Novartis Sector: | |
| 1 tablet | | Drug Ineffective | | | | Pharma | ORAL |
| morning and | | Muscle Twitching | | | | | |
| noon | | Tremor | | | | | |
| Unspecified | | Vision Blurred | | Zoloft | C | | |
| Unspecified | | | | Risperidone | C | | |
| Unspecified | | | | Seroquel | C | | |

Date:09/09/03ISR Number: 4184756-1Report Type:Direct Company Report #CTU 201447

Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| 10 MG #90 | | Drug Ineffective | | Ritalin | PS | | |
| | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |

Date:09/10/03ISR Number: 4183089-7Report Type:Expedited (15-DaCompany Report #PHBS2003US09314

Age:82 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------------------|---------------|-----------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Obsessive-Compulsive | | Methylphenidate | PS | Novartis Sector: | |
| 5 mg, BID | 20160MIN | Disorder | | | | Pharma | |
| 10 mg, BID | | | | Methylphenidate | SS | Novartis Sector: | |
| | | | | | | Pharma | |
| | | | | Donepezil | C | | |

Date:09/10/03ISR Number: 4183095-2Report Type:Expedited (15-DaCompany Report #PHFR2003GB03421
Age:6 HR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------|----------|-------------------------------------|---------------|---------------------|------|-------------------------|-------|
| Death | | Drug Exposure During Pregnancy | | Ritaline | PS | Novartis Sector: Pharma | |
| TRANSPLACENTAL | | Neonatal Respiratory | | Distalgesic "Lilly" | C | | |
| TRANSPLACENTAL | | Distress Syndrome Premature Baby | | | | | |

Date:09/10/03ISR Number: 4183098-8Report Type:Expedited (15-DaCompany Report #PHFR2003GB03494
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------|----------|---|---------------|----------|------|-------------------------|-------|
| Other | | Bradycardia Foetal Caesarean Section | | Ritaline | PS | Novartis Sector: Pharma | |
| TRANSPLACENTAL | | Drug Exposure During Pregnancy | | | | | |

Date:09/10/03ISR Number: 4183112-XReport Type:Expedited (15-DaCompany Report #PHFR2003GB01311
Age:14 YR Gender:Male I/FU:F

| Outcome | PT |
|------------|--|
| Disability | Cyanosis Echocardiogram Abnormal Livedo Reticularis Pain In Extremity |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|------------|------|----------------------------|-------|
| | | Peripheral Coldness Poor Peripheral Circulation | | | | |
| 20mg/day | 20160MIN | Raynaud'S Phenomenon Tachycardia | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 40mg/day | 10080MIN | Ventricular Septal Defect | Ritalin-Sr | SS | Novartis Sector: Pharma | |
| 10-20ml/BID/P | | | Lactulose | C | | ORAL |
| RN | | | | | | |

Date:09/10/03ISR Number: 4188648-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030600551
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|--------------------------------------|--|------|--------------|-------|
| Dose Other | | Intentional Misuse Medication Error | Literature Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | NASAL |
| INTRA-NASAL | | | | | | | |

Date:09/10/03ISR Number: 4188649-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030600552
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|--------------------------------------|--|------|--------------|-------|
| Dose Other | | Intentional Misuse | Literature Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | NASAL |
| SEE IMAGE | | | | | | | |

Date:09/10/03ISR Number: 4188660-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030600491
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------------|--------------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Intentional Misuse | Literature Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| INTRA-NASAL | | | | | PS | | NASAL |

Date:09/11/03ISR Number: 4183882-0Report Type:Expedited (15-DaCompany Report #PHBS2003ZA09019
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Death | | Brain Oedema Circulatory Collapse | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | 20 mg/d | 90 DAY | | | | | |
| UNKNOWN | 50 | Sudden Death | | Budesonide | C | | |
| UNKNOWN | 50 | | | | | | |
| UNKNOWN | 50 | | | | | | |
| UNKNOWN | 50 | | | Flixonase | C | | |
| UNKNOWN | 50 | | | Inflammid | C | | |
| UNKNOWN | 50 | 73 DAY | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/11/03ISR Number: 4189714-9Report Type:Direct
Age:9 YR Gender:Female I/FU:I

Company Report #USP 042095

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---------|------|---------------|-------|
| Dose | | Medication Error | | Ritalin | PS | Md Pharmaceut | |
| TABLET | | | | Ritalin | SS | Md Pharmaceut | |
| TABLET | | | | | | | |

Date:09/15/03ISR Number: 4186451-1Report Type:Expedited (15-DaCompany Report #PHEH2003US07979
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|---------|------|----------------------------|-------|
| Dose | | Diabetes Mellitus Insulin-Dependent | | Ritalin | PS | Novartis Sector: Pharma | |
| Other | | | | | | | |
| UNK/UNK | | | | | | | |

Date:09/15/03ISR Number: 4190633-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030603419
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Bleeding Time Prolonged Blood Glucose Increased Fall Glucose Urine Present Haematoma | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| 1 | | Mouth Haemorrhage | | | | | |
| TABLET/DAILY. | | Nasopharyngitis Oral Mucosal Petechiae Petechiae Skin Haemorrhage Thrombocytopenia | | Medikinet (Methylphenidate Hydrochloride) Tablets | C | | |

Date:09/16/03ISR Number: 4187008-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0409645A
Age:7 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|-------------------------|---------------|----------|------|-----------------|-------|
| Hospitalization - 12 DAY | | Aggression | | Paxil Cr | PS | Glaxosmithkline | ORAL |
| Initial or Prolonged 5MG At night | | Drug Interaction | | Zyprexa | SS | | ORAL |
| Other 22 DAY | | Excoriation | | Metadate | SS | | ORAL |
| 36MG Twice per day | | Hallucination | | Concerta | C | | ORAL |
| | | Hallucination, Auditory | | | | | |
| | | Laceration | | | | | |
| | | Nightmare | | | | | |
| | | Psychotic Disorder | | | | | |
| | | Self Mutilation | | | | | |

Date:09/16/03ISR Number: 4190693-9Report Type:Direct Company Report #USP 080683
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|------------------|---------------|------------|------|--------------|-------|
| TABLET | | Medication Error | | Ritalin | PS | Ciba | |
| TABLET, EXTENDED RELEASE | | | | Ritalin Sr | SS | Ciba | |

Other Anorexia Concerta 36 Mg PS ORAL

(75 LBS) 36

MG ORAL

Advair C

Date:09/17/03ISR Number: 4188691-4Report Type:Expedited (15-DaCompany Report #PHNU2003DE01337

Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Activated Partial Thromboplastin Time | | Ritaline | PS | Novartis Sector: Pharma | |
| 365 | DAY | Prolonged Antibody Test Positive Antinuclear Antibody Positive Von Willebrand'S Disease | | Ritaline | SS | Novartis Sector: Pharma | ORAL |

Date:09/17/03ISR Number: 4191788-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030901965

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------------|---|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anger Intentional Self-Injury | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

27 MG, 1 IN 1

DAY, ORAL

18-Aug-2005 11:49 AM

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/17/03ISR Number: 4192841-3Report Type:Expedited (15-DaCompany Report #CEL-2003-01127-ROC
 Age:7 YR Gender:Male I/FU:F

| Outcome Dose Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged 20 MG (20 MG, DAILY AT 3 PM), PO | Aggression Anxiety Blood Glucose Blood Thyroid Stimulating Hormone | Health Professional | Metadate Er (Methylphenidate Hydrochloride) | PS | | ORAL |
| 5 MG (5 MG, HS), PO | Depression Dissociation Excoriation | | Zyprexa (Olanzapine) | SS | | ORAL |
| 12.5 MG (12.5 MG, IN THE MORNING), PO | Haematocrit Haemoglobin Hallucination Hallucination, Auditory Laceration | | Paxil Cr (Paroxetine Hydrochloride) | SS | | ORAL |
| 72 MG (72 MG, IN THE MORNING) | Nightmare Platelet Count Increased Psychotic Disorder Red Blood Cell Count Self Mutilation White Blood Cell Count | | Concerta (Methylphenidate Hydrochloride) | SS | | ORAL |

Date:09/17/03ISR Number: 4193520-9Report Type:Expedited (15-DaCompany Report #PHBS2003ZA0919
 Age:12 YR Gender:Male I/FU:F

| Outcome Dose Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|---|-----------------------------------|---|------|--------------|-------|
| Death 20 MG/D, | Brain Oedema Circulatory Collapse Speech Disorder | Foreign Health Professional | Ritalin(Methylphenid ate Hydrochloride) Unknown | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|-----------|------|----------------------------|-------|
| | | Eating Disorder Hallucination Hallucination, Visual | | | | |
| 10 mg/day | 69120MIN | Mental Impairment Nausea | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 150 mg/day | 34560MIN | Pneumonia Aspiration | Symmetrel | SS | | ORAL |
| 100 mg/day | 23040MIN | Po2 Decreased | Symmetrel | SS | | ORAL |
| 50 mg/day | 11520MIN | Pyrexia | Gramalil | C | | ORAL |
| 25 mg/day | 57600MIN | Respiratory Distress | Gramalil | C | | ORAL |
| 5 mg/day | 11520MIN | Somnolence | Myslee | C | | ORAL |
| INTRAVENOUS | | Tremor | Vitaject | C | | |
| INTRAVENOUS | | White Blood Cell Count | Hicaliq | C | | |
| INTRAVENOUS | | | Glucose | C | | |
| INTRAVENOUS | | | Mineralin | C | | |
| INTRAVENOUS | | | Amiparen | C | | |

Date:09/22/03ISR Number: 4189437-6Report Type:Expedited (15-DaCompany Report #PHEH2003US05548
Age:41 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------------|---------------|---------------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged 5 mg, QD | | Arterial Occlusive Disease | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| | | Chest Pain | | Levothyroxine | C | | |
| | | Myocardial Infarction | | Prozac | C | | |

Date:09/22/03ISR Number: 4194070-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030600469
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------------------------|---------------|-------------------|------|--------------|-------|
| Dose | | Alanine Aminotransferase | Consumer | Concerta | | | |
| Other | | Anaemia | Health | (Methylphenidate | | | |
| | | Aspartate | Professional | Hydrochloride) | | | |
| | | Aminotransferase | | Sustained Release | | | |
| | | Blood Albumin | | Tablets | PS | | ORAL |
| SEE IMAGE | | Crohn'S Disease | | | | | |
| | | Decreased Appetite | | | | | |
| | | Defaecation Urgency | | | | | |
| | | Fatigue | | | | | |
| | | Haemoglobin | | | | | |
| | | Headache | | | | | |
| | | Inflammatory Bowel | | | | | |
| | | Disease | | | | | |
| | | Insomnia | | | | | |
| | | Lipoma | | | | | |
| | | Liver Function Test | | | | | |
| | | Abnormal | | | | | |
| | | Rectal Haemorrhage | | | | | |
| | | Red Blood Cell | | | | | |
| | | Sedimentation Rate | | | | | |
| | | Somnolence | | | | | |
| | | Weight Decreased | | | | | |

Date:09/23/03ISR Number: 4191752-7Report Type:Expedited (15-DaCompany Report #PHRM2003FR02358
Age:6 YR Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------|---------------|----------|------|------------------|-------|
| Dose | | Colitis | | Ritaline | PS | Novartis Sector: | |
| Other | | | | | | Pharma | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/23/03ISR Number: 4195122-7Report Type:Direct
Age: Gender: I/FU:I

Company Report #USP 08024

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|--------------------------------|------|--------------|-------|
| | | Medication Error | | Methylphenidale 5 Mg And 10 Mg | PS | | |
| TAB | | | | | | | |
| | | | | Methadone 5 Mg And 10 Mg | SS | | |
| TAB | | | | | | | |

Date:09/23/03ISR Number: 4195230-0Report Type:Direct
Age: Gender:Not SpecifiI/FU:I

Company Report #USP 080297

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------------------|---------------|----------------------------------|------|--------------|-------|
| | | Medication Error Overdose | | Ritalin 10 Mg Methylphenidate | PS | Ciba | |
| 10 MG TAB | | | | | | | |
| | | | | Reglan 10 Mg Metoclorpamide | SS | | |
| 10 MG TAB | | | | | | | |

Date:09/23/03ISR Number: 4195296-8Report Type:Direct
Age: Gender: I/FU:I

Company Report #USP 080035

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|------------------|---------------|------------------|------|--------------|-------|
| Other TABLET | | Medication Error | | Methylphenidate | PS | | |
| | | | | Methyclothiazide | SS | | |
| TABLET | | | | | | | |

Date:09/23/03ISR Number: 4198095-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030903850
Age: Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|----------|------|--------------|-------|
| Other ORAL | | Convulsion | Health | Concerta | PS | | |

Mania

Professional

Date:09/23/03ISR Number: 4198230-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030706439

Age:8 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blister Photosensitivity Reaction Systemic Lupus Erythematosus Urticaria | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

36 MG, 1 IN 1

DAY; ORAL

Date:09/24/03ISR Number: 4192164-2Report Type:Expedited (15-DaCompany Report #PHNU2003DE03424

Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine Phosphokinase Increased | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

20 mg/day

Date:09/24/03ISR Number: 4192169-1Report Type:Expedited (15-DaCompany Report #PHNU2003DE03430

Age: Gender:Female I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|----------|--|---------------|----------|------|----------------------------|-------|
| Other | 10 mg, QD | | Diarrhoea Palpitations Psychosomatic Disease Weight Decreased | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:09/24/03ISR Number: 4193177-7Report Type:Expedited (15-DaCompany Report #PHNU2003DE02967

Age: Gender:Female I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|----------|------------------------|----------|------|----------------------------|-------|
| Other | 15mg/day | | Morphoea | Health Professional | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:09/24/03ISR Number: 4193179-0Report Type:Expedited (15-DaCompany Report #PHBS2003NO02324

Age:11 YR Gender:Male I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|-----------|--|------------------------|----------|------|----------------------------|-------|
| Other | 10 mg/day | | Confusional State Hallucination, Visual | Health Professional | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| UNKNOWN | | 36 mg/day | | | Concerta | I | | |

Date:09/29/03ISR Number: 4197047-XReport Type:Expedited (15-DaCompany Report #PHRM2003FR02358

Age:6 YR Gender:Unknown I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------|----------|---------|---------------|----------|------|----------------------------|-------|
| Other | | | Colitis | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--------------------------------------|---|--------------------|--------------|-------|
| Death | | Agitation Coma Intentional Misuse Oxygen Saturation Decreased Pulmonary Oedema Respiratory Disorder Somnolence Stupor | Literature Health Professional | Methylphenidate(Meth ylphenidate) Methadone (Methadone) Cocaine (Cocaine) | PS SS SS | | |

Date:09/30/03ISR Number: 4199141-6Report Type:Direct Company Report #USP 080374
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|--------------------------------|--------------|-------------------|-------|
| TABLET | | Medication Error | | Ritalin Methylphenidate | PS SS | Md Pharmaceutical | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/01/03ISR Number: 4204360-6Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030904646
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|---------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose Disability Other | | Systemic Lupus Erythematosus | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | | | | | | | |

Date:10/02/03ISR Number: 4199649-3Report Type:Expedited (15-DaCompany Report #PHNU2003DE02965
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged 20mg/day | | Ear Discomfort Hypoacusis Vertigo | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:10/02/03ISR Number: 4199694-8Report Type:Expedited (15-DaCompany Report #PHNU2003DE02479
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|------------|------|----------------------------|-------|
| Dose Other | | Anxiety Decreased Activity | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 20 mg, BID | | Depression | | Telfast | C | | ORAL |
| 120 mg, QD | 20160MIN | Drug Interaction Hearing Impaired Hyperacusis Psychiatric Symptom Stress | | | | | |

Date:10/02/03ISR Number: 4199837-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE03439
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Bundle Branch Block Right Electrocardiogram Qt | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 5 mg/day | | | | | | | |
| | | Corrected Interval Prolonged | | Ritaline | SS | Novartis Sector: Pharma | ORAL |
| 10 mg/day | | | | | | | |
| | | Electrocardiogram Qt Prolonged | | Ritaline | SS | Novartis Sector: Pharma | ORAL |
| 5 mg/day | | | | | | | |

Date:10/02/03ISR Number: 4199840-6Report Type:Expedited (15-DaCompany Report #PHRM2003FR02358
Age:6 YR Gender:Unknown I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | No Adverse Drug Effect | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:10/03/03ISR Number: 4206150-7Report Type:Expedited (15-DaCompany Report #EMADSS2003001588
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination, Visual | Foreign Health Professional | Concerta Methylphenidate Hydrochloride) | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

36 MG, 1 IN 1
 DAY, ORAL

Sustained Release
 Tablets PS ORAL

10 MG, ORAL

Ritalin
 (Methylphenidate
 Hydrochloride)
 Tablets SS ORAL

Date:10/03/03ISR Number: 4206152-0Report Type:Expedited (15-DaCompany Report #EMADSS2003001588
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|-----------------------|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Hallucination, Visual | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | | | | | | | |

| | | | | | | | |
|-------------|--|--|--|--|----|--|------|
| 10 MG, ORAL | | | | Ritalin (Methylphenidate Hydrochloride) Tablets | SS | | ORAL |
|-------------|--|--|--|--|----|--|------|

Date:10/03/03ISR Number: 4206153-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030906118
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Alanine Aminotransferase Increased Aspartate Aminotransferase Increased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | | Blood Lactate Dehydrogenase Increased | | | | | |

Gamma-Glutamyltransferase
Increased

Date:10/03/03ISR Number: 4206154-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030906118
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alanine Aminotransferase | Foreign | Concerta | PS | | ORAL |
| 36 MG, 1 IN 1 | | Increased | Health | | | | |
| DAY, ORAL | | Aspartate Aminotransferase Increased Blood Lactate Dehydrogenase Increased Gamma-Glutamyltransferase Increased | Professional | | | | |

Date:10/07/03ISR Number: 4206077-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE03439
Age:9 YR Gender:Male I/FU:I

| | |
|---------|---|
| Outcome | PT |
| Other | Bundle Branch Block Right Electrocardiogram Qt Corrected Interval |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Prolonged
Electrocardiogram Qt
Prolonged

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--|------|--------------|-------|
| 5 MG/DAY, ORAL; 10 MG/DAY, ORAL; 5 MG/DAY, ORAL | | Foreign Health Professional Other | Ritaline (Methylphenidate Hydrochloride) Tablet | PS | | ORAL |

Date:10/07/03ISR Number: 4207598-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20030906286
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|------------------------------------|-----------------------------------|--|------|--------------|-------|
| Disability | | Dyspnoea Influenza Like Illness | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) Sustained | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | | | | Ritalin (Methylphenidate Hydrochloride) | C | | |

Date:10/08/03ISR Number: 4203694-9Report Type:Expedited (15-DaCompany Report #PHRM2003FR02631
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-----------|---------------|----------|------|----------------------------|-------|
| Other 40 mg/day | | Hepatitis | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:10/08/03ISR Number: 4206134-9Report Type:Expedited (15-DaCompany Report #PHNU2003DE02479
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Decreased Activity Depression Drug Interaction | Foreign Health Professional | Ritalin-Sr(Methylphe nidate Hydrochloride)Tablet | PS | | ORAL |
| 20 MG, BID, ORAL | | Hyperacusis Mental Impairment Stress | Other | Telfast (Fexofenadine) Film-Coated Tablet | C | | |

Date:10/08/03ISR Number: 4206258-6Report Type:Direct Company Report #USP 080109
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| TAB | | Medication Error | | Ritalin Sr 20 | PS | Ciba | |
| TAB | | | | Ritalin 20 Mg | SS | Ciba | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/08/03ISR Number: 4207859-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030906368
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Aggression Anxiety Blood Glucose | Health Professional | Concerta (Methylphenidate Hydrochloride) S R | PS | | |
| 72 MG, IN 1 DAY | | Blood Thyroid Stimulating Hormone | | Zyprexa (Olanzapine) | SS | | |
| 5 MG, 1 IN 1 DAY | | Depression Excoriation Haematocrit | | Paxil Cr (Paroxetine Hydrochloride) | SS | | |
| 12.5 MG, 1 IN 1 DAY | | Haemoglobin Hallucination, Auditory Initial Insomnia | | Metadate Er (Methylphenidate) | SS | | |
| 20 MG, 1 IN 1 DAY | | Laceration Nightmare Platelet Count Increased Psychotic Disorder Red Blood Cell Count Refusal Of Treatment By Relative Self Mutilation White Blood Cell Count | | | | | |

Date:10/08/03ISR Number: 4208733-7Report Type:Direct Company Report #CTU 203517
 Age:20 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|----------|-----------------------------------|---------------|----------|------|--------------|-------|
| 2 TAB BY MOUTH IN MORNING | | Dizziness Dyspnoea Ear Pain | | Concerta | PS | Mcneil | ORAL |

| | | |
|-----------------|---------------|---|
| Glossodynia | Trileptal | C |
| Headache | Piroxicam | C |
| Lymphadenopathy | Clonidine Hcl | C |
| Swollen Tongue | Zoloft | C |
| Tongue Disorder | | |

Date:10/09/03ISR Number: 4205158-5Report Type:Expedited (15-DaCompany Report #PHEH2003US06719
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------------|---------------|--------------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Balance Disorder | | Ritalin La | PS | Novartis Sector: | |
| | | Dysarthria | | | | Pharma | ORAL |
| 20 mg, QD | 38880MIN | | | | | | |
| | | Mood Swings | | Flonase | C | | |
| | | Musculoskeletal Stiffness | | Montelukast Sodium | C | | |
| | | Posture Abnormal | | | | | |

Date:10/10/03ISR Number: 4206183-0Report Type:Expedited (15-DaCompany Report #PHBS2003JP10909
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Dependence | | Ritalin | PS | Novartis Sector: | |
| | | | | | | Pharma | ORAL |
| 60 mg/day | | | | | | | |
| | | | | Ludiomil | C | | ORAL |
| 50 mg/day | | | | | | | |
| | | | | Paxil | C | | ORAL |
| 4 mg/day | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/10/03ISR Number: 4209062-8Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20031000841
Age:11 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Cold Sweat Hyperhidrosis Palpitations Panic Attack | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 1 IN 1 DAY, ORAL | | | | Luvox (Fluvoxamine Maleate) | C | | |

Date:10/10/03ISR Number: 4209921-6Report Type:Direct Company Report #USP 080710
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---------|------|--------------|-------|
| TABLET | | Medication Error | | Ritalin | PS | Ciba Geigy | |
| TABLET | | | | Ritalin | SS | Ciba Geigy | |

Date:10/15/03ISR Number: 4208728-3Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0311627A
Age:7 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|--------------------------------------|---|---------------|-----------------------|---------|-----------------|-------|
| Other UNKNOWN | 5ML Four times per day 7 DAY | Attention Deficit/Hyperactivity Disorder | | Amoxicillin | PS | Glaxosmithkline | |
| UNKNOWN | 36MG Per day 3MG Twice per day | Condition Aggravated Drug Interaction Intentional Self-Injury | | Concerta Melatonin | SS C | | |

Date:10/15/03ISR Number: 4208983-XReport Type:Expedited (15-DaCompany Report #PHBS2003ZA09019
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-------------------|--------------------------------------|---------------|-------------|------|----------------------------|-------|
| Death | | Brain Oedema Circulatory Collapse | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | 20 mg/d | Fall | | Budesonide | C | | |
| UNKNOWN | 50 microgram/d | Inflammation | | | | | |
| UNKNOWN | | Lung Disorder | | Flixonase | C | | |
| UNKNOWN | | Sudden Death | | Inflammiide | C | | |

Date:10/15/03ISR Number: 4210983-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031000797
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|--|------|--------------|-------|
| Other | | Growth Retardation Weight Decreased | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

SEE IMAGE

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/15/03ISR Number: 4213606-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030603419
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Fall Haematoma Petechiae Thrombocytopenia | Foreign Consumer Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| 1 TABLET/DAILY. | | | | Medikinet (Methylphenidate Hydrochloride) Tablets | C | | |

Date:10/17/03ISR Number: 4214621-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030705720
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|--|------|--------------|-------|
| Other | | Anxiety Gastrooesophageal Reflux Disease Ulcer Vomiting | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| SEE IMAGE | | | | | | | |

Date:10/20/03ISR Number: 4211945-XReport Type:Expedited (15-DaCompany Report #PHNU2003DE03424
Age:5 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|---|---------------|----------|------|----------------------------|-------|
| Other | 20 mg/day | Blood Creatine Phosphokinase Increased | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:10/20/03ISR Number: 4211947-3Report Type:Expedited (15-DaCompany Report #PHBS2003ZA09019
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|--------------|----------------------|---------------|------------|------|----------------------------|-------|
| Death | | Arrhythmia | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/day | | Brain Oedema | | | | | |
| UNKNOWN | 50 | Circulatory Collapse | | Budesonide | C | | |
| microgram/d | | Sudden Death | | | | | |
| 200 ug, BID | | | | Flixonase | C | | NASAL |
| UNKNOWN | one or twice | | | Inflammid | C | | |
| every three | | | | Ventolin | C | | |
| months | | | | | | | |

Date:10/20/03ISR Number: 4214877-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031002540
Age:45 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Myocardial Infarction | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | Vioxx (Rofecoxib) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/21/03ISR Number: 4215874-7Report Type:Expedited (15-DaCompany Report #HQWYE149510OCT03
Age:20 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Confusional State Drug Interaction Feeling Hot | Health Professional Other | Efexor (Venlafaxine Hydrochloride, Tablet) | PS | | ORAL |
| 150 MG 1X PER | | Vertigo | | | | | |
| 1 DAY | | | | Bexin (Dextromethorphan Hydrobromide,) | SS | | ORAL |
| 25 MG 1X PER | | | | | | | |
| 1 DAY | 1 DAY | | | Nemexin (Naltrexone Hydrochloride,) | SS | | ORAL |
| 100 MG 1X PER | | | | | | | |
| 1 DAY | | | | Ritalin (Methylphenidate Hydrochloride,) | SS | | ORAL |
| 60 MG 1X PER | | | | | | | |
| 1 DAY | | | | Sinquan (Doxepin Hydrochloride,) | SS | | ORAL |
| 50 MG 1X PER | | | | | | | |
| 1 DAY | | | | | | | |

Date:10/21/03ISR Number: 4215945-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031002658
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Other | | Asthenia Blood Lactate Dehydrogenase Increased Gamma-Glutamyltransferase Increased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |

DAY, ORAL

Date:10/21/03ISR Number: 4215950-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031002658

Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia Blood Lactate Dehydrogenase Increased Gamma-Glutamyltransferase Increased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

36 MG, 1 IN 1

DAY, ORAL

Date:10/22/03ISR Number: 4215399-9Report Type:Direct Company Report #CTU 204306

Age:26 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | | Methylphenidate | PS | | |

Date:10/23/03ISR Number: 4215648-7Report Type:Expedited (15-DaCompany Report #PHNU2003DE02479

Age: Gender:Male I/FU:F

| | |
|---------|---|
| Outcome | PT |
| Other | Anxiety Decreased Activity Delusion |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|--------------------|----------|--|---------------|------------|------|----------------------------|-------|
| Dose | Duration | Depression Drug Ineffective Drug Interaction | Report Source | Product | Role | Manufacturer | Route |
| 20 to 40 mg/day | | Hearing Impaired Stress | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 120 mg, QD | 20160MIN | | | Telfast | SS | | ORAL |

Date:10/23/03ISR Number: 4215650-5Report Type:Expedited (15-DaCompany Report #PHNU2003DE01089
Age:7 YR Gender:Male I/FU:F

| | | | | | | | |
|--------------------|----------|---|---------------|----------|------|----------------------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Autoimmune Thyroiditis Blood Thyroid Stimulating | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Other | | Hormone Increased | | | | | |
| 10mg-0-5mg/da y | | Hypothyroidism Thyroid Atrophy | | | | | |

Date:10/23/03ISR Number: 4224064-3Report Type:Expedited (15-DaCompany Report #CEL-2003-03447-ROC
Age: Gender:Male I/FU:I

| | | | | | | | |
|---|----------|--------------------------|------------------------|--|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Stevens-Johnson Syndrome | Health Professional | Methylphenidate Er Tablets (Strength Unspecified) (Methlphenidate Hydrochloride) | PS | | |
| Hospitalization - Initial or Prolonged | | | | | | | |

Date:10/24/03ISR Number: 4219241-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031001855
Age:9 YR Gender:Male I/FU:I

| | | | | | | | |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |

Other Contusion Foreign Concerta Xl
Rash Pruritic Health (Methylphenidate
Professional Sustained Release
Tablets PS

SEE IMAGE

Date:10/24/03ISR Number: 4219464-1Report Type:Expedited (15-DaCompany Report #DK-JNJFOC-20031003529

Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Depression Psychiatric Symptom | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | PS |

54 MG, 1 IN 1

DAY,

Date:10/24/03ISR Number: 4219467-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031003840

Age:7 YR Gender:Female I/FU:I

| | |
|------------------|--|
| Outcome Other | PT Abnormal Behaviour Attention Deficit/Hyperactivity |
|------------------|--|

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Disorder Condition Aggravated Disturbance In Attention Drug Interaction | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|--|-----------------------------------|---|------|--------------|-------|
| 36 MG, 1 IN 1 DAY, | | | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| 5 ML, 4 IN 1 DAY, | | | | Amoxicillin (Amoxicillin) | SS | | |
| | | | | Melatonin (Melatonin) | C | | |

Date:10/24/03ISR Number: 4219667-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031004151
Age: Gender:Unknown I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|-----------|---------------|--|------|--------------|-------|
| | | Hepatitis | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |

Date:10/24/03ISR Number: 4219674-3Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20031003637
Age:6 YR Gender:Male I/FU:I

| Outcome Dose Hospitalization - Initial or Prolonged | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------------|--|------|--------------|-------|
| 18 MG, 1 IN 1 | | Constipation Gastrointestinal Obstruction | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

DAY, ORAL

Clonidine
(Clonidine) Tablets C

Date:10/24/03ISR Number: 4219682-2Report Type:Expedited (15-DaCompany Report #BE-JNJFOC-20030902595
Age:39 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|-----------------------------------|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Alanine Aminotransferase Aspartate Aminotransferase Blood Creatine Phosphokinase | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 | Delusion | | | | | |
| DAY, ORAL | Hallucination, Auditory Mania Psychotic Disorder Suicide Attempt | | Seroxat (Paroxetine Hydrochloride) Unknown | C | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/24/03ISR Number: 4219757-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031003780
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------|---------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pica | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| SEE IMAGE | | | | Albuterol (Salbutamol) | C | | |

Date:10/24/03ISR Number: 4219774-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031003652
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Stevens-Johnson Syndrome | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |

Date:10/24/03ISR Number: 4219794-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031003781
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Sleep Walking | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 54 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| | | | | Wellbutrin (Bupropion Hydrochloride) | SS | | |
| 150 MG | | | | | | | |

Date:10/24/03ISR Number: 4220199-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031004293
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Tourette'S Disorder | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY | | | | | | | |

Date:10/27/03ISR Number: 4218853-9Report Type:Expedited (15-DaCompany Report #PHRM2003FR02822
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------------------------|---------------|----------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Gastritis | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 10 mg/day | | | | | | | |
| Syncope | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/27/03ISR Number: 4221093-0Report Type:Expedited (15-DaCompany Report #2003111995
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|---|------|--------------|-------|
| Hospitalization - 50 MG, ORAL | | Confusional State | Foreign | Sinequan (Doxepin) | PS | | ORAL |
| Initial or Prolonged 50 MG, (BID), ORAL | | Drug Interaction Temperature Intolerance Vertigo | Health Professional | Dextromethorphan Hydrobromide (Bextromethorpahn Hydrobromide) | SS | | ORAL |
| | | | | Venlafaxine Hydrochloride (Venlfafaxine Hydrochloride) | SS | | ORAL |
| 150 MG, ORAL | | | | Methylpehenidate Hydrochloride (Methylphenidate Hydrochloride) | SS | | ORAL |
| 60 MG, ORAL | | | | Naltrexone Hydrochloride (Naltrexone Hydrochloride) | SS | | ORAL |
| 100 MG, ORAL | | | | | | | |

Date:10/28/03ISR Number: 4219888-2Report Type:Expedited (15-DaCompany Report #PHBS2003ZA09019
 Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|--------------------------------------|---------------|--------------------------|--------|----------------------------|-------|
| Death 20 mg/day | | Arrhythmia Brain Oedema | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| UNKNOWN microgram/d | 50 | Circulatory Collapse Sudden Death | | Budesonide | C | | |
| 200 ug, BID | | | | Flixonase Inflammiide | C C | | NASAL |

UNKNOWN one or twice
every three
months
Ventolin C

Date:10/28/03ISR Number: 4220499-3Report Type:Direct Company Report #CTU 204718
Age:22 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Pharmaceutical Product | | Methyphenydate Sr 20 Ritalin Manufacturer | PS | | ORAL |
| 2 PO BID, 3-4 YRS Complaint | | | | | | | |

Date:10/28/03ISR Number: 4222815-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031002164
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|----------------------------------|---------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Obsessive-Compulsive Disorder | Study Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 DAY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/28/03ISR Number: 4222818-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031002164
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Obsessive-Compulsive Disorder | Study Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:10/28/03ISR Number: 4223336-6Report Type:Expedited (15-DaCompany Report #CEL-2003-03436-ROC
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Health Professional | Metadate Cd (Methylphenite Hydrochloride) | PS | | |
| 60 MG | | | | | | | |
| Ssi (Ssri) C | | | | | | | |

Date:10/29/03ISR Number: 4221835-4Report Type:Direct Company Report #CTU 204803
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|----------------------------------|---------------|--------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression | | Methylphenidate 20 Mg | PS | | |
| 1 1/2 TAB @ | | | | | | | |
| 0800/1200/160 | | | | | | | |
| 0 | | | | | | | |
| Pharmaceutical Product | | | | | | | |
| Complaint | | | | | | | |
| Psychomotor Hyperactivity | | | | | | | |

Date:10/29/03ISR Number: 4221837-8Report Type:Direct Company Report #CTU 204804
Age:51 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|------------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin 10 Mg | PS | | ORAL |
| ONE DOSE | PO | | | | | | |
| QID | | | | | | | |

Date:10/30/03ISR Number: 4224266-6Report Type:Expedited (15-DaCompany Report #KII-2003-0002834
Age:26 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|--|----------------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Body Temperature Increased Confusional State | Health Professional | Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet | PS | | ORAL |
| Other | | Disorientation Dyslogia Logorrhoea Multiple Drug Overdose | | Oxycodone Hydrochloride (Oxycodone Hydrochloride) | SS | | ORAL |
| ORAL | | Pain Tachycardia Tremor | | Promethazine (Promethazine) Paregoric (Benzoic Acid, Camphor, Anise Oil, Opium) Protonix (Pantoprazole) Ambien (Zolpidem Tartrate) | SS SS SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

UMOL,

| | |
|-------------------|----|
| Prednisone | |
| (Prednisone) | SS |
| Amitriptyline | |
| (Amitriptyline) | SS |
| Strattera | |
| (Atomoxetine) | SS |
| Ocean Nasal Spray | |
| (Sodium Chloride) | SS |
| Metronidazole | |
| (Metronidazole) | SS |
| Methylphenidate | |
| (Methylphenidate) | SS |

Date:10/31/03ISR Number: 4224791-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031004165
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression Paranoia | Study Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:10/31/03ISR Number: 4225613-1Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20031001540
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alopecia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tabltes | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:10/31/03ISR Number: 4225615-5Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20031005088
Age:11 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|-----------------------------------|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Delusion Disorientation Feeling Abnormal Gastroenteritis Viral Hallucination | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | Medication Error Nausea Overdose Vomiting | | | | | |

Date:11/03/03ISR Number: 4226107-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20031005987
Age:7 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|---|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Hallucination Medication Error Psychotic Disorder Skin Disorder | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, ORAL | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/03ISR Number: 4226201-3Report Type:Expedited (15-DaCompany Report #NSADSS2002046188
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---|--|------------------------|--|------|--------------|-------|
| Death | | Cardiac Arrest Circulatory Collapse Sudden Cardiac Death Syncope Ventricular Tachycardia | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| | 18 MG, 1 IN 1 DAY, ORAL; 36 MG, 1 IN 1 DAY, ORAL | | | | | | |

Date:11/04/03ISR Number: 4225361-8Report Type:Expedited (15-DaCompany Report #PHNU2003DE02607
Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|----------------------------|---------------|----------|------|----------------------------|-------|
| Other | | Amaurosis Fugax Scotoma | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | 15 mg/day | | | | | | |

Date:11/04/03ISR Number: 4225366-7Report Type:Expedited (15-DaCompany Report #PHBS2003CA11766
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|--------------------------------|---------------|----------|------|----------------------------|-------|
| Other | | Aggression High Risk Sexual | | Ritaline | PS | Novartis Sector: Pharma | |
| UNKNOWN | 5 mg, BID | Behaviour | | Dilantin | C | | |
| UNKNOWN | | Perseveration | | Warfarin | C | | |
| UNKNOWN | | Sexual Activity Increased | | Losec | C | | |
| UNKNOWN | | | | Colace | C | | |

UNKNOWN UNK, UNK

Tylenol

C

Date:11/04/03ISR Number: 4227518-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031004293
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Tourette'S Disorder | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | |
| 36 MG, 1 IN 1 | | | | | | | |

DAY

Date:11/06/03ISR Number: 4230649-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031006198
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Mechanical Ileus | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 54 MG, ORAL | | | | | | | |

Date:11/07/03ISR Number: 4230015-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0392935A
Age: Gender:Female I/FU:F

| Outcome | PT |
|---------|---------------------|
| | Drug Interaction |
| | Liver Function Test |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Abnormal
Road Traffic Accident

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|------|----------|---------------|------------|------|-----------------|-------|
| YR | | | Wellbutrin | PS | Glaxosmithkline | ORAL |
| YR | | | Ritalin | SS | | |

Date:11/10/03ISR Number: 4231205-0Report Type:Expedited (15-DaCompany Report #PHBS2003CA12032
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|------------|------|----------------------------|-------|
| Dose Other | | Chest Discomfort Depressed Level Of Consciousness Dyspepsia Glossodynia Headache | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |

Date:11/12/03ISR Number: 4234039-6Report Type:Direct Company Report #CTU 205842
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|----------------|------|--------------|-------|
| Hospitalization - ORAL Initial or Prolonged | | Antibody Test Positive Dermatitis Exfoliative Erythema Multiforme Penile Ulceration Skin Depigmentation | | Concerta ? J&J | PS | J&J | ORAL |

Date:11/13/03ISR Number: 4234113-4Report Type:Expedited (15-DaCompany Report #PHBS2003CH05877
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|-----------|--------------------------------|---------------|---------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged UNKNOWN | 10 mg/day | Abdominal Pain Pancreatitis | | Ritalin | PS | Novartis Sector: Pharma | |

Ritalin

SS

Novartis Sector:
Pharma

UNKNOWN

Date:11/13/03ISR Number: 4234122-5Report Type:Expedited (15-DaCompany Report #PHNU2003DE03876

Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|---------------|-------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated Decreased Appetite | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Unknown | | Nausea | | Decortin | C | | ORAL |
| 2.5 mg/day | | Rheumatoid Arthritis | | Methotrexat | C | | ORAL |
| Unknown | | | | | | | |

Date:11/13/03ISR Number: 4235760-6Report Type:Expedited (15-DaCompany Report #CEL-2003-03659-ROC (0)

Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|---|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Eye Movement Disorder Hallucination Insomnia Oral Intake Reduced | Consumer | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG (20 MG, OAM), PO | | Psychotic Disorder | | | | | |
| 20 MG (20 MG | | Schizophrenia | | Paxil (Paroxetine Hydrochloride) | SS | | ORAL |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Q HS), PO

Date:11/14/03ISR Number: 4235463-8Report Type:Expedited (15-DaCompany Report #PHEH2003US06984
 Age:33 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|------------------|----------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Alcohol Use Amnesia | | Tegretol | PS | Novartis Sector: Pharma | |
| UNK,UNK | | Bradyphrenia Drug Interaction | | Tegretol | SS | Novartis Sector: Pharma | |
| UNK,UNK | | Hallucination Judgement Impaired | | Ritalin Luvox | SS SS | | |
| UNK,UNK | | Loss Of Consciousness | | Luvox | SS | | |
| UNK,UNK | | Memory Impairment Sexual Offence Theft Thinking Abnormal | | Alcohol | SS | | |

Date:11/17/03ISR Number: 4237033-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031002658
 Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia Blood Lactate Dehydrogenase Increased Gamma-Glutamyltransferase Increased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | ORAL |
| 36 MG, 1 IN 1 | | | | | PS | | |

DAY, ORAL

Date:11/17/03ISR Number: 4237053-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031100962
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|---|-----------------------------------|--|------|--------------|-------|
| Life-Threatening Other | | Aggression Laceration Suicide Attempt | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| 18 MG | | | | | PS | | |

Date:11/17/03ISR Number: 4237057-7Report Type:Expedited (15-DaCompany Report #DK-JNJFOC-20031100693
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Malaise Palpitations Sinus Tachycardia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| 36 MG, 1 IN 1 DAY | | | | | PS | | |

Date:11/17/03ISR Number: 4237060-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031100960
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------------------|-----------------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Blood Pressure Decreased Syncope | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Sustained Release
Tablets PS

36 MG, 1 IN 1

DAY

Date:11/17/03ISR Number: 4237063-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031001518
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Alkaline Phosphatase Increased Haemoglobin Decreased Liver Function Test | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | | | |
| | | Abnormal | | | PS | | ORAL |

36 MG, 1 IN 1

DAY ORAL

Date:11/18/03ISR Number: 4237721-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20031003652
Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Mycoplasma Infection | Health | Concerta | | | |
| ORAL | | Stevens-Johnson Syndrome | Professional | | PS | | ORAL |

Date:11/18/03ISR Number: 4237722-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031100660
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Body Height Below Normal | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| | | | | | PS | | ORAL |

27 MG, 1 IN 1

DAY, ORAL

Date:11/19/03ISR Number: 4237465-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0379987A
Age:35 YR Gender:Female I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|-------------------------------------|---------------|-----------------|------|-----------------|-------|
| Dose | Duration | | | | | |
| Death | Acidosis | Consumer | Bupropion | PS | Glaxosmithkline | ORAL |
| Hospitalization - UNKNOWN | Cardiovascular Disorder | | Venlafaxine | SS | | |
| Initial or Prolonged UNKNOWN | Completed Suicide | | Methylphenidate | SS | | |
| | Convulsion | | Quetiapine | SS | | |
| | Depressed Level Of Consciousness | | Clonazepam | SS | | |
| | Hypotension | | Trazodone | SS | | |
| | Hypothermia | | Gabapentin | SS | | |
| | Intentional Misuse | | Lansoprazole | SS | | |
| | Respiratory Depression | | | | | |

Date:11/19/03ISR Number: 4238576-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031100960
Age: Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------------------------|-----------------------------------|---|------|--------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - Initial or Prolonged | Hypotension Syncope | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) | | | |
| 36 MG, 1 IN 1 | | | Sustained | PS | | |

DAY

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/19/03ISR Number: 4238945-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031002300
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation Weight Gain Poor White Blood Cell Count Decreased | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |

Date:11/19/03ISR Number: 4239181-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031103067
Age:30 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Heart Rate Irregular Medication Error Overdose | Consumer | Concerta (Methylphenidate Hydrochloride) | PS | | |
| INJECTION | | | | | | | |

Date:11/20/03ISR Number: 4238136-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0430642A
Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|---------------|------------|------|-----------------|-------|
| Dose | | | | | | | |
| 150MG Per day | 2 MON | Joint Sprain | | Wellbutrin | PS | Glaxosmithkline | ORAL |
| 54MG Per day | | Sleep Walking | | Concerta | SS | | ORAL |

Date:11/21/03ISR Number: 4239170-7Report Type:Expedited (15-DaCompany Report #PHBS2003JP12770
Age:34 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Dependence | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 30 mg/day | | | | | | | |

Date:11/21/03ISR Number: 4239370-6Report Type:Expedited (15-DaCompany Report #PHFR2003GB04372
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Anaemia | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, TID | | Contusion | | | | | |

Date:11/21/03ISR Number: 4239952-1Report Type:Direct Company Report #CTU 206624
Age:27 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Suicidal Ideation | | Ritalin | PS | | |

Date:11/21/03ISR Number: 4240503-6Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20031005088
Age:11 YR Gender:Female I/FU:F

| Outcome | PT |
|---|---|
| Hospitalization - Initial or Prolonged | Delusion Diarrhoea Disorientation Feeling Abnormal Gastroenteritis Viral Hallucination |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Nausea Vomiting | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------|-----------------------------|--|------|--------------|-------|
| SEE IMAGE | | | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

Date:11/24/03ISR Number: 4241392-6Report Type:Expedited (15-DaCompany Report #2003-03948
 Age:38 YR Gender:Unknown I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------|----------|-------|--------------------------------|---|----------------|---------------------|-------|
| Death | | | Death | Literature Health Professional | Methylphenidate Hydrochloride (Watson Laboratories) (Methylphenidate Verapamil (Watson Laboratories) (Verapamil Hydrochloride) Unknopwn Trandolapril (Trandolapril) | PS SS SS | Watson Laboratories | |

Date:11/24/03ISR Number: 4241769-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031103820
 Age:16 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-------------------------|----------|--|---------------------|--|----------|--------------|-------|
| Death | 36 MG, 3 IN 1 DAY, ORAL | | Brain Death Cardiac Arrest Cerebral Haemorrhage Drug Abuser Drug Ineffective Drug Interaction | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets Adderall (Obetrol) | PS SS | | ORAL |

Date:11/24/03ISR Number: 4242046-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031103246
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Leukopenia | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 54 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:11/24/03ISR Number: 4242047-4Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031100962
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|--|------------------------|------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Aggression | Foreign | Concerta | | | |
| Other | | Intentional Self-Injury Suicidal Ideation | Health Professional | (Methylphenidate Hydrochloride) | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

18 MG, 1 IN 1
 DAY, ORAL
 Sustained Release
 Tablets PS ORAL

Date:11/25/03ISR Number: 4240737-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0383130A
 Age:42 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------------|---------------|-----------------|------|-----------------|-------|
| Death | | Coma | | Bupropion | PS | Glaxosmithkline | ORAL |
| | | Convulsion | | Methylphenidate | SS | | |
| UNKNOWN | | Depressed Level Of Consciousness | | Librax | C | | |
| | | Drug Ineffective | | Montelukast | C | | |
| | | Intentional Misuse | | Synthroid | C | Glaxosmithkline | |

Date:11/25/03ISR Number: 4242238-2Report Type:Direct Company Report #CTU 206868
 Age:60 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------------|---------------|--------------------|------|--------------|-------|
| 2 Q AM 1 Q | | Fatigue | | Generic Ritalin 10 | | | |
| | | Pharmaceutical Product | | Mg | PS | | |
| NOON | 30 DAY | Complaint | | | | | |

Date:11/25/03ISR Number: 4242349-1Report Type:Expedited (15-DaCompany Report #HQWYE168918NOV03
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|----------------------|------|--------------|-------|
| Other | | Convulsion | Consumer | Dimetapp Nd | | | |
| | | Drug Interaction | | (Loratadine, Tablet, | | | |
| | | Dyskinesia | | Orally | | | |
| 1 TABLET | | | | Disintegrating) | PS | | ORAL |
| EVERY OTHER | | | | | | | |

DAY, ORAL

Concerta
(Methylphenidate,) SS

ORAL

54 MG DAILY,

ORAL

Date:11/25/03ISR Number: 4242524-6Report Type:Expedited (15-DaCompany Report #03P-163-0241068-00

Age:38 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|-------------------|-----------------------------------|------|--------------|-------|
| Death | | Completed Suicide | Literature Health | Trandolapril/Verapamil (Tarka Er) | PS | | ORAL |
| ORAL | | | Professional | Methylphenidate | SS | | ORAL |
| ORAL | | | | | | | |

Date:11/26/03ISR Number: 4242202-3Report Type:Direct Company Report #CTU 206943

Age:60 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------------------|---------------|-----------------------|------|--------------|-------|
| | | Fatigue Pharmaceutical Product | | Generic Ritalin 10 Mg | PS | Geneva | |
| 2Q AM 1Q NOON | 30 DAY | Complaint | | Methylphenidate 10 Mg | SS | Mallinckrodt | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/28/03ISR Number: 4243218-3Report Type:Direct
Age: Gender: I/FU:I

Company Report #USP 56179

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error | | Methylphenidate | PS | Watson | |
| TABLET | | | | | | | |

Date:12/02/03ISR Number: 4246500-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030906118
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alanine Aminotransferase Increased Aspartate Aminotransferase Increased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | | | | | | | |
| Blood Lactate Dehydrogenase Increased Gamma-Glutamyltransferase Increased Liver Function Test Abnormal | | | | | | | |

Date:12/03/03ISR Number: 4244708-XReport Type:Expedited (15-DaCompany Report #PHNR2003AU01641
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------------------------------|---------------|------------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia Confusional State | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 40 mg mance 2880 MIN Crying Discomfort Dry Mouth Fatigue Headache Heart Rate Increased Muscle Twitching Pain | | | | | | | |

Panic Attack
Tremor

Date:12/03/03ISR Number: 4245233-2Report Type:Expedited (15-DaCompany Report #PHBS2001JP08737
Age:19 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|--|---------------|-------------------------------------|-------------|----------------------------|-------|
| Dose | | | | | | |
| Life-Threatening | Blood Creatine Phosphokinase Increased Convulsion | | Ritaline Psychotropic Agents | PS C | Novartis Sector: Pharma | ORAL |
| UNKNOWN | Depressed Level Of Consciousness Hyperthermia Malignant Shock | | | | | |

Date:12/03/03ISR Number: 4246675-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031002540
Age:45 YR Gender:Male I/FU:F

| Outcome | PT | Report Source |
|---|--------------------------------|-----------------------------------|
| Hospitalization - Initial or Prolonged | Acute Myocardial Infarction | Health Professional Company |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Representative

| Dose | Duration | Product | Role | Manufacturer | Route |
|------|----------|--|------|--------------|-------|
| ORAL | | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| | | Vioxx (Rofecoxib) | C | | |

Date:12/03/03ISR Number: 4246799-9Report Type:Expedited (15-DaCompany Report #CEL-2003-03659-ROC
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|---|---------------|---|------|--------------|-------|
| Dose Other | | Eye Movement Disorder Fear Hallucination Insomnia | Consumer | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG (20 MG, QAM), PO | | Muscle Twitching | | | | | |
| 20 MG, (20 MG, Q HS), PO | | Oral Intake Reduced Psychotic Disorder Schizophrenia Thinking Abnormal | | Paxil (Paroxetine Hydrochloride) | SS | | ORAL |

Date:12/03/03ISR Number: 4246841-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030906118
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose Other | | Alanine Aminotransferase Increased Aspartate Aminotransferase Increased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablet | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |

Blood Lactate
Dehydrogenase Increased
Gamma-Glutamyltransferase
Increased

Date:12/05/03ISR Number: 4251824-5Report Type:Expedited (15-DaCompany Report #CEL-2003-04227-ROC
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Psychotic Disorder | Health Professional Company Representative | Metadate Cd Capsules (Strength Unspecified) (Methylphenidate | PS | | |

Date:12/08/03ISR Number: 4248762-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031105182
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypothyroidism | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

36 MG, 1 IN 1

DAY, ORAL
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/08/03ISR Number: 4248763-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030803159
 Age:18 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Discomfort Agitation Disturbance In Attention Miosis Nausea | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 DAY, ORAL | | Restlessness Tachycardia Vertigo | | Medikinet (Methylphenidate Hydrochloride) | C | | |

Date:12/08/03ISR Number: 4248764-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031105179
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|----------------|-----------------------------------|--|------|--------------|-------|
| Other | | Hypothyroidism | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | | | | | | | |

Date:12/08/03ISR Number: 4248765-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031200008
 Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|-----------------------------------|--|------|--------------|-------|
| Other | | Hyperthyroidism | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |

DAY, ORAL

Date:12/08/03ISR Number: 4249345-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-200030705724

Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Glossodynia | Health | Concerta | | | |
| | | Local Swelling | Professional | (Methylphenidate | | | |
| | | Oedema Peripheral | | Hydrochloride) | | | |
| | | Platelet Count Decreased | | Sustained Release | | | |
| | | Pyrexia | | Tablets | PS | | ORAL |
| 54 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | Rash Erythematous | | | | | |
| | | Swollen Tongue | | Risperdal | | | |
| | | | | (Risperidone) | | | |
| | | | | Unspecified | SS | | |
| | | | | Keflex (Cefalexin | | | |
| | | | | Monohydrate) | C | | |
| | | | | Prozac (Fluoxetine | | | |
| | | | | Hydrochloride) | C | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/09/03ISR Number: 4248604-3Report Type:Expedited (15-DaCompany Report #PHNU2003DE04286
Age:19 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-----------------|---------------|----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged 40mg/day Other | | Drug Dependence | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | | | | Sinquan | | | |
| | | | | /Den/ | C | | ORAL |

Date:12/11/03ISR Number: 4250967-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20031103067
Age:30 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|------------------------------------|---|------|--------------|-------|
| Death | | Depressed Level Of Consciousness Glomerulosclerosis Heart Rate Irregular | Consumer Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | |
| INJECTION | | Overdose Self-Medication | | | | | |

Date:12/12/03ISR Number: 4250320-9Report Type:Expedited (15-DaCompany Report #PHBS2001JP08737
Age:19 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|---|------------------------|---------------------|------|----------------------------|-------|
| Life-Threatening | | Blood Creatine Phosphokinase Increased Convulsion | Health Professional | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| UNKNOWN | | Depressed Level Of Consciousness Enteritis Extrapyramidal Disorder Gastrointestinal Necrosis Hyperthermia Malignant Multi-Organ Failure Nasopharyngitis Neuroleptic Malignant | | Psychotropic Agents | C | | |

Syndrome
Rhabdomyolysis
Self-Medication
Shock
Tremor

Date:12/12/03ISR Number: 4250324-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE04299
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---------------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Ventricular Extrasystoles | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 30mg/day | | | | Bisoprolol | C | | ORAL |

Date:12/15/03ISR Number: 4251323-0Report Type:Expedited (15-DaCompany Report #PHNU2003DE04318
Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------------------------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Joint Effusion Juvenile Arthritis | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 35 mg/day | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/16/03ISR Number: 4252008-7Report Type:Expedited (15-DaCompany Report #PHNU2003DE04298
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------|----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | 10mg/day | Coma | Difficulty In Walking | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Other | | Drug Level Increased Electroencephalogram Abnormal Tic | | Ritaline | SS | Novartis Sector: Pharma | |

Date:12/17/03ISR Number: 4253201-XReport Type:Direct Company Report #CTU 208200
 Age:49 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|-----------------|------|--------------|-------|
| Other | | Asthenia Headache Nausea Pharmaceutical Product Complaint Vision Blurred Vomiting | | Generic Ritalin | PS | | |

Date:12/17/03ISR Number: 4253334-8Report Type:Direct Company Report #CTU 208195
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|--|---------------|---|------|--------------|-------|
| 20 MG THREE TIMES DAY BY MOUTH | | Pharmaceutical Product Complaint Psychomotor Hyperactivity | | Methylphenidate 20 Mg (Celltech Brand) | PS | Celltech | |

Date:12/17/03ISR Number: 4254297-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031201156
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Delusion | Foreign | Concerta Xl | PS | | |
| 18 MG, 1 IN 1 | | Hallucination, Auditory | Health | | | | |
| DAY | | Hallucination, Visual Psychotic Disorder Thinking Abnormal | Professional | | | | |

Date:12/17/03ISR Number: 4254300-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031201154
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Grand Mal Convulsion | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| Other | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/17/03ISR Number: 4254304-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031200590
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Confusional State Epilepsy Eye Pain Restlessness Retrograde Amnesia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| 36 MG, 1 IN 1 DAY, ORAL | | Sleep Walking Tremor | | | PS | | ORAL |

Date:12/17/03ISR Number: 4267017-1Report Type:Periodic Company Report #2013191
 Age:44 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|------------------------|---|------|--------------|-------|
| Death | | Overdose | Health Professional | Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride Ethyl Alcohol (Ethanol) Alfenta (Alfentanil Hydrochloride) Sublimaze (Fentanyl) Sufenta (Sufentanil Citrate) Ritalin (Methylphenidate Hydrochloride) Percodan (Acetylsalicylic Acid, Oxycodone Hydrochl) | | | |
| | | | | | PS | | |
| | | | | | SS | | |
| | | | | | SS | | |
| | | | | | SS | | |
| | | | | | SS | | |
| | | | | | SS | | |

Date:12/18/03ISR Number: 4255942-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031105182
 Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Hypothyroidism | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| Equasym (Methylphenidate Hydrochloride) | | | | | | | |
| C | | | | | | | |

Date:12/18/03ISR Number: 4255950-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031105179
Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Hypothyroidism Thyroiditis | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

DAY, ORAL

Date:12/18/03ISR Number: 4273919-2Report Type:Periodic Company Report #HQ9570718DEC2001
 Age:31 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|------------------------|---|------|--------------|-------|
| Dose Other | | Abortion Spontaneous Drug Withdrawal Syndrome Infertility Female Nausea Pregnancy | Health Professional | Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release) | PS | | ORAL |

SEE IMAGE

ORAL

| | | |
|---|----|--|
| Ritalin (Methylphenidate Hydrochloride,) | SS | |
| Wellbutrin (Amfebutamone Hydrochloride) | C | |
| Methylphenidate (Methylphenidate) | C | |

Date:12/19/03ISR Number: 4254769-XReport Type:Expedited (15-DaCompany Report #PHFR2003GB04698
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------|----------|------------|---------------|----------|------|----------------------------|-------|
| Disability 5 mg, BID | | Paraplegia | | Ritaline | PS | Novartis Sector: Pharma | |

Date:12/19/03ISR Number: 4254792-5Report Type:Expedited (15-DaCompany Report #PHBS2003JP13732
 Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------------------|---------------|---------|------|----------------------------|-------|
| Dose Other | | Drug Exposure During Pregnancy | | Ritalin | PS | Novartis Sector: Pharma | |

TRANSPLACENTAL

| | | | | | | | |
|---|----------|-------------------------------------|---------------|---------------|------|----------------------------|-------|
| TRANSPLACENTAL | | Drug Toxicity | | Paxil | | C | |
| TRANSPLACENTAL | | | | Flunitrazepam | | C | |
| Date:12/19/03ISR Number: 4254816-5Report Type:Expedited (15-DaCompany Report #PHNR2003AU01542 | | | | | | | |
| Age: Gender:Male I/FU:F | | | | | | | |
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Other | | Abdominal Pain Upper Chest Pain | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 10 mg morning and 10 mg noon | | Diarrhoea Nausea | | | | | |
| unspecified | | Pharmaceutical Product Complaint | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| Date:12/19/03ISR Number: 4254824-4Report Type:Expedited (15-DaCompany Report #PHBS2003JP13893 | | | | | | | |
| Age: Gender:Unknown I/FU:I | | | | | | | |
| Outcome | | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| Other | | Drug Abuser | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | | | | | | | |
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/19/03ISR Number: 4256482-1Report Type:Expedited (15-DaCompany Report #DK-JNJFOC-20031201656
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Chest Wall Pain | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY ; 36 MG | | | | | | | |

Date:12/19/03ISR Number: 4256552-8Report Type:Expedited (15-DaCompany Report #SUSI-2003-00501
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---|---------------|---|--------------|--------------|-------|
| Death | | Brain Death Cardiac Arrest Cerebral Haemorrhage Drug Ineffective | Other | Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Concerta (Methylphenidate Hydrochloride) | PS SS | | ORAL |
| 36 MG 3 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| Cocaine (Cocaine) SS | | | | | | | |

Date:12/19/03ISR Number: 4256580-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030803159
Age:18 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Discomfort Agitation Disturbance In Attention Miosis Nausea | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |

DAY, ORAL
 Paraesthesia
 Restlessness
 Tachycardia
 Vertigo
 Medikinet (Tablets)
 Methylphenidate
 Hydrochloride C

Date:12/22/03ISR Number: 4256155-5Report Type:Expedited (15-DaCompany Report #PHBS2003JP13732
 Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------|----------|---|------------------------|---------------|------|----------------------------|-------|
| Other | | Cyanosis Neonatal Drug Exposure During | Health Professional | Ritalin | PS | Novartis Sector: Pharma | |
| TRANSPLACENTAL | | Pregnancy | | Solanax | SS | | |
| TRANSPLACENTAL | | Drug Toxicity | | Paxil | C | | |
| TRANSPLACENTAL | | Maternal Drugs Affecting Foetus | | Flunitrazepam | C | | |

Date:12/23/03ISR Number: 4256921-6Report Type:Expedited (15-DaCompany Report #PHNU2003DE04364
 Age:6 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------------------------|---------------|----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged 15 mg/day | | Henoch-Schonlein Purpura | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | | | | Ritaline | SS | Novartis Sector: | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

15 mg/day

Date:12/23/03ISR Number: 4256922-8Report Type:Expedited (15-DaCompany Report #PHFR2003GB04787
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Mania | | Ritaline | PS | Novartis Sector: Pharma | |

Date:12/23/03ISR Number: 4258081-4Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031202846
 Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Confusional State Disorientation Nervousness Pain In Extremity | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained | PS | | ORAL |
| 18 MG, 1 IN 1 DAY, ORAL | | Tremor Visual Brightness | | | | | |

Date:12/23/03ISR Number: 4258208-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031203572
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening Hospitalization - Initial or Prolonged | | Sudden Cardiac Death | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| RECEIVED OROS METHYLPHENIDA TE HYDROCHLORIDE | | | | | | | |

Date:12/23/03ISR Number: 4258417-4Report Type:Direct
 Age:26 YR Gender:Male I/FU:I

Company Report #CTU 208657

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | | Methylphenidate | PS | | |

Date:12/23/03ISR Number: 4258940-2Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20031000841
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Cold Sweat Crying Dyspnoea Ear Discomfort Hyperhidrosis | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 1 IN 1 DAY, ORAL | | Oral Intake Reduced Pallor Palpitations Panic Attack Salivary Hypersecretion | | Luvox (Fluvoxamine Maleate) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/24/03ISR Number: 4257435-XReport Type:Expedited (15-DaCompany Report #PHBS2003NL14116
Age:24 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| | | Alcohol Use | | | | | |
| | | Dyspnoea | | Citalopram | C | | |
| UNKNOWN | | | | | | | |

Date:12/24/03ISR Number: 4257507-XReport Type:Expedited (15-DaCompany Report #PHFR2003GB03027
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Sinus Tachycardia | Health | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | | Ventricular Hypertrophy | Professional | | | | |
| 15 mg, BID | | | | | | | |

Date:12/24/03ISR Number: 4257728-6Report Type:Expedited (15-DaCompany Report #PHBS2003JP13732
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|----------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Apnoea | | Ritalin | PS | Novartis Sector: Pharma | |
| | | Cyanosis Neonatal | | | | | |
| TRANSPLACENTAL | | | | | | | |
| | | Drug Exposure During | | Paxil | SS | | |
| TRANSPLACENTAL | | | | | | | |
| | | Pregnancy | | Rohypnol | SS | | |
| TRANSPLACENTAL | | | | | | | |
| | | Drug Toxicity | | Solanax | SS | | |
| TRANSPLACENTAL | | | | | | | |
| | | Hypotonia Neonatal | | | | | |
| | | Irritability | | | | | |
| | | Neonatal Disorder | | | | | |
| | | Tremor | | | | | |

Date:12/26/03ISR Number: 4258306-5Report Type:Expedited (15-DaCompany Report #PHNU2003DE04318
Age:15 YR Gender:Female I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|----------|------------------------|---------------------|----------|------|-------------------------|-------|
| Other | | | Arthralgia | Health Professional | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | 35 mg/day | | Blood Immunoglobulin G | | | | | |
| | | | Increased | | Ritaline | SS | Novartis Sector: Pharma | ORAL |
| | 35 mg/day | | Blood Immunoglobulin M | | | | | |
| | | | Increased | | | | | |
| | | | Erythema Infectiosum | | | | | |
| | | | Joint Effusion | | | | | |
| | | | Joint Warmth | | | | | |
| | | | Juvenile Arthritis | | | | | |

Date:12/26/03ISR Number: 4260481-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031204142
Age:15 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------|----------|--|---------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | | Blood Creatine Phosphokinase Increased | Health Professional | Concerta (Methyylphenidate Hydrochloride) | | | |
| | | | Blood Uric Acid Increased | | Sustained Release Tablets | PS | | ORAL |
| ORAL | | | Muscle Enzyme Increased | | | | | |
| | | | Renal Failure | | | | | |
| | | | Vomiting | | Docycyline (Doxycycline) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/26/03ISR Number: 4260485-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031103427
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression Antisocial Behaviour Pyromania Refusal Of Treatment By Relative | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |

Date:12/26/03ISR Number: 4260493-XReport Type:Expedited (15-DaCompany Report #CEL-2003-04228-SLO
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Alanine Aminotransferase Increased Aspartate | Foreign Health Professional | Equasym 20mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG (20 MG, DAILY), PO | | Aminotransferase Increased Blood Creatine Phosphokinase Increased Blood Lactate Dehydrogenase Increased Viral Myositis | Other | | | | |

Date:12/30/03ISR Number: 4260450-3Report Type:Expedited (15-DaCompany Report #PHBS2003CA11766
Age:69 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 2.5 mg, BID | | Disinhibition High Risk Sexual Behaviour | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| 5 mg, BID | | | | Ritalin | SS | Novartis Sector: | |

| | | | | | |
|---------------|---------------------------|--|---------------|--------|----------------------------|
| 12.5 mg/day | Perseveration | | | Pharma | ORAL |
| | Sexual Activity Increased | | Ritalin | SS | Novartis Sector: Pharma |
| 5 mg, BID | | | Ritalin | SS | Novartis Sector: Pharma |
| 7.5 mg, BID | | | Phenytoin | C | |
| UNKNOWN | 225 mg, QHS | | Salbutamol | C | |
| UNKNOWN | 80 mg/day | | Asa | C | |
| UNKNOWN | 20 mg/day | | Allopurinol | C | |
| UNKNOWN | | | Lactulose | C | |
| UNKNOWN | | | Domperidone | C | |
| UNKNOWN | 20 mg, Q6H | | Pulmicort | C | |
| UNKNOWN | UNK, UNK | | Tylenol | C | |
| UNKNOWN | | | Colace | C | |
| UNKNOWN | | | Losec | C | |
| UNKNOWN | | | Warfarin | C | |
| UNKNOWN | | | Dilantin | C | |
| UNKNOWN | | | Symbicort | C | |
| UNKNOWN | | | Acetaminophen | C | |
| UNKNOWN | PRN | | Diazepam | C | |
| INTRAMUSCULAR | PRN | | Mom | C | |
| UNKNOWN | PRN | | Dulcolax | C | |
| UNKNOWN | PRN | | Selsun | C | |
| PRN | | | Aveeno Oil | C | |
| UNKNOWN | PRN | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/02/04ISR Number: 4264591-6Report Type:Expedited (15-DaCompany Report #CEL-2003-03447-ROC
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Stevens-Johnson Syndrome | Health Professional | Methylphenidate - Slow Release (Methylphenidate Hydrochloride) | PS | | |

Date:01/02/04ISR Number: 4264642-9Report Type:Expedited (15-DaCompany Report #2003189650JP
 Age:1 DY Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|--|-------------------|---|------|--------------|-------|
| Life-Threatening | | Apgar Score Abnormal Cyanosis Central | Foreign Health | Solanax (Alprazolam) Tablet | PS | | ORAL |
| 0.8 MG/DAY, ORAL | | Drug Exposure During | Professional | | | | |
| 30 MG/DAY, ORAL | | Pregnancy Drug Withdrawal Syndrome | Other | Paxil (Paroxetine Hydrochloride) | SS | | ORAL |
| 2 MG/DAY, ORAL | | Neonatal Hypersensitivity Hypopnoea | | Rohypnol (Flunitrazepam) | SS | | ORAL |
| 100 MG/DAY, ORAL | | Hypotonia Irritability Muscle Twitching Neonatal Apnoeic Attack | | Ritalin (Methylphenidate Hydrochloride) | SS | | ORAL |
| | | Therapeutic Agent Toxicity | | | | | |

Date:01/04/04ISR Number: 4263190-XReport Type:Direct Company Report #CTU 209285
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
|---------|----------|----|---------------|---------|------|--------------|-------|

20 MG TID

Drug Effect Decreased

Ritalin PS

Pharmaceutical Product
Complaint

Date:01/06/04ISR Number: 4263860-3Report Type:Expedited (15-DaCompany Report #PHNU2003DE04299
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Other | | Ventricular Extrasystoles | | | | | |
| 10 mg, TID | | | | Bisoprolol | C | | ORAL |
| 10 mg, QD | | | | | | | |

Date:01/06/04ISR Number: 4265397-4Report Type:Direct Company Report #CTU 209435
Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------------|----------|--|---------------|----------------|------|--------------|-------|
| Hospitalization - GIVEN 2 ONLY | | Abnormal Behaviour | | Concerta 54 Mg | PS | | |
| Initial or Prolonged | | Blood Pressure Increased Crying Difficulty In Walking Hyperventilation Medication Error Posturing | | | | | |

| | | | | | |
|------------------|-------------------------------------|------------------------|----------|----|----------------------------|
| Life-Threatening | Apgar Score Low Cyanosis Central | Health Professional | Ritalin | PS | Novartis Sector: Pharma |
| TRANSPLACENTAL | | | | | |
| | Drug Abuser | | Paxil | SS | |
| TRANSPLACENTAL | | | | | |
| | Drug Exposure During | | Rohypnol | SS | |
| TRANSPLACENTAL | | | | | |
| | Pregnancy | | Solanax | SS | |
| TRANSPLACENTAL | | | | | |
| | Drug Toxicity | | | | |
| | Drug Withdrawal Syndrome | | | | |
| | Neonatal | | | | |
| | Hypotonia Neonatal | | | | |
| | Irritability | | | | |
| | Meconium Stain | | | | |
| | Neonatal Apnoeic Attack | | | | |
| | Neonatal Disorder | | | | |
| | Tremor Neonatal | | | | |

Date:01/08/04ISR Number: 4268596-0Report Type:Expedited (15-DaCompany Report #IL-JNJFOC-20040100024
Age:11 YR Gender:Male I/FU:I

Outcome PT
Other Chest Pain
Electrocardiogram Qt
Prolonged

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Tachycardia

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------------|--|------|--------------|-------|
| 36 MG, ORAL | | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

Date:01/08/04ISR Number: 4268603-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031002658
 Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|-----------------------------|--|------|--------------|-------|
| Dose Other | | Asthenia Blood Lactate Dehydrogenase Increased Gamma-Glutamyltransferase Increased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | | Liver Function Test Abnormal | | | | | |

Date:01/09/04ISR Number: 4267535-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0422163A
 Age:33 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|---------------------------------------|---------------|------------|------|-----------------|-------|
| Dose 150MG Twice per day | | Drug Interaction Drug Screen False | | Wellbutrin | PS | Glaxosmithkline | ORAL |
| 54MG Per day | | Positive | | Concerta | SS | | ORAL |

Date:01/09/04ISR Number: 4267638-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0433001A
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|------------|------|-----------------|-------|
| Dose | | Heart Rate Increased | | Wellbutrin | PS | Glaxosmithkline | ORAL |
| 150MG | Unknown | | | Concerta | SS | | ORAL |
| 18MG | Per day | | | | | | |

Date:01/09/04ISR Number: 4269136-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031105477
Age:15 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | Abortion Spontaneous | Foreign | Concerta Xr Concerta | | | |
| Other | | Complications Of Maternal | Health | Xr (Methylphenidate | | | |
| | | Exposure To Therapeutic | Professional | Hydrochloride)Sustai | PS | | ORAL |
| | | Drugs | | ned Release Tablets | | | |
| 54 MG, IN 1 | | Drug Exposure During | | | | | |
| DAY, ORAL | | Pregnancy | | | | | |
| | | Unintended Pregnancy | | | | | |

Date:01/12/04ISR Number: 4269346-4Report Type:Direct Company Report #CTU 209767
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------------|---------------|---------|------|--------------|-------|
| Dose | | Drug Ineffective | | Ritalin | PS | | |
| 20 MG TID | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/13/04ISR Number: 4270799-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031002164
Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Obsessive-Compulsive Disorder | Study Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| | | | | | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:01/13/04ISR Number: 4271521-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031002658
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Alanine Aminotransferase Increased Aspartate | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | | | |
| | | | | | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| Aminotransferase | | | | | | | |
| Increased | | | | | | | |
| Asthenia | | | | | | | |
| Blood Lactate | | | | | | | |
| Dehydrogenase Increased | | | | | | | |
| Gamma-Glutamyltransferase | | | | | | | |
| Increased | | | | | | | |

Date:01/14/04ISR Number: 4270535-3Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0319266A
Age:42 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------|---------------|------------------|----------|-----------------|-------|
| Dose | | | | | | | |
| Other | | Drug Abuser | | Zyban Ritalin | PS SS | Glaxosmithkline | |

Date:01/15/04ISR Number: 4274303-8Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040101263
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Headache | Foreign | Concerta | | | |
| Other | | Leukopenia | Health | (Methylphenidate | | | |
| | | Neutropenia | Professional | Hydrochloride) | PS | | ORAL |
| 18 MG, ORAL | | | | | | | |

Date:01/16/04ISR Number: 4273163-9Report Type:Expedited (15-DaCompany Report #PHNU2003DE03876
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----------|---------------|-------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia | Health | Ritaline | PS | Novartis Sector: | |
| | | Nausea | Professional | | | Pharma | ORAL |
| Unknown | | | | | | | |
| | | | | Decortin | C | | ORAL |
| 2.5 mg/day | | | | | | | |
| | | | | Methotrexat | C | | ORAL |
| Unknown | | | | | | | |

Date:01/16/04ISR Number: 4276414-XReport Type:Expedited (15-DaCompany Report #DK-JNJFOC-20031201656
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Chest Pain | Foreign | Concerta | | | |
| Initial or Prolonged | | Dyslexia | Health | (Methylphenidate | | | |
| | | | | Hydrochloride) | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Sustained Release
Tablets PS

18 MG, 1 IN 1

DAY; SEE

IMAGE

Date:01/20/04ISR Number: 4274637-7Report Type:Expedited (15-DaCompany Report #PHBS2004SE00847
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|---------------|---------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper Aggression | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 0.5 mg/day | | Decreased Appetite Depression | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| 60 mg/day | | Dry Mouth Hallucination Palpitations Psychomotor Hyperactivity Sleep Disorder Suicidal Ideation | | | | | |

Date:01/20/04ISR Number: 4276318-2Report Type:Direct Company Report #CTU 210483
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|---------------|-------------------------|------|--------------|-------|
| Dose | | | | | | | |
| 1 1/2 TABS | | Educational Problem Pharmaceutical Product | | Methylphenidate 10mg | PS | | |
| TID | | Complaint | | | | | |

Date:01/21/04ISR Number: 4275165-5Report Type:Expedited (15-DaCompany Report #PHBS2003JP13732
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|---|--------------------------------------|---------------------|----------|----|----------------------------|
| Life-Threatening Hospitalization - TRANSPLACENTAL | Apgar Score Low Cyanosis Neonatal | Health Professional | Ritalin | PS | Novartis Sector: Pharma |
| Initial or Prolonged TRANSPLACENTAL | Drug Abuser | | Paxil | SS | |
| TRANSPLACENTAL | Drug Exposure During | | Rohypnol | SS | |
| TRANSPLACENTAL | Pregnancy | | Solanax | SS | |
| | Drug Toxicity | | | | |
| | Drug Withdrawal Syndrome | | | | |
| | Neonatal | | | | |
| | Hypotonia Neonatal | | | | |
| | Irritability | | | | |
| | Meconium Stain | | | | |
| | Neonatal Apnoeic Attack | | | | |
| | Neonatal Disorder | | | | |
| | Tremor Neonatal | | | | |

Date:01/23/04ISR Number: 4316812-9Report Type:Direct Company Report #USP 56369
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------------|------|--------------|-------|
| | | Medication Error | | Methylin 5 Mg | PS | Mallincrodt | |
| TABLET | | | | Methadone 5 Mg | SS | Roxane | |
| TABLET | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/26/04ISR Number: 4279919-0Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040101913
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------|-----------------------------|--|------|--------------|-------|
| Disability | | Alopecia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 36 MG, ORAL | | | | Ritalin (Methylphenidate Hydrochloride) Unknown | C | | |

Date:01/26/04ISR Number: 4280106-0Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040101912
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|-----------------------------|--|------|--------------|-------|
| Other | | Haemoglobin Decreased Leukopenia Red Blood Cell Count Decreased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 36 MG, ORAL | | White Blood Cell Count Decreased | | | | | |

Date:01/26/04ISR Number: 4280109-6Report Type:Expedited (15-DaCompany Report #TW-JNJFOC-20031204885
 Age:7 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|-----------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Depressed Level Of Consciousness Heart Rate Increased Hypokinesia Medication Error | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |

DAY, ORAL

Date:01/26/04ISR Number: 4280110-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20031002658
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|-------------------|------|--------------|-------|
| Dose | | Alanine Aminotransferase | Foreign | Concerta | | | |
| Other | | Increased | Health | (Methylphenidate | | | |
| | | Aspartate | Professional | Hydrochloride) | | | |
| | | Aminotransferase | | Sustained Release | | | |
| 36 MG, 1 IN 1 | | Increased | | Tablets | PS | | ORAL |
| DAY, ORAL | | Asthenia | | | | | |
| | | Blood Lactate | | | | | |
| | | Dehydrogenase Increased | | | | | |
| | | Gamma-Glutamyltransferase | | | | | |
| | | Increased | | | | | |

Date:01/27/04ISR Number: 4280381-2Report Type:Expedited (15-DaCompany Report #MK200401-0144-1
Age:48 YR Gender:Female I/FU:I

| Outcome | PT |
|----------------------|-------------------|
| Hospitalization - | Back Pain |
| Initial or Prolonged | Confusional State |
| | Convulsion |
| | Disorientation |

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| | | | | | |
|---------------|-------------|---|--|----|------|
| Other | Tachycardia | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | ORAL |
| 54 MG, 1 IN 1 | | | | | |
| DAY, ORAL | | | Zoloft (Sertraline Hydrochloride) | SS | |
| 25 MG | | | | | |

Date:01/30/04ISR Number: 4284453-8Report Type:Direct Company Report #USP 56289
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------|------|--------------|-------|
| | | Medication Error | | Oxycontin | PS | Mallinckrodt | |
| TABLET | | | | Methylin | SS | Mallinckrodt | |
| TABLET | | | | | | | |

Date:01/30/04ISR Number: 4284709-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040103489
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------|-----------------------------------|--|------|--------------|-------|
| Other | | Blindness Coloboma | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/30/04ISR Number: 4288742-2Report Type:Periodic Company Report #PHEH2003US00900
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Mania | Consumer | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | |

Date:01/30/04ISR Number: 4288748-3Report Type:Periodic Company Report #PHEH2003US01093
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----------------------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged Other | | Dependence Psychotic Disorder | Other | Ritalin (Methylphenidate Hydrochloride) Tablet | PS | | |

Date:01/30/04ISR Number: 4288752-5Report Type:Periodic Company Report #PHEH2003US01390
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | Health Professional Company Representative | Ritalin La(Methylphenidate Hydrochloride) Extended Release Capsules | PS | | ORAL |

40 MG, QD,
 ORAL

| | | | | | | | |
|--|--|--|--|---|----|--|------|
| | | | | Ritalin (Methylphenidate Hydrochloride) Tablet | SS | | ORAL |
|--|--|--|--|---|----|--|------|

10 MG, Q4PM,
 ORAL

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Health Professional | Ritalin (Methylphenidate Hydrochloride), 5 Mg | PS | | |
| 25 MG, TID | | | | Methadone Hydrochloride (Methadone Hydrochloride) 10 Mg | SS | | |
| 100 MG, TID | | | | Msir (Morphine Sulfate) 15 Mg | SS | | |
| 60 MG, Q3-4HR | | | | | | | |
| PRN | | | | Actiq(Fentanyl Citrate) | SS | | ORAL |
| PRN, ORAL | | | | Provigil (Modafinil) | SS | | |
| 300MG/DAY | | | | Efexor (Venlafaxine Hydrochloride) | SS | | |
| 225 MG, QHS | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/30/04ISR Number: 4288767-7Report Type:Periodic Company Report #PHEH2003US02805
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Mental Disorder | Consumer | Ritalin (Methylphenidate Hydrochloride) | PS | | |

Date:01/30/04ISR Number: 4288789-6Report Type:Periodic Company Report #PHEH2003US04566
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour | Consumer | Ritalin (Methylphenidate Hydrochloride) | PS | | |

Date:01/30/04ISR Number: 4288792-6Report Type:Periodic Company Report #PHEH2003US04816
 Age:39 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Overdose | Health Professional | Ritalin (Methylphenidate Hydrochloride) | PS | | |
| 5 MG | | | | Methylphenidate Hydrochloride (Methylphenidate) | SS | | |
| 5 MG | | | | Ddvat | C | | |

Date:01/30/04ISR Number: 4288794-XReport Type:Periodic Company Report #PHEH2003US04828
 Age:34 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------------------|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Arrhythmia Condition Aggravated | Health Professional | Ritalin(Methylphenid ate Hydrochloride) | PS | | |

Date:01/30/04ISR Number: 4288796-3Report Type:Periodic Company Report #PHEH2003US05205
Age:2 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Accidental Exposure | Health | Ritalin La | | | |
| | | Dyskinesia | Professional | (Methylphenidate | | | |
| | | Heart Rate Abnormal | | Hydrochloride) | PS | | ORAL |
| 40 MG, | | | | | | | |
| ONCE/SINGLE, | | Insomnia | | | | | |
| ORAL | | Logorrhoea | | | | | |
| | | Psychomotor Hyperactivity | | | | | |
| | | Vomiting | | | | | |

Date:02/02/04ISR Number: 4283366-5Report Type:Expedited (15-DaCompany Report #PHNU2004DE00618
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatinine | Health | Ritaline | PS | Novartis Sector: | |
| | | Increased | Professional | | | Pharma | ORAL |
| 10 mg, BID | | | | | | | |
| | | Glomerulonephritis | | | | | |
| | | Proteinuria | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/02/04ISR Number: 4284784-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031201156
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Delusion Hallucinations, Mixed Psychotic Disorder Thinking Abnormal | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) Sustained Release Tablets | | | PS |
| 18 MG, 1 IN 1 DAY | | | | | | | |

Date:02/02/04ISR Number: 4285493-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040103955
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Intracranial Aneurysm | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | | | PS |

Date:02/02/04ISR Number: 4285495-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031100960
 Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Condition Aggravated Loss Of Consciousness Orthostatic Hypotension Syncope | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride)Sustained Release Tablets | | | PS |
| SEE IMAGE | | | | | | | |
| | | | | Becotide (Beclometasone Dipropionate) Inhalat ion | | | C |
| | | | | Ventolin (Salbutamol) Inhalation | | | C |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------------------------------|------------------------|-----------------------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Depression Palpitations | Health Professional | Diovan | PS | Novartis Sector: Pharma | ORAL |
| 80 mg/day | 99360MIN | | | Diovan | SS | Novartis Sector: Pharma | ORAL |
| 160 mg/day | 7200 MIN | Psychotic Disorder Tachycardia | | Diovan | SS | Novartis Sector: Pharma | ORAL |
| 40 mg/day | 10080MIN | | | Ritalin | SS | | ORAL |
| | | | | Amoxan | SS | | ORAL |
| | | | | Serenal | SS | | ORAL |
| | | | | Rohypnol | SS | | ORAL |
| | | | | Lofepamine Hydrochloride | SS | | ORAL |
| | | | | Toledomin | SS | | ORAL |
| | | | | Diovan | SS | Novartis Sector: Pharma | ORAL |
| 80 mg/day | | | | Adalat | C | | ORAL |
| 40 mg/day | 8640 MIN | | | Bayaspirin | C | | ORAL |
| 100 mg, UNK | | | | Herbesser "Tanabe" | C | | ORAL |
| 200 mg, UNK | 10080MIN | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|-----------|----------|--|---------------|--|------|----------------------------|-------|
| TRANSDERMAL | 50 mg/dat | | | | Nitroderm Tts | C | | |
| Date:02/03/04ISR Number: 4601314-2Report Type:Periodic Company Report #PHEH2004US12534 | | | | | | | | |
| Age:6 YR Gender:Male I/FU:I | | | | | | | | |
| Other | | | Aggression Eye Rolling Headache | Consumer | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | |
| 5 MG, BID | | | | | | | | |
| Psychomotor Hyperactivity Psychotic Disorder | | | | | | | | |
| Date:02/03/04ISR Number: 4601316-6Report Type:Periodic Company Report #PHEH2004US12841 | | | | | | | | |
| Age:7 YR Gender:Male I/FU:I | | | | | | | | |
| Other | | | Drug Withdrawal Syndrome Sleep Disorder | Consumer | Ritalin La(Methylphenidate Hydrochloride) Extended Release Capsules | PS | | ORAL |
| 50 MG, QD, ORAL | | | | | | | | |
| Unspecified Medication For Adhd() | | | | | | | | |
| SS | | | | | | | | |
| Date:02/04/04ISR Number: 4284872-XReport Type:Expedited (15-DaCompany Report #PHFR2004GB00789 | | | | | | | | |
| Age:18 YR Gender:Female I/FU:I | | | | | | | | |
| Other | | | Aggression Drug Dependence | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 20 mg, BID | | | | | | | | |
| Psychiatric Symptom | | | | | | | | |

Schizophrenia

Date:02/04/04ISR Number: 4284879-2Report Type:Expedited (15-DaCompany Report #PHBS2003ZA09019
 Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|--------------|----------------------------|------------------------|------------|------|----------------------------|-------|
| Death | | Arrhythmia Brain Oedema | Health Professional | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/day | | | | | | | |
| UNKNOWN | 50 | Circulatory Collapse | | Budesonide | C | | |
| microgram/d | | Rhinitis Allergic | | | | | |
| | | Sudden Death | | Flixonase | C | | NASAL |
| 200 ug, BID | | Wheezing | | Inflammid | C | | |
| UNKNOWN | one or twice | | | Ventolin | C | | |
| every three | | | | | | | |
| months | | | | | | | |

Date:02/04/04ISR Number: 4285301-2Report Type:Expedited (15-DaCompany Report #PHBS2004JP01478
 Age: Gender:Male I/FU:I

| Outcome | PT |
|---------|---------------------------|
| Death | Completed Suicide |
| Other | Depression Drug Abuser |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Insomnia Intentional Misuse Overdose | Report Source | Product | Role | Manufacturer | Route |
|------|----------|--|---------------|----------|------|----------------------------|-------|
| | | Suicide Attempt | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| | | | | Lexotan | C | | |
| | | | | Wypax | C | | |
| | | | | Flumezin | C | | |
| | | | | Akineton | C | | |
| | | | | Brovarin | C | | |
| | | | | Isomytal | C | | |

Date:02/05/04ISR Number: 4287303-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040200246
Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|---------------------------------|---------------|--|------|--------------|-------|
| Dose Other | | Glaucoma Optic Nerve Cupping | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 DAY, ORAL | | | | | | | |

Date:02/05/04ISR Number: 4288543-5Report Type:Expedited (15-DaCompany Report #2003189650JP
Age:1 DY Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-------------------|-------------------------------------|------|--------------|-------|
| Life-Threatening 0.8 MG/DAY, ORAL | | Apgar Score Low Cyanosis Central | Foreign Health | Solanax (Alprazolam) Tablet | PS | | ORAL |
| | | Drug Toxicity | Professional | | | | |
| 30 MG/DAY, ORAL | | Drug Withdrawal Syndrome Heart Rate Increased | Other | Paxil (Paroxetine Hydrochloride) | SS | | ORAL |
| | | Hypersensitivity | | | | | |
| | | Hypopnoea | | Rohypnol | | | |

| | | | | |
|-------------|--------------------------|------------------|----|------|
| 2 MG/DAY, | Hypotonia | (Flunitrazepam) | SS | ORAL |
| ORAL | Hypotonia Neonatal | | | |
| | Irritability | Ritalin | | |
| | Maternal Drugs Affecting | (Methylphenidate | | |
| | Foetus | Hydrochloride) | SS | ORAL |
| 100 MG/DAY, | Muscle Twitching | | | |
| ORAL | Neonatal Apnoeic Attack | | | |

Date:02/06/04ISR Number: 4289271-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040103955
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Intracranial Aneurysm | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | |

Date:02/06/04ISR Number: 4290062-7Report Type:Direct Company Report #CTU 211694
Age:12 YR Gender:Female I/FU:I

Outcome
Life-Threatening
Required

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Intervention to Prevent Permanent Impairment/Damage

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------|---------------|---------------------|------|--------------|-------|
| 27 MG ONE | | Depression | | Concerta 27 Mg Alza | PS | Alza | ORAL |
| DAILY ORAL | | Suicidal Ideation | | | | | |

Date:02/09/04ISR Number: 4289948-9Report Type:Expedited (15-DaCompany Report #PHBS2004JP01531
 Age: Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|-----------|----------|----------------------|---------------|----------|------|-------------------------|-------|
| Hospitalization - Initial or Prolonged | 10 mg/day | | Aggression | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| | | | Drug Dependence | | | | | |
| | 80 mg/day | | Persecutory Delusion | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| | | | | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| | 300 mg | 1440 MIN | | | Tofranil | C | | ORAL |
| UNKNOWN | | | | | Lexotan | C | | |
| UNKNOWN | | | | | Depas | C | | |

Date:02/09/04ISR Number: 4290182-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031103481
 Age:10 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------|----------|----------------------|---------------|---------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | | Disorientation | Health | Concerta | | | |
| Other | | | Grand Mal Convulsion | Professional | (Methylphenidate Hydrochloride) | | | |
| | | | Incontinence | | Sustained Release Tablets | PS | | ORAL |

SEE IMAGE

Date:02/09/04ISR Number: 4290188-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031003780
Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------|------------------------|---|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety Pica | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablet | PS | | ORAL |
| SEE IMAGE | | | | Albuterol (Salbutamol) Singulair (Tablets) Montelukast Sodium Tablets | C C | | |

Date:02/09/04ISR Number: 4290900-8Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040106204
Age:9 YR Gender:Female I/FU:I

| Outcome | PT |
|---|---|
| Hospitalization - Initial or Prolonged | Abdominal Pain Dehydration Enterococcal Infection Hypertension Insomnia Nausea Psychomotor Hyperactivity Urinary Tract Infection |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Vomiting

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|--|------|--------------|-------|
| 54 MG, 1 IN 1 DAY, ORAL | | Foreign Study Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| | | | Clonidine (Clonidine) | C | | |

Date:02/10/04ISR Number: 4290240-7Report Type:Expedited (15-DaCompany Report #PHNU2003DE03032
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged Unknown | | Aggression Anger | Consumer | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Other 18mg/day | | Anxiety | | Concerta | C | | ORAL |
| 75 mg/day | | Blister | | Truxal | C | | ORAL |
| 75 mg/day | | Cardiovascular Disorder | | Atosil | C | | ORAL |
| 1600 mg/day | | Chest Pain | | Tegretal | C | | |
| | | Depression Drug Dependence Drug Toxicity Drug Withdrawal Syndrome Erectile Dysfunction Fatigue Feeling Abnormal Heart Rate Increased Libido Increased Nervousness Nightmare Rash Renal Pain Restlessness | | | | | |

Sleep Disorder
Suicide Attempt

Date:02/10/04ISR Number: 4293368-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040200827
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety Crying Depressed Mood Fear Insomnia | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| 18 MG, 1 IN 1 | | | | | PS | | ORAL |
| DAY, ORAL | | Nervousness Speech Disorder Suicidal Ideation | | | | | |

Date:02/11/04ISR Number: 4291423-2Report Type:Expedited (15-DaCompany Report #PHBS2004JP00800
Age:48 YR Gender:Male I/FU:F

| Outcome | PT |
|---------|----------------------------|
| Other | Depression Palpitations |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Psychotic Disorder
Tachycardia

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-------------|-----------|---------------|------------------------------|------|--------------|-------|
| 80 mg/day | 99360MIN | | Diovan | PS | | ORAL |
| 160 mg/day | 7200 MIN | | Diovan | SS | | ORAL |
| 40 mg/day | 10080MIN | | Diovan | SS | | ORAL |
| 10 mg/day | | | Ritalin | SS | | ORAL |
| 25 mg/day | | | Amoxan | SS | | ORAL |
| 10 mg/day | | | Serenal | SS | | ORAL |
| 1 mg/day | | | Rohypnol | SS | | ORAL |
| 25 mg/day | | | Lofepramine Hydrochloride | SS | | ORAL |
| 25 mg/day | | | Toledomin | SS | | ORAL |
| 80 mg/day | | | Diovan | SS | | ORAL |
| 40 mg/day | 8640 MIN | | Adalat | C | | ORAL |
| 100 mg, UNK | | | Bayaspirin | C | | ORAL |
| 200 mg, UNK | 10080MIN | | Herbesser "Tanabe" | C | | ORAL |
| TRANSDERMAL | 50 mg/dat | | Nitroderm Tts | C | | |

Date:02/11/04ISR Number: 4294240-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031204142
Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Blood Creatine Phosphokinase Increased Blood Uric Acid Increased Muscle Enzyme Increased | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 54 MG 1 IN 1 | | | | | | | |

DAY ORAL
 Nausea
 Renal Failure Acute
 Vomiting
 Docycyline
 C

Date:02/12/04ISR Number: 4293858-0Report Type:Expedited (15-DaCompany Report #PHFR2003GB04698
 Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|------------------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia Hypokinesia | Health Professional | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 5 mg, BID | | Nasopharyngitis Pain In Extremity Paraplegia | | | | | |

Date:02/12/04ISR Number: 4295943-6Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040201870
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Amnesia Bipolar Disorder Childhood Psychosis Drug Effect Decreased Mania | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 72 MG, 1 IN 1 | | Overdose | | | | | |
| DAY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/04ISR Number: 4294170-6Report Type:Expedited (15-DaCompany Report #PHEH2004US01627
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Asthma | | Ritalin La | PS | Novartis Sector: Pharma | |
| | | Tachycardia | | | | | |
| | | | | Albuterol | C | | |
| 20 mg, QD | | | | | | | |
| UNK, PRN | | | | | | | |

Date:02/13/04ISR Number: 4297425-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040102092
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Decreased Appetite | Consumer | Concerta | | | |
| | | Drug Ineffective | | (Methylphenidate | | | |
| | | Fear | | Hydrochloride) | | | |
| | | Hallucination, Visual | | Sustained Release | | | |
| | | Headache | | Tablets | PS | | ORAL |
| SEE IMAGE | | | | | | | |
| | | Medication Error | | Atropine Drops | | | |
| | | | | (Atropine) | C | | |

Date:02/13/04ISR Number: 4297427-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040202177
 Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression | Health | Concerta | | | |
| | | Suicidal Ideation | Professional | (Methylphenidate | | | |
| | | | | Hydrochloride) | | | |
| | | | | Sustained | PS | | ORAL |
| ORAL | | | | | | | |

Date:02/16/04ISR Number: 4295347-6Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0413387A
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Other Colitis Lamictal PS Glaxosmithkline ORAL
Ritalin SS

Date:02/16/04ISR Number: 4295863-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0440866A
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------|------|-----------------|-------|
| Dose | | Drug Interaction | | Lamictal | PS | Glaxosmithkline | ORAL |
| | | Sedation | | Ritalin | SS | | |

Date:02/17/04ISR Number: 4296344-7Report Type:Expedited (15-DaCompany Report #PHNU2004DE00823
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged 400 mg, ONCE/SINGLE | | Agitation General Physical Health Deterioration Heart Rate Increased Overdose Poor Peripheral Circulation Tachycardia | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/17/04ISR Number: 4299018-1Report Type:Expedited (15-DaCompany Report #2004007535
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | Consumer | Zoloft (Sertraline) | PS | | ORAL |
| 50 MG | | Anger | | | | | |
| (DAILY), ORAL | | Asthma | | Methylphenidate | | | |
| | | Emotional Disorder | | Hydrochloride | | | |
| | | Feeling Abnormal | | (Methylphenidate | | | |
| 20 MG (DAILY) | | Psychotic Disorder | | Hydrochloride) | SS | | |
| | | Screaming | | Atomoxetine | | | |
| | | | | Hydrochloride | | | |
| | | | | (Atomoxetine | | | |
| 36 MG (BID), | | | | Hydrochloride) | SS | | |
| | | | | Salmeterol Xinafoate | | | |
| | | | | (Salmeterol | | | |
| | | | | Xinafoate) | SS | | |
| | | | | Levothyroxine Sodium | | | |
| | | | | (Levothyroxine | | | |
| | | | | Sodium) | C | | |
| | | | | Bupropion | | | |
| | | | | Hydrochloride | | | |
| | | | | (Bypropion | | | |
| | | | | Hydrochloride) | C | | |
| | | | | Fluticasone | | | |
| | | | | Propionate | | | |
| | | | | (Fluticasone | | | |
| | | | | Propionate) | C | | |
| | | | | Salbutamol | | | |
| | | | | (Salbutamol) | C | | |

Date:02/17/04ISR Number: 4299495-6Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040201307
 Age:6 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | | | |

Date:02/19/04ISR Number: 4299470-1Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0498217A
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|--------------------|-------------|------|-----------------|-------|
| Dose | | | | | | | |
| Other | | | | | | | |
| 20MG At night | | | Abnormal Dreams | Paxil | PS | Glaxosmithkline | ORAL |
| 20MG In the | | | Decreased Appetite | Metadate Cd | SS | | ORAL |
| morning | 1 YR | | Hallucination | | | | |
| | | | Insomnia | | | | |
| | | | Muscle Twitching | | | | |
| | | | Psychotic Disorder | | | | |
| | | | Schizophrenia | | | | |

Date:02/19/04ISR Number: 4301422-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040201255
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | | | | | |
| | | | Hepatitis | Concerta (Methylphenidate Hydrochloride) | | | |
| | | | Foreign Health Professional | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

54 MG, IN 1
 DAY, ORAL

Sustained Release
 Tablets PS ORAL

Date:02/20/04ISR Number: 4300540-XReport Type:Expedited (15-DaCompany Report #PHBS2004DK02324
 Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-----------------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 40320MIN | | Confusional State | | | | | |
| | | Eye Movement Disorder | | | | | |

Date:02/20/04ISR Number: 4301926-XReport Type:Expedited (15-DaCompany Report #CEL-2003-04228-SLO
 Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Alanine Aminotransferase Increased | Foreign Health Professional | Equasym 20mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG (20 MG, DAILY), PO | | Aspartate Aminotransferase Increased Blood Creatine Phosphokinase Increased Blood Lactate Dehydrogenase Increased Viral Myositis | | | | | |

Date:02/20/04ISR Number: 4301973-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040203041
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Concussion Vomiting | Health Professional Company | Concerta (Methylphenidate Hydrochloride) | | | |

Representative

Sustained Release
Tablets

PS

ORAL

36 MG, 1 IN 1

DAY, ORAL

Date:02/20/04ISR Number: 4301978-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040202455

Age:10 YR Gender:Female I/FU:I

| Outcome Dose Hospitalization - Initial or Prolonged | PT Cholelithiasis Decreased Appetite Eating Disorder Insomnia Weight Gain Poor | Report Source Consumer | Product Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | Role PS | Manufacturer | Route ORAL |
|--|---|---------------------------|---|------------|--------------|---------------|
| ORAL; 54 MG, 1 IN 1 DAY, ORAL | | | Methylphenidate (Methylphenidate) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/20/04ISR Number: 4302144-1Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040106204
 Age:9 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--|--|-------------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Dehydration Enterococcal Infection Hypertension Insomnia | Foreign Study Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| 54 MG 1 IN 1 DAY ORAL | | Nausea Psychomotor Hyperactivity Urinary Tract Infection Vomiting White Blood Cell Count Increased | | Clonidine | PS C | | ORAL |

Date:02/23/04ISR Number: 4302697-3Report Type:Direct Company Report #CTU 212870
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|---|------|---------------------------|-------|
| Other | | Pharmaceutical Product Complaint Sedation | | Methylphenidate 5 Mg Able Laboratories, Inc | PS | Able Laboratories, Inc | |

Date:02/23/04ISR Number: 4302837-6Report Type:Direct Company Report #CTU 212846
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---|------|---------------------------|-------|
| Other | | Drug Ineffective | | Methylphenidate Hydrochloride 20 Mg Able Laboratories, Inc | PS | Able Laboratories, Inc | |

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--|---|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged Other | Blood Glucose Increased Fall Haematoma Haemorrhage Helicobacter Infection | Foreign Consumer Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| 1 TABLET DAILY | Idiopathic Thrombocytopenic Purpura Mouth Haemorrhage Nasopharyngitis Petechiae Pharyngolaryngeal Pain Purulence Road Traffic Accident Thrombocytopenia Traumatic Haematoma | | Medikinet (Methylphenidate Hydrochloride) Tablets | PS | | C |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/24/04ISR Number: 4302712-7Report Type:Expedited (15-DaCompany Report #PHNU2003DE04286
Age:19 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|------------------------|---------------------------------------|-----------------|----------------------------|----------------------|
| Hospitalization - Initial or Prolonged 20 mg, BID Other | | Drug Dependence Personality Disorder | Health Professional | Ritalin-Sr Siquan /Den/ | PS C | Novartis Sector: Pharma | ORAL ORAL |

Date:02/24/04ISR Number: 4304573-9Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20040202794
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------------|-----------------------------------|---|------|--------------|-------|
| Other | | Neutrophil Count Decreased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | |

Date:02/26/04ISR Number: 4304886-0Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0491723A
Age:75 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|--|---------------|---|--------------------|--|--------------------------|
| 150MG Per day 1 14 MON | 1 MON | Abnormal Behaviour Constipation Dissociative Identity Disorder Gallbladder Operation | | Wellbutrin Wellbutrin Ritalin | PS SS SS | Glaxosmithkline Glaxosmithkline | ORAL ORAL ORAL |

Date:02/26/04ISR Number: 4305792-8Report Type:Direct Company Report #CTU 213275
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|---------------|----------------------|------|--------------|-------|
| Other | | Dyspepsia | | Methylphenidate 5 Mg | | | |

Irritability
Nausea

Mfr-Sandoz Pharm
(Geneva)

PS Sandoz Pharm
(Geneva)

ORAL

5 MG PO BID

Date:02/27/04ISR Number: 4307089-9Report Type:Expedited (15-DaCompany Report #PHNR2004AU00583
Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Epistaxis | | Ritalin La | PS | Novartis Sector: Pharma | |
| 30 mg, QD | 1440 MIN | | | Ritalin | C | | |
| unspecified | | | | | | | |

Date:02/27/04ISR Number: 4307090-5Report Type:Expedited (15-DaCompany Report #PHBS2004BR01969
Age:24 YR Gender:Male I/FU:F

| Outcome | PT |
|---------|---|
| Other | Aggression Depression Divorced Dizziness Irritability Loss Of Employment Physical Assault |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Treatment Noncompliance

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|----------|------|----------------------------|-------|
| | | Consumer | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| 1 tablet, BID | | | Ritalina | SS | Novartis Sector: Pharma | ORAL |
| 1 tablet/day | | | Ritalina | SS | Novartis Sector: Pharma | ORAL |
| 3 tablets/day | | | Ritalina | SS | Novartis Sector: Pharma | ORAL |
| 2 tablets/day | | | Ritalina | SS | Novartis Sector: Pharma | ORAL |

Date:02/27/04ISR Number: 4308855-6Report Type:Expedited (15-DaCompany Report #MK200402-0235-1
Age:23 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|--|--|--------------|-------|
| Hospitalization - Initial or Prolonged | | Cardiac Arrest Loss Of Consciousness Pancreatic Pseudocyst Pancreatitis Acute | Foreign | Anafranil Capsules Melleril Lexotan Pyrethia Vegetamin A Hirnamin Isomytal Halcion Ritalin | PS SS SS SS SS SS SS SS SS | | |

Date:03/01/04ISR Number: 4308498-4Report Type:Expedited (15-DaCompany Report #99J--10250
Age:23 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|----------------------------------|----------------|--------------|-------|
| Hospitalization - UNKNOWN Initial or Prolonged UNKNOWN | | Cardiac Arrest 1440 MIN Cardiac Fibrillation 1440 MIN Coma | Health Professional | Melleril Anafranil Lexotan | PS SS SS | | |

UNKNOWN

| | | | |
|---------|---------------------------|-------------|----|
| UNKNOWN | Electrocardiogram | Pyrethia | SS |
| UNKNOWN | Abnormal | Vegetamin A | SS |
| UNKNOWN | Hypothermia | Hirnamin | SS |
| UNKNOWN | Inflammation | Isomytal | SS |
| UNKNOWN | Loss Of Consciousness | Halcion | SS |
| UNKNOWN | 1440 MIN | | |
| UNKNOWN | Multiple Drug Overdose | Ritalin | SS |
| UNKNOWN | 1440 MIN | | |
| | Mydriasis | | |
| | Oedema | | |
| | Overdose | | |
| | Pancreatic Pseudocyst | | |
| | Pancreatitis Acute | | |
| | Pupillary Reflex Impaired | | |
| | Suicide Attempt | | |

Date:03/01/04ISR Number: 4309700-5Report Type:Expedited (15-DaCompany Report #MK200402-0202-1
Age:22 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|--------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | |
| Duration | | | | | | |
| Hospitalization - | Nausea | Consumer | Methylphenidate Hcl | | | |
| Initial or Prolonged | Paraesthesia | | Tabs, Usp. 10mg | PS | | |
| 10 MG, BID | | | | | | |
| | Pyrexia | | | | | |
| | Rash | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/04ISR Number: 4310829-6Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040203651
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Urine Renal Pain | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| | | | | | PS | | |

SEE IMAGE

Date:03/02/04ISR Number: 4310872-7Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040204255
 Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Bipolar Disorder Drug Interaction Hallucination, Auditory Mood Swings | Foreign Study Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| | | | | | PS | | ORAL |

54 MG, 1 IN 1

DAY, ORAL

10 MG, 2 IN 1

DAY, ORAL

| | | | | | | | |
|--|--|--|--|--|----|--|------|
| | | | | Celexa (Citalopram Hydrobromide) | SS | | ORAL |
| | | | | Risperidone (Risperidone) | C | | |
| | | | | Ditropan Ir (Oxybutynin Hydrochloride) | C | | |

Date:03/03/04ISR Number: 4310428-6Report Type:Expedited (15-DaCompany Report #PHBS1999JP03379
 Age:23 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------------------|------------------------|---------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Abdominal Pain Cardiac Arrest | Health Professional | Melleril (Thioridazine | | | |

| | | | | | |
|---------|-------------|----------|---------------------------|----------------------|----|
| UNKNOWN | UNSPECIFIED | 1440 MIN | Cardiac Fibrillation | Hydrochloride) | PS |
| | | | Electrocardiogram | Anafranil | SS |
| UNKNOWN | UNSPECIFIED | 1440 MIN | Abnormal | Lexotan (Bromazepam) | SS |
| UNKNOWN | UNSPECIFIED | 1440 MIN | Hypothermia | Pyrethia | |
| | | | Loss Of Consciousness | (Promethazine | |
| | | | Mydriasis | Hydrochloride) | SS |
| UNKNOWN | UNSPECIFIED | 1440 MIN | Overdose | Vegetamin-A | |
| | | | Pancreatic Pseudocyst | (Vegetamin A) | SS |
| UNKNOWN | UNSPECIFIED | 1440 MIN | Pancreatitis Acute | Hirnamin | |
| | | | Pupillary Reflex Impaired | (Levomepromazine) | SS |
| UNKNOWN | UNSPECIFIED | 1440 MIN | | Isomytal | |
| | | | | (Amobarbital) | SS |
| UNKNOWN | UNSPECIFIED | 1440 MIN | | Halcion (Triazolam) | SS |
| UNKNOWN | UNSPECIFIED | 1440 MIN | | Ritalin | SS |
| UNKNOWN | UNSPECIFIED | 1440 MIN | | | |

Date:03/03/04ISR Number: 4311943-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040206108
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine Phosphokinase Increased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablet | PS | | ORAL |
| 36 MG, IN 1 | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

DAY, ORAL

Date:03/04/04ISR Number: 4311745-6Report Type:Direct Company Report #CTU 213852
 Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|------------------|---------------|------------------|------|--------------|-------|
| Dose Required | | Trichotillomania | | Strattera 60 Mg | PS | | |
| Intervention to | | | | | | | |
| DAILY | | | | | | | |
| Prevent Permanent | | | | Ritalin La 20 Mg | SS | | |
| ONE DOSE Q AM | | | | | | | |
| Impairment/Damage | | | | | | | |

Date:03/04/04ISR Number: 4313184-0Report Type:Expedited (15-DaCompany Report #CEL-2004-00224-ROC
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|----------------------|----------------|----------------------|------|--------------|-------|
| Dose Other | | Abnormal Behaviour | Health | Metadate Cd Capsules | | | |
| Required | | Grand Mal Convulsion | Professional | 20 Mg | | | |
| Intervention to | | Incoherent | Company | (Methylphenidate | | | |
| Prevent Permanent | | Postictal State | Representative | Hydrochloride) | PS | | |
| 40 MG QAM | | | | | | | |
| Impairment/Damage | | Thinking Abnormal | | Metadate Er Tablets | | | |
| | | | | 10mg (Methylphnidate | | | |
| | | | | Hydrochloride) | SS | | |
| 10 MG QD | | | | | | | |

Date:03/08/04ISR Number: 4313671-5Report Type:Expedited (15-DaCompany Report #PHBS2004BR01969
 Age:24 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------|---------------|----------|------|------------------|-------|
| Dose Other | | Aggression | | Ritalina | PS | Novartis Sector: | |
| | | Depression | | | | Pharma | ORAL |
| 1 tablet, BID | | | | | | | |
| | | Dizziness | | Ritalina | SS | Novartis Sector: | |
| | | Irritability | | | | Pharma | ORAL |
| 1 tablet/day | | | | | | | |

| | | | | |
|---------------|----------|----|----------------------------|------|
| 3 tablets/day | Ritalina | SS | Novartis Sector: Pharma | ORAL |
| 2 tablets/day | Ritalina | SS | Novartis Sector: Pharma | ORAL |

Date:03/08/04ISR Number: 4314090-8Report Type:Direct Company Report #CTU 214038
 Age:15 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|--|---------------|--|------|--------------|-------|
| Life-Threatening | | Idiopathic Thrombocytopenic Purpura | | Methylphenidate Methylin-20 Mg Tab Mallinkckro | PS | Mallinkckro | ORAL |
| 2 1/2 DAILY | | | | | | | |
| ORAL | | | | | | | |

Date:03/10/04ISR Number: 4315319-2Report Type:Direct Company Report #CTU 214234
 Age:52 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------------------|---------------|---|--------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Febrile Neutropenia Pneumonia | | D-Threo-Methylphenid ate Hcl (D-Mph) | PS | | ORAL |
| 15 MG BID 1 | | | | | | | |
| PO | | | | Radiation Temodar | C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/10/04ISR Number: 4315325-8Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 214246

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Pharmaceutical Product | | Adderall Generic And Brand Name | PS | | |
| 5 MG | | Complaint | | | | | |
| INCREASED TO | | | | | | | |
| 20 | | | | Concerta | SS | | |
| 18 INCREASING | | | | | | | |
| TO 54 | | | | Strattera | SS | | |

Date:03/10/04ISR Number: 4315477-XReport Type:Direct
 Age:6 YR Gender:Male I/FU:I

Company Report #CTU 214226

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Pharmaceutical Product | | Concerta Er | PS | Alza | |
| TAKE 1 TABLET | | Complaint | | Claritin | C | | |
| EVERY MORNING | | | | | | | |

Date:03/10/04ISR Number: 4315723-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040300344
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety Fear Hallucination, Visual | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | |
| SEE IMAGE | | Sleep Disorder | | | | | |

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination Nightmare | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | |

Age:23 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|-----------------------------------|--------------------------------|----------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged ONE TIME DOSE | | Cardiac Arrest Cardiac Fibrillation | Foreign Health Professional | Anafranil Capsules Melleril | PS SS | | |
| ONE TIME DOSE | | Hypothermia | Professional | Lexotan | SS | | |
| ONE TIME DOSE | | Loss Of Consciousness | Other | Pyrethia | SS | | |
| ONE TIME DOSE | | Mydriasis | | Vegetamin A | SS | | |
| ONE TIME DOSE | | Oedematous Pancreatitis | | Hirnamin | SS | | |
| ONE TIME DOSE | | Overdose | | Isomytal | SS | | |
| ONE TIME DOSE | | Pancreatic Pseudocyst | | Halcion | SS | | |
| ONE TIME DOSE | | Pancreatitis Acute | | Ritalin | SS | | |
| ONE TIME DOSE | | Pupil Fixed Suicide Attempt | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/11/04ISR Number: 4315619-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0502000A
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------|---------------|---------|------|-----------------|-------|
| Hospitalization - | | Anger | | Paxil | PS | Glaxosmithkline | ORAL |
| Initial or Prolonged | | Depression | | Zoloft | SS | | ORAL |
| | | Diabetes Mellitus | | Effexor | SS | | ORAL |
| | | Fear | | Ritalin | SS | | ORAL |
| | | Feeling Abnormal | | | | | |
| | | Homicidal Ideation | | | | | |
| | | Hypertension | | | | | |
| | | Nightmare | | | | | |
| | | Suicidal Ideation | | | | | |
| | | Suicide Attempt | | | | | |

Date:03/11/04ISR Number: 4316851-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040206433
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-----------------|---------------|-------------------|------|--------------|-------|
| Hospitalization - | | Suicide Attempt | Consumer | Concerta | | | |
| Initial or Prolonged | | | | (Methylphenidate | | | |
| Other | | | | Hydrochloride) | | | |
| | | | | Sustained Release | | | |
| | | | | Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:03/12/04ISR Number: 4316039-0Report Type:Expedited (15-DaCompany Report #99J--10250
 Age:23 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------|-----------|------|--------------|-------|
| Hospitalization - | | Cardiac Arrest | | Melleril | PS | | |
| UNKNOWN | | 1440 MIN | | | | | |
| Initial or Prolonged | | Cardiac Fibrillation | | Anafranil | SS | | |
| UNKNOWN | | 1440 MIN | | | | | |
| | | Electrocardiogram | | Lexotan | SS | | |
| UNKNOWN | | | | | | | |
| | | Abnormal | | Pyrethia | SS | | |
| UNKNOWN | | | | | | | |

| | | | |
|---------|---------------------------|-------------|----|
| UNKNOWN | Hypothermia | Vegetamin A | SS |
| UNKNOWN | Loss Of Consciousness | Hirnamin | SS |
| UNKNOWN | Multiple Drug Overdose | Isomytal | SS |
| UNKNOWN | Mydriasis | Halcion | SS |
| UNKNOWN | 1440 MIN | | |
| UNKNOWN | Oedema | Ritalin | SS |
| UNKNOWN | 1440 MIN | | |
| | Overdose | | |
| | Pancreatic Pseudocyst | | |
| | Pancreatitis Acute | | |
| | Pupillary Reflex Impaired | | |
| | Suicide Attempt | | |

Date:03/12/04ISR Number: 4317155-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030603419
Age:14 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | |
| Duration | | | | | | |
| Hospitalization - | Fall | Foreign | Concerta | | | |
| Initial or Prolonged | Haematoma | Consumer | (Methylphenidate | | | |
| Other | Iron Deficiency | | Hydrochloride) | | | |
| | Petechiae | | Sustained Release | | | |
| | Skin Haemorrhage | | Tablets | PS | | |
| 1 TABLET | | | | | | |
| DAILY | Thrombocytopenia | | | | | |
| | | | Mediknet | | | |
| | | | (Methylphenidate | | | |
| | | | Hydrochloride) | | | |
| | | | Tablet | C | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/12/04ISR Number: 4317158-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040301164
 Age:34 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------------|--|-----------------------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Discomfort Heart Rate Increased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets Ritalin (Methylphenidate Hydrochloride) Unknown | PS C | | |

Date:03/15/04ISR Number: 4317741-7Report Type:Expedited (15-DaCompany Report #PHHO2004CH03334
 Age:54 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------------------------|---------------|--------------------|--------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Drug Level Decreased | | Methylphenidate | PS | Novartis Sector: Pharma | |
| 10 mg, UNK | | | | | | | |
| 15 mg, QD | 23040MIN | Drug Level Increased | | Remeron | SS | | |
| | | Irritability | | Becozym Benerva | C C | | |
| 300 mg, QD | | | | | | | |
| 900 mg, QD | 34560MIN | | | Orfiril | C | | |

Date:03/15/04ISR Number: 4318196-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040200246
 Age:7 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|------------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| | | Glaucoma | Consumer Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |

DAY, ORAL

Date:03/16/04ISR Number: 4317807-1Report Type:Expedited (15-DaCompany Report #PHBS2004BR02935

Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Agitation Developmental Delay | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| 2.5 tablets/day | | Eosinophil Count Increased Growth Retardation Insomnia Skin Odour Abnormal Tooth Disorder Vomiting Weight Gain Poor | | | | | |

Date:03/16/04ISR Number: 4318475-5Report Type:Direct Company Report #CTU 214446

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|---|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Resistance | | Ritalin 20 Mg | PS | | ORAL |
| TWO AM, NOON , 3 PM PO | | Pharmaceutical Product Complaint | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/17/04ISR Number: 4320336-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040301166
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyspnoea Tachycardia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| | | | | | PS | | |
| 36 MG | | | | | | | |

Date:03/19/04ISR Number: 4320565-8Report Type:Direct Company Report #CTU 214836
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|---------------------------------|----------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination, Visual Pharmaceutical Product Complaint | | Adderall Xr Ritalin La 20 Mg | PS SS | | |

Date:03/19/04ISR Number: 4322060-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040302317
 Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|------------------------|--|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Erythema Heart Rate Increased Initial Insomnia Medication Error | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| | | | | | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL; | | | | | | | |
| | | Psychomotor Hyperactivity | | | | | |
| | | Rash | | | | | |
| 27 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL; | | | | | | | |
| | | Urinary Incontinence | | Prevacid (Lansoprazole) Albuterol (Salbutamol) Atrovent | C C | | |

(Ipratropium
Bromide)

C

Date:03/22/04ISR Number: 4321088-2Report Type:Expedited (15-DaCompany Report #PHNU2003DE00635
Age:39 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|---------------|----------------------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Abortion Induced Anxiety | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 60 mg/day | | | | | | | |
| | | Complications Of Maternal Exposure To Therapeutic | | Trevilor - Slow Release | C | | ORAL |
| 450 mg/day | | | | | | | |
| | | Drugs Condition Aggravated Depressive Symptom Maternal Drugs Affecting Foetus Pregnancy | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/22/04ISR Number: 4322289-XReport Type:Direct
 Age:63 YR Gender:Female I/FU:I

Company Report #CTU 214981

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|--------------|-------------------------|---------------|--------------------|------|--------------|-------|
| Hospitalization - | 15 MG PO BID | Agitation | | D-Mph 5 Mg Celgene | PS | Celgene | ORAL |
| Initial or Prolonged | | Disorientation | | Decadron | C | | |
| | | Mental Status Changes | | Zoloft | C | | |
| | | Thrombocytopenia | | Detrol La | C | | |
| | | Urinary Tract Infection | | Xanax | C | | |
| | | | | Celebrax | C | | |
| | | | | Ambien | C | | |
| | | | | Diflucan | C | | |
| | | | | Cipro | C | | |

Date:03/22/04ISR Number: 4322291-8Report Type:Direct
 Age:45 YR Gender:Male I/FU:I

Company Report #CTU 214979

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|--------------|---|---------------|--------------------|------|--------------|-------|
| Hospitalization - | 5 MG ONE BID | Mass | | D-Mph 5 Mg Tablets | PS | | |
| Initial or Prolonged | INCREASED TO | Mental Status Changes | | | | | |
| THREE BID | | Neoplasm | | | | | |
| | | Nuclear Magnetic Resonance Imaging Abnormal | | | | | |

Date:03/22/04ISR Number: 4322293-1Report Type:Direct
 Age:60 YR Gender:Male I/FU:I

Company Report #CTU 214978

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|--------------|-----------------------|---------------|---------------------|------|--------------|-------|
| Hospitalization - | 15 MG BID PO | Convulsion | | D-Mph 5 Mg -Celgene | PS | Celgene | ORAL |
| Initial or Prolonged | | Depression | | Celebrax | C | | |
| | | Disease Recurrence | | Dilantin | C | | |
| | | Mental Status Changes | | Decadron | C | | |
| | | | | . | C | | |
| | | | | Imiprazole | C | | |

Zantac

C

Date:03/22/04ISR Number: 4322294-3Report Type:Direct
Age:52 YR Gender:Female I/FU:I

Company Report #CTU 214977

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|---------------------|---------------|-------------------------------------|------|--------------|-------|
| Dose Duration | | | | | | |
| Hospitalization - | Febrile Neutropenia | | D-Threo-Methylphenidate Hic (D-Mph) | PS | | ORAL |
| Initial or Prolonged | Pneumonia | | | | | |
| 15 MG BID /PO | | | Temodar | C | | |
| | | | Rt | C | | |

Date:03/22/04ISR Number: 4322297-9Report Type:Direct
Age:63 YR Gender:Female I/FU:I

Company Report #CTU 214976

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-------------------------|---------------|--------------------|------|--------------|-------|
| Dose Duration | | | | | | |
| Hospitalization - | Abnormal Behaviour | | D-Mph 5 Mg Celgene | PS | Celgene | ORAL |
| 15 MG BID PO | | | | | | |
| Initial or Prolonged | Agitation | | Zoloft | C | | |
| | Hallucination, Visual | | Decadron | C | | |
| | Insomnia | | Detrol | C | | |
| | Treatment Noncompliance | | Xanax | C | | |
| | | | Celebrex | C | | |
| | | | Ambien | C | | |
| | | | Blinded Study Drug | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/22/04ISR Number: 4324653-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040302004
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|---------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Drug Ineffective Food Craving Self Esteem Inflated Suicidal Ideation | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | ORAL |
| 36 MG, IN 1 | | | | | PS | | |
| DAY, ORAL | | | | | | | |

Date:03/23/04ISR Number: 4323752-8Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040204255
Age:7 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--|--|------------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Anger Bipolar Disorder Crying Decreased Appetite | Foreign Study Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | ORAL |
| 54 MG, 1 IN 1 | | | | | PS | | |
| DAY, ORAL | | Drug Interaction | | | | | |
| | | Hallucination, Auditory Homicidal Ideation | | Celexa (Citalopram Hydrobromide) | SS | | ORAL |
| 10 MG, 3 IN 1 | | | | | | | |
| DAY, ORAL | | Mood Swings | | | | | |
| | | Nausea Vomiting | | Risperidone (Risperidone) Ditropan Ir (Oxybutynin Hydrochloride) | C C | | |

Date:03/23/04ISR Number: 4323753-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040302348
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|-------------|--------------|-----------------------------|--|----|------|
| Other | Eosinophilia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | ORAL |
| 18 MG, IN 1 | | | | | |
| DAY, ORAL | | | | | |

Date:03/23/04ISR Number: 4323754-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040302601
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------|--|-----------------------------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Dreams Hallucination Post Procedural Complication Skin Laceration | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) Cefuroxime (Cefuroxime) Ondansetron (Ondansetron) Paracetamol (Paracetamol) Diclofenac (Diclofenac) Cyclizine (Cyclizine) Co-Codamol | PS C C C C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Panadeine Co) C

Date:03/23/04ISR Number: 4323756-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040303081

Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aspartate Aminotransferase Increased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 36 MG, IN 1 DAY, ORAL | | Eosinophilia | | | | | |

Date:03/23/04ISR Number: 4323757-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20030603419

Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Biopsy Bone Marrow Abnormal | Foreign Consumer Health | Concerta (Methylphenidate Hydrochloride) | PS | | |
| Other | | Blood Glucose Increased | | | | | |
| 1 TABLET /DAILY | | Glucose Urine Present | Professional | | | | |
| | | Helicobacter Infection Hyperplasia Iron Deficiency Nasopharyngitis Petechiae Pharyngolaryngeal Pain Poikilocytosis Purulence Skin Haemorrhage Thrombocytopenia | Other | Medikinet (Methylphenidate Hydrochloride) | C | | |

Date:03/25/04ISR Number: 4322971-4Report Type:Expedited (15-DaCompany Report #PHBS2004BR03858

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | | |
| Death | | Completed Suicide | | Ritalina | PS | Novartis Sector: | |

| | | | | | | | | |
|-----------|----------|--|--|------------|----|--------|----------------------------|------|
| 40 mg/day | | | | Ritalina | SS | Pharma | Novartis Sector: Pharma | ORAL |
| 30 mg/day | | | | Ritalina | SS | | Novartis Sector: Pharma | ORAL |
| 20 mg/day | | | | Sertraline | C | | | ORAL |
| UNKNOWN | 25 to 50 | | | | | | | |
| mg/day | | | | | | | | |

Date:03/25/04ISR Number: 4327846-2Report Type:Expedited (15-DaCompany Report #PT-JNJFOC-20040302154
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Back Pain Chest Pain Delusion Diplopia Headache | Foreign Health Professional Other | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/29/04ISR Number: 4330576-4Report Type:Expedited (15-DaCompany Report #CEL-2004-00320-ROC
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|------------------------|---|------|--------------|-------|
| Dose Other Required Intervention to Prevent Permanent Impairment/Damage 60MG | | Depressed Level Of Consciousness Incontinence Postictal State Somnolence | Health Professional | Metadate Cd Capsules (Strength Unspecified) (Methylphenidate Hydrochloride) | PS | | |

Date:03/29/04ISR Number: 4331403-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040304100
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other 54 MG, 1 IN 1 DAY, ORAL | | Cerebral Haemorrhage Cerebrovascular Accident Headache Hemiplegia | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| | | | | Remeron (Mitazapine) | C | | |

Date:03/29/04ISR Number: 4336843-2Report Type:Periodic Company Report #USA040156295
Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--|---------------|---|------|--------------|-------|
| Dose 25 MG/DAY | 6 WK | Disturbance In Attention Psychomotor Hyperactivity Tic | Consumer | Strattera (Atomoxetine Hydrochloride) | PS | | |
| | | | | Concerta(Methylpheni date Hydrochloride) | I | | |

Date:03/30/04ISR Number: 4332568-8Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040101912
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------------------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Iron Deficiency Anaemia Leukopenia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 36 MG, ORAL | | | | | | | |

Date:03/30/04ISR Number: 4332569-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040201307
Age:6 YR Gender:Unknown I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination, Visual | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| 36 MG | | | | | | | |

Date:03/30/04ISR Number: 4332570-6Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040201665
Age:11 YR Gender:Male I/FU:I

| Outcome | PT |
|---------|---------------------------|
| Other | Anorexia Gynaecomastia |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | |
|-------------|----------|------------------------------|-----------------------------------|---|------|--------------|
| | | Insomnia Weight Decreased | | | | |
| Dose | Duration | | Report Source | Product | Role | Manufacturer |
| | | | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | |
| 54 MG, ORAL | | | | | | ORAL |

Date:03/31/04ISR Number: 4331141-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040203041
Age:8 YR Gender:Male I/FU:F

| | | | | | | | |
|----------------------------|----------|--|---|--|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Concussion Head Injury Malabsorption Vomiting | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | | | | | | | |

| | | | | | | |
|--|--|--|--|---|---|--|
| | | | | Clonidine (Clonidine) Tablets | C | |
| | | | | Ritalin (Methylphenidate Hydrochloride) | C | |

Date:03/31/04ISR Number: 4332112-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040305787
Age: Gender: I/FU:I

| | | | | | | | |
|---------|----------|---|-----------------------------------|--|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Depressive Symptom Suicidal Ideation | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depressive Symptom Suicidal Ideation | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |

Age:12 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blindness Transient Blindness Unilateral Colour Blindness Acquired | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | |

54 MG,

UNKNOWN

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/04ISR Number: 4333345-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040104848
 Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|--|---|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia Loss Of Consciousness Tachycardia | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 54 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| 25 MG, ORAL | | | | | | | |
| Zoloft (Sertraline Hydrochloride) | | | | | | | |
| SS | | | | | | | |
| ORAL | | | | | | | |

Date:04/02/04ISR Number: 4333770-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040304857
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haematuria | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | |
| 54 MG, IN 1 | | | | | | | |
| DAY | | | | | | | |

Date:04/02/04ISR Number: 4333771-3Report Type:Expedited (15-DaCompany Report #DK-JNJFOC-20040304590
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Henoch-Schonlein Purpura | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Talbetes | PS | | ORAL |
| 36 MG, IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:04/02/04ISR Number: 4333773-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20031105477

Age:15 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abortion Spontaneous Complications Of Maternal Exposure To Therapeutic Drugs Maternal Drugs Affecting Foetus Unintended Pregnancy | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 54 MG, IN 1 DAY, ORAL | | | | | | | |

Date:04/02/04ISR Number: 4337205-4Report Type:Periodic Company Report #PHEH2004US01439

Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|---|---------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety Confusional State Drug Abuser Fatigue Headache Lethargy | Consumer | Ritalin La (Methylphenidate Hydrochloride) Extended Release Capsules Accutane (Isotretinoin) Over The Conter | PS C | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Antihistamines C

Date:04/05/04ISR Number: 4331504-8Report Type:Expedited (15-DaCompany Report #PHNU2004DE01402
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Facial Paresis | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |

Date:04/05/04ISR Number: 4331621-2Report Type:Expedited (15-DaCompany Report #PHBS2004BR04217
Age:69 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------------|-----------------------------|------------------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Apathy Confusional State | Health Professional | Methylphenidate | PS | Novartis Sector: Pharma | |
| UNKNOWN | 5 mg/day | | | Methylphenidate | SS | Novartis Sector: Pharma | |
| UNKNOWN | 2.5 mg/day | | | | | | |
| UNKNOWN | 50 mg/day | | | Sertraline | C | | |

Date:04/05/04ISR Number: 4334745-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040306437
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Blood Pressure Increased Headache | Health Professional Company | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| Other | | | Representative | Risperdal (Risperidone) | C | | |

Date:04/05/04ISR Number: 4334746-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040306436
Age:10 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---------------|---------------|---|-----------------------------------|--|------|--------------|-------|
| Other | | | Blood Pressure Increased Dizziness Headache | Health Professional Company | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| | 36 MG, 1 IN 1 | | | Representative | | | | |
| | | DAY, ORAL; 27 | | | | | | |
| | MG, 1 IN 1 | | | | | | | |
| | | DAY, ORAL; 18 | | | | | | |
| | MG, 1 IN 1 | | | | Risperdal (Risperidone) | C | | |
| Date:04/05/04ISR Number: 4334747-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040304599 | | | | | | | | |
| Age:12 YR Gender:Male I/FU:F | | | | | | | | |
| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Other | | | Blindness Transient Blindness Unilateral | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| | 54 MG ORAL | | | Other | | | | |
| 18-Aug-2005 11:49 AM | | | | | | | | |
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/05/04ISR Number: 4334819-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040305776
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Psychotic Disorder Suicidal Ideation | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, IN 1 DAY, ORAL | | | | | | | |

Date:04/06/04ISR Number: 4333699-9Report Type:Direct Company Report #CTU 216062
 Age:49 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|-------------------------|---------------|----------------|------|--------------|-------|
| Death 150 MG | | Intentional Self-Injury | | Effexor 150 Mg | PS | | |
| NIGHTLY 27 MG DAILY + | | | | | | | |
| | | | | Concerta 27 Mg | SS | | |
| | | | | Risperdal | C | | |
| | | | | Synthroid | C | | |
| | | | | Atkins Diet | C | | |

Date:04/07/04ISR Number: 4334699-5Report Type:Direct Company Report #CTU 216102
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|---|---------------|----------------|------|--------------|-------|
| Life-Threatening 1 DAY ORAL | | Hair Plucking | | Paxil 20 Mg | PS | | ORAL |
| 1 DAY ORAL | | | | | | | |
| | | Intentional Self-Injury | | Concerta 35 Mg | SS | | ORAL |
| | | Self Injurious Behaviour Suicidal Ideation | | | | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dyspnoea Oesophageal Spasm Oesophagitis | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 108 MG, 1IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| | | | | Dexmethylphenidate Hydrochloride (Methylphenidate) | C | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|-------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Ritalin (Sr) 20 Mg 1 Po Qd | PS | | ORAL |
| 1 PO QD | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/08/04ISR Number: 4337854-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040400309
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------------------|--|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Oral Intake Reduced Urticaria | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 1 DOSE (S), 1 | | | | | | | |
| IN 1 DAY, | | | | | | | |
| ORAL | | | | | | | |
| | | | | Oxybutynin Methylphenidate | C C | | |

Date:04/09/04ISR Number: 4335446-3Report Type:Expedited (15-DaCompany Report #PHBS2004BE04601
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Dependence | | Ritaline | PS | Novartis Sector: Pharma | |

Date:04/09/04ISR Number: 4338458-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040400865
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Abnormal Dreams Hallucination Insomnia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 18 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |
| | | | | Melatonin (Tablets) | C | | |

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|---|-----------------------------------|--|------|--------------|-------|
| Dose Duration Hospitalization - Initial or Prolonged | Alanine Aminotransferase Increased Cyanosis | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, IN 1 DAY, ORAL | | | | | | |

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|---|-----------------------------------|--|------|--------------|-------|
| Dose Duration Hospitalization - Initial or Prolonged | Body Temperature Decreased Cyanosis Difficulty In Walking Pain In Extremity | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | Paraesthesia Vascular Occlusion | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/09/04ISR Number: 4338462-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040303081
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aspartate Aminotransferase Increased Eosinophilia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release | PS | | ORAL |
| 36 MG, IN 1 DAY, ORAL | | | | | | | |

Date:04/09/04ISR Number: 4338469-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040303304
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain Circulatory Collapse Dyspnoea | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54 MG, 1 IN 1 DAY, ORAL | | | | | | | |
| | | Pain In Extremity Pallor | | | | | |

Date:04/14/04ISR Number: 4338655-2Report Type:Expedited (15-DaCompany Report #PHNU2004DE01468
Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|--|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Aplastic Anaemia Biopsy Bone Marrow | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 1095 DAY Abnormal Pancytopenia | | | | | | | |

Date:04/14/04ISR Number: 4340628-0Report Type:Expedited (15-DaCompany Report #CEL-2004-00589-ROC
Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|---|------------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abdominal Pain Chest Pain Drug Ineffective Headache | Consumer | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20MG ONCE PO | | Hyperventilation Hypoaesthesia Joint Stiffness Palpitations | | Ditropan (Oxybutynin) Sudafed (Pseudoephedrine Hydrochloride) | C C | | |

Date:04/15/04ISR Number: 4339419-6Report Type:Expedited (15-DaCompany Report #PHNU2004DE01472
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|----------|------|----------------------------|-------|
| Other | | Myocardial Infarction | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:04/15/04ISR Number: 4339855-8Report Type:Direct Company Report #CTU 216731
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-------------------------------------|---------------|------------------|------|--------------|-------|
| Other TWO DAILY | | Migraine | | Ritalin Sr 20 Mg | PS | | ORAL |
| ORAL | 1 YR | Pharmaceutical Product Complaint | | Ritalin 10 Mg | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

ORAL 1 YR

Date:04/15/04ISR Number: 4340039-8Report Type:Direct Company Report #CTU 216720
 Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pharmaceutical Product | | Ritalin | | | |
| | | Complaint | | (Methylphenidate) | | | |
| | | Rash | | Generic | PS | | |
| 15 GM Q 4 PRN | | | | | | | |

Date:04/19/04ISR Number: 4341108-9Report Type:Expedited (15-DaCompany Report #PHEH2004US02905
 Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------------|---------------|------------|------|------------------|-------|
| Dose | | | | | | | |
| Disability | | Movement Disorder | | Ritalin-Sr | PS | Novartis Sector: | |
| | | Throat Irritation | | | | Pharma | ORAL |
| 20 mg, QD | | | | | | | |
| | | Tic | | | | | |

Date:04/19/04ISR Number: 4343669-2Report Type:Expedited (15-DaCompany Report #CEL-2003-04227-ROC
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--------------------|----------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Psychotic Disorder | | Metadate Cd Capsules | | | |
| Required | | | Health | (Strength | | | |
| Intervention to | | | Professional | Unspecified) | | | |
| Prevent Permanent | | | Company | (Methylphenidate | | | |
| Impairment/Damage | | | Representative | Hydrochloride) | PS | | |

Date:04/19/04ISR Number: 4343732-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040200827
 Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety | Consumer | Concerta | | | |

| | | | | | |
|---------------|--------------------|--------------|-------------------|----|------|
| 18 MG, 1 IN 1 | Crying | Health | (Methylphenidate | | |
| | Depressed Mood | Professional | Hydrochloride) | | |
| | Fear | | Sustained Release | PS | ORAL |
| | Head Injury | | Tablets | | |
| | Insomnia | | | | |
| DAY, ORAL | Nervousness | | | | |
| | Pressure Of Speech | | | | |
| | Suicidal Ideation | | | | |

Date:04/21/04ISR Number: 4345216-8Report Type:Direct Company Report #CTU 217150
 Age:42 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Ritalin La 30 Mg | | | |
| | | Activities Of Daily | | Novaritis | PS | Novaritis | |
| 1 CAPSUL | | Living Impaired | | | | | |
| MORNING | | Feeling Abnormal | | | | | |
| | | Paranoia | | | | | |
| | | Staring | | | | | |
| | | Suicidal Ideation | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/22/04ISR Number: 4347965-4Report Type:Expedited (15-DaCompany Report #PHEH2004US02905
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---|------------------------|---|------|--------------|-------|
| Disability | | Movement Disorder Throat Irritation Tic | Health Professional | Ritalin-Sr(Methylphe nidate Hydrochloride) Slow Release Tablet | PS | | ORAL |
| 20 MG, QD,ORAL | | | | | | | |

Date:04/26/04ISR Number: 4349407-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040301164
Age:34 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Other | | Chest Discomfort Dyspnoea Heart Rate Increased Palpitations | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Release Tablets | PS | | ORAL |
| 90 MG, IN 1 DAY, ORAL | | | | | | | |

Date:04/27/04ISR Number: 4348366-5Report Type:Expedited (15-DaCompany Report #PHBS2004BR02935
Age:7 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|--|---------------|----------------------------|--------|----------------------------|-------|
| Other | | Agitation Asthma | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| 2.5 tablets/day | | Developmental Delay | | | | | |
| | | Eosinophil Count Increased Growth Retardation Headache Insomnia Penis Disorder Skin Odour Abnormal | | Polivitamine Revitam Jr | C C | | |

Testicular Retraction
Tooth Disorder
Vomiting
Weight Gain Poor

Date:04/27/04ISR Number: 4348378-1Report Type:Expedited (15-DaCompany Report #PHEH2004US04276
Age:35 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Depression Suicidal | | Ritalin La | PS | Novartis Sector: Pharma | |
| 20 mg, QD | | | | Wellbutrin | C | | |
| | | | | Serzone | C | | |
| | | | | Allegra-D | | | |
| | | | | /01367401/ | C | | |

Date:04/27/04ISR Number: 4348971-6Report Type:Direct Company Report #CTU 217488
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| | | Decreased Appetite | | Ritalin | PS | | |
| | | Drug Effect Decreased | | Concerta | SS | | |
| | | Tic | | Adderal | SS | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/27/04ISR Number: 4350817-7Report Type:Expedited (15-DaCompany Report #CEL-2004-00656-ROC
 Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------|---|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hepatic Failure | Health Professional Company Representative | Metadate Cd Capsules (Strength Unspecified) (Methylphenidate Hydrochloride) | PS | | |
| 40MG ONCE | | | | | | | |
| DAILY | ; | | | | | | |
| SEVERAL YEARS | | | | | | | |
| AGO | | | | Methylphenidate (Brand Unspecified) Methylphenidate | SS | | |
| 10 MG | | | | | | | |
| FREQUENCY AND | | | | | | | |
| ROUTE UNKNOWN | | | | | | | |

Date:04/28/04ISR Number: 4349418-6Report Type:Expedited (15-DaCompany Report #PHBS2004BE04601
 Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------------------------|---------------|----------|------|----------------------------|-------|
| Other | | Dependence Drug Abuser | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 150 mg/day | | | | Ritaline | SS | Novartis Sector: Pharma | ORAL |
| 60 mg/day | | | | Prozac | C | | |
| UNKNOWN | | | | | | | |

Date:04/28/04ISR Number: 4351507-7Report Type:Expedited (15-DaCompany Report #CEL-2004-00675-ROC
 Age:26 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|--|------|--------------|-------|
| Other Required Intervention to Prevent Permanent 20MG DAILY PO Impairment/Damage | | Facial Palsy Muscle Twitching Tympanic Membrane Perforation | Consumer | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:04/28/04ISR Number: 4352177-4Report Type:Expedited (15-DaCompany Report #CEL-2004-00330-SLO
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------------|--|------|--------------|-------|
| Disability | | Initial Insomnia Paradoxical Drug Reaction Tic | Foreign Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 20 MG ONCE | | | | Ritalin (Methylphenidate Hydrochloride) | C | | |
| DAILY, ORALLY | | | | Clonidine (Clonidine) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/04ISR Number: 4353060-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040404867
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|------------|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Dyskinesia | Foreign Health Professional | Concerta(Methylpheni date Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, IN 1 DAY, ORAL | | | | | | | |

Catapresan
(Clonidine) C

Date:04/30/04ISR Number: 4352687-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20040405349
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Alcohol Poisoning Legal Problem Physical Assault | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

SEE IMAGE

Antidepressant
(Antidepressants) SS

Date:04/30/04ISR Number: 4352688-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040405591
 Age:21 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------------|---------------|---|------|--------------|-------|
| Dose Other | | Hypertension Palpitations | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained | PS | | ORAL |

54 MG, 1 IN 1

DAY, ORAL

Date:04/30/04ISR Number: 4353380-XReport Type:Expedited (15-DaCompany Report #CEL-2004-00656-ROC
 Age:8 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------|--|--|------|--------------|-------|
| Life-Threatening Hospitalization - Initial or Prolonged | | Hepatic Failure | Health Professional Company Representative | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 40 MG QAM PO | | | | Methylphenidate (Brand Unspecified) (Methylphenidate) | SS | | ORAL |
| 10 MG DAILY | | | | | | | |
| PO | | | | | | | |

Date:05/04/04ISR Number: 4352632-7Report Type:Expedited (15-DaCompany Report #PHEH2004US04593
 Age:72 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------------------|---------------|-----------|------|-------------------------|-------|
| Death | | Medication Error Movement Disorder | | Ritalin | PS | Novartis Sector: Pharma | |
| 20 mg, BID | | | | | | | |
| 200 mg, QHS | | Sudden Death | | Clozapine | SS | | |
| | | | | Compazine | SS | | |
| | | | | Percocet | SS | | |
| | | | | Paxil | C | | |
| 50 mg, QD | | | | | | | |
| (50mg QAM) | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

1 mg, TID

Ativan C

Date:05/04/04ISR Number: 4352724-2Report Type:Expedited (15-DaCompany Report #04-03-0377
 Age:72 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|-------|---------------|--------------------------------|--------------|-----------------|--------------|
| Death | | Death | | Compazine Clozapine | PS SS | Glaxosmithkline | ORAL |
| 200MG At night | | | | Ritalin | SS | | ORAL |
| 20MG Twice per day | | | | Percocet Paxil Cr Ativan | SS C C | Glaxosmithkline | ORAL ORAL |
| 1MG Three times per day | | | | | | | |

Date:05/04/04ISR Number: 4355363-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040405168
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Other | | Inner Ear Disorder Nausea Nystagmus Vertigo | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | | | | | | | |

Date:05/04/04ISR Number: 4355365-6Report Type:Expedited (15-DaCompany Report #BE-JNJFOC-20040400872
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|-----------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Agitation Burns Second Degree Hypoaesthesia Oral Insomnia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| ORAL | | Logorrhoea Memory Impairment Muscle Twitching Mydriasis Overdose Self Mutilation Vision Blurred | | | | | |

Date:05/06/04ISR Number: 4353919-4Report Type:Periodic Company Report #20030906351
 Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-----------|---------------|-----------|------|-----------------|-------|
| 3 DAY | | Urticaria | | Amoxillin | PS | Glaxosmithkline | ORAL |
| 18MG Per day | DAY | | | Concerta | SS | | ORAL |

Date:05/06/04ISR Number: 4354107-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040404867
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|------------------|---------------|-----------|------|--------------|-------|
| Other OROPHARINGEAL | | Drug Ineffective | | Concerta | PS | | |
| | | Dyskinesia | | Medikinet | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Medikinet SS
 Catapresan C

Date:05/06/04ISR Number: 4354108-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040303304
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | | Concerta | PS | | |
| OROPHARINGEAL | | Circulatory Collapse Dyspnoea Pain In Extremity Pallor | | | | | |

Date:05/06/04ISR Number: 4354109-1Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040402217
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia | | Concerta | PS | | |
| OROPHARINGEAL | | Weight Decreased | | | | | |

Date:05/06/04ISR Number: 4354265-5Report Type:Expedited (15-DaCompany Report #PHBS2004CA05701
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Dyspepsia | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:05/06/04ISR Number: 4357303-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040500445
 Age:38 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Bundle Branch Block Left Electrocardiogram Qt | Health Professional | Concreta(Methylpheni date Hydrochloride) | | | |

| | | | | | |
|-----------|-------------------------------|---------------------------|------------------------------|----|------|
| SEE IMAGE | Prolonged Muscle Twitching | Company Representative | Sustained Release Tablets | PS | ORAL |
| | Nervousness Tremor | | | | |

Date:05/06/04ISR Number: 4357305-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040406592
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|------------------------------------|--|------|--------------|-------|
| Dose Other | | Intestinal Obstruction | Consumer Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |

Date:05/06/04ISR Number: 4357306-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040406333
 Age:11 YR Gender:Male I/FU:I

| | |
|---------|---|
| Outcome | PT |
| Other | Blood Pressure Increased Chest Pain Dilatation Atrial |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Dizziness

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------|----------|----|---------------------|--|------|--------------|-------|
| | | | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

SEE IMAGE

Date:05/07/04ISR Number: 4356824-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040404867
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------------------|-----------------------------|--|------|--------------|-------|
| Dose Other | | Condition Aggravated Dyskinesia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

18 MG, IN 1

DAY, ORAL

SEE IMAGE

Medikinet (Methylphenidate Hydrochloride) SS
 Catapresan(Clonidine) C

Date:05/07/04ISR Number: 4356827-8Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040402217
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------------|---|--|------|--------------|-------|
| Dose Other | | Anorexia Weight Decreased | Foreign Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

54 MG, 1 IN 1

DAY, ORAL

Date:05/07/04ISR Number: 4356830-8Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040303304

Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain Circulatory Collapse Dyspnoea | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54 MG, 1 IN 1 | | Pain In Extremity | | | | | |
| DAY, ORAL | | Pallor | | | | | |

Date:05/10/04ISR Number: 4354920-7Report Type:Expedited (15-DaCompany Report #PHEH2004US04863

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Death | | Renal Failure | | Ritalin | PS | Novartis Sector: Pharma | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/10/04ISR Number: 4354930-XReport Type:Expedited (15-DaCompany Report #PHFR2004GB01949

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Accommodation Disorder | | Ritaline | PS | Novartis Sector: Pharma | |
| UNKNOWN | | | | | | | |

Date:05/10/04ISR Number: 4357504-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040406129

Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|----------------------------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Psychotic Disorder | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |
| 54 MG, IN 1 DAY, ORAL | | | | | | | |

Date:05/11/04ISR Number: 4356663-2Report Type:Direct Company Report #CTU 218312

Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Ritalin 10 Mg | PS | | ORAL |
| 1 PO BID Pharmaceutical Product Complaint | | | | | | | |

Date:05/12/04ISR Number: 4357226-5Report Type:Direct Company Report #CTU 218503

Age:40 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Heart Rate Increased | | Concerta 36 Mg | PS | | |
| 36 MG | | | | | | | |

Date:05/12/04ISR Number: 4359306-7Report Type:Expedited (15-DaCompany Report #CEL-2004-0224-ROC
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|----------------------|----------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | Health | Metadate Cd Capsules | | | |
| Required | | Grand Mal Convulsion | Professional | 20 Mg | | | |
| Intervention to | | Incoherent | Company | (Methylphenidate | | | |
| Prevent Permanent | | Postictal State | Representative | Hydrochloride) | PS | | ORAL |
| 40MG QAM PO | | | | | | | |
| Impairment/Damage | | Thinking Abnormal | | Metadate Er Tablets | | | |
| | | | | 10mg | | | |
| | | | | (Methylphenidate | | | |
| | | | | Hydrochloride) | SS | | |

10MG AT 5:00

PM,

Date:05/12/04ISR Number: 4359349-3Report Type:Expedited (15-DaCompany Report #BE-JNJFOC-20040500353
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression | Foreign | Concerta | | | |
| | | Self Injurious Behaviour | Health | (Methylphenidate | | | |
| | | Suicidal Ideation | Professional | Hydrochloride) | | | |
| | | | | Unspecified | PS | | ORAL |

36 MG, IN 1

DAY; ORAL

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/12/04ISR Number: 4359472-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040500741
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------------------------|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Cholecystitis Acute Dehydration | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, 1 IN 1 DAY, ORAL | | | | | | | |

Date:05/14/04ISR Number: 4358356-4Report Type:Expedited (15-DaCompany Report #PHNU2003DE04364
 Age:6 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------|---------------|----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | | Henoch-Schonlein Purpura | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 15 mg/day | | | | | | | |
| 15 mg/day | | | | | | | |

Date:05/14/04ISR Number: 4358696-9Report Type:Direct Company Report #CTU 218657
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|-----------------------------|------|--------------|-------|
| Other | | Drug Ineffective Pharmaceutical Product | | Methylin 5mg Mallinckrot | PS | Mallinckrot | |
| AURICULAR (OTIC) DAILY AURICULAR (OT | | | | | | | |

Date:05/14/04ISR Number: 4360267-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040502040
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Condition Aggravated Psychomotor Hyperactivity | Consumer | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |

ORAL

Date:05/14/04ISR Number: 4360268-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040502012
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Pressure Increased | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

ORAL

Date:05/17/04ISR Number: 4358726-4Report Type:Expedited (15-DaCompany Report #PHFR2004GB02013
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------------|------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | 5-10mg prn | | | Concerta | SS | | ORAL |
| | 54mg/day | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/17/04ISR Number: 4360344-9Report Type:Expedited (15-DaCompany Report #C03-T-061
 Age:18 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Consumer | Methylphenidate Hydrochloride Tablets, Usp 20mg | PS | Able Laboratories, Inc. | |

Date:05/18/04ISR Number: 4359423-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040501520
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|-------------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - OROPHARINGEAL | | Hallucinations, Mixed 6 WK | | Concerta | PS | | |
| Initial or Prolonged | | Schizoaffective Disorder | | | | | |
| Other | | Thinking Abnormal | | | | | |

Date:05/18/04ISR Number: 4362690-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040405591
 Age:21 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Heart Rate Increased Hypertension Palpitations | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

54 MG, 1 IN 1

DAY, ORAL

Date:05/18/04ISR Number: 4363193-0Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040502767
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-------------------|------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Intentional Misuse Medication Error | Foreign Health | Concerta (Methylphenidate | | | |

Professional Hydrochloride)
Sustained Release
Tablets PS ORAL

54 MG, ORAL

Date:05/18/04ISR Number: 4363194-2Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040406054

Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Intentional Misuse Medication Error | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | NASAL |

54 MG,

INTRA-NASAL

Dexedrine Extended
Release
(Dexamfetamine
Sulfate) C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/18/04ISR Number: 4363198-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040203651
 Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|---------------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Back Pain Haematuria Renal Pain | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| 54 MG; 72 MG, 1 IN 1 DAY, | | | | | PS | | |

Date:05/19/04ISR Number: 4360127-XReport Type:Expedited (15-DaCompany Report #PT-JNJFOC-20040501746
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Diarrhoea | | Concerta | | | |
| OROPHARINGEAL Diarrhoea Haemorrhagic | | | | | PS | | |

Date:05/19/04ISR Number: 4363892-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040501520
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucinations, Mixed Schizophrenia Thinking Abnormal | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | |
| Hospitalization - Initial or Prolonged 36 MG, 1 IN 1 DAY, ORAL | | | | | PS | | ORAL |

Date:05/20/04ISR Number: 4361257-9Report Type:Expedited (15-DaCompany Report #PHNU2004DE01767
 Age:37 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----|------------------------------------|-----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | | | Chest Pain Troponin I Increased | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 25 mg/day | | | | Rytmonorm | C | | ORAL |
| Unknown | | | | | | | |

Date:05/20/04ISR Number: 4361258-0Report Type:Expedited (15-DaCompany Report #PHFR2004GB02075
 Age:40 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----|---------------------|-----------------|------|----------------------------|-------|
| Other | | | Blindness Transient | Methylphenidate | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, TID | | | | | | | |

Date:05/20/04ISR Number: 4365919-9Report Type:Expedited (15-DaCompany Report #PT-JNJFOC-20040501746
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|----|-----------------------------------|--|------|--------------|-------|
| Other | | | Diarrhoea Haemorrhagic | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 18 MG, IN 1 DAY, ORAL | | | Foreign Health Professional | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/21/04ISR Number: 4362495-1Report Type:Expedited (15-DaCompany Report #PHNU2004DE01816
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Electroencephalogram Abnormal Fall Loss Of Consciousness Syncope | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:05/21/04ISR Number: 4363857-9Report Type:Direct Company Report #CTU 219257
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| ONE PO QD | | Abnormal Behaviour Distractibility Pharmaceutical Product Complaint | | Metadate Sr 10 Mg | PS | | ORAL |

Date:05/25/04ISR Number: 4364357-2Report Type:Expedited (15-DaCompany Report #PHNU2004DE01846
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Cerebral Artery Occlusion Cerebral Infarction | | Methylphenidate | PS | Novartis Sector: Pharma | ORAL |
| Unknown | 60480MIN | Dysarthria Facial Paresis Monoparesis Vith Nerve Paralysis | | | | | |

Date:05/25/04ISR Number: 4369041-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040104427
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Angina Pectoris | Foreign | Concerta | | | |

| | | | | | |
|-------------|---|------------------------|------------------------------------|----|------|
| 36 MG, IN 1 | Dyspnoea Exertional Electrocardiogram St | Health Professional | (Methylphenidate Hydrochloride) | PS | ORAL |
| DAY, ORAL | Segment Elevation Sinus Tachycardia | | | | |

Date:05/25/04ISR Number: 4369044-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040302601
Age:12 YR Gender:Male I/FU:F

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--|-----------------------------------|--|---------------------------|--------------|-------|
| 72 MG, 1 IN 1 | | Abnormal Dreams Anticipatory Anxiety Hallucination, Visual | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) | PS | | ORAL |
| DAY, ORAL | | Post Procedural Complication Skin Laceration Tendon Injury Thermal Burn Vascular Injury | | Cefuroxime (Cefuroxime) Ondansetron (Ondansetron) Paracetamol (Paracetamol) Diclofenac (Diclofenac) Cyclizine (Cyclizine) | C C C C C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Co-Codamol
(Panadeine Co) C
Cefuroxime
(Cefuroxime) Unknown C

Date:05/26/04ISR Number: 4367230-9Report Type:Expedited (15-DaCompany Report #2004-116006-NL
Age:74 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------------|------|--------------|-------|
| Death | | Asthenia | Health | Remeron Soltab | PS | | ORAL |
| 7.5 MG QD | | Depressed Level Of | Professional | | | | |
| ORAL | 2 | DAY | | | | | |
| | | Consciousness | | Remeron Soltab | SS | | ORAL |
| 15 MG QD ORAL | 4 | DAY | | | | | |
| | | Dysarthria | | Remeron Soltab | SS | | ORAL |
| 22.5 MG QD | | Hepatic Failure | | | | | |
| ORAL | 3 | DAY | | | | | |
| | | Oedema | | Remeron Soltab | SS | | ORAL |
| 30 MG QD ORAL | | Renal Failure | | Ritalin | SS | | ORAL |
| 2.5 MG BID | | | | | | | |
| ORAL | | | | | | | |
| | | | | Ritalin | SS | | ORAL |
| 5 MG BID ORAL | | | | | | | |
| | | | | Ritalin | SS | | ORAL |
| 7.5 MG BID | | | | | | | |
| ORAL | | | | | | | |
| | | | | Bextra | SS | | ORAL |
| 10 MG QD ORAL | | | | | | | |
| | | | | Prevacid | SS | | ORAL |
| 30 MG QD ORAL | | | | | | | |
| | | | | Avandia | SS | | ORAL |
| 4 MG DAILY | | | | | | | |
| ORAL | | | | | | | |
| | | | | Avandia | SS | | ORAL |
| 8 MG DAILY | | | | | | | |
| ORAL | | | | | | | |

5 MG QD ORAL

| | | |
|---------------------|----|------|
| Norvasc | SS | ORAL |
| Hydrochlorothiazide | C | |
| Levaquin | C | |
| Ativan | C | |
| Actonel | C | |
| Dilantin | C | |
| Wygesic | C | |
| Altace | C | |
| Os-Cal | C | |
| Catapressan | C | |
| Persantine | C | |
| Colace | C | |
| Lexapro | C | |
| Pepcid | C | |
| Coumadine | C | |
| Flonase | C | |
| Glyburide | C | |

Date:05/26/04ISR Number: 4372657-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040504699
 Age:10 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------------------------------|------------------------|---|------|--------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - Initial or Prolonged | Hypertension Pulmonary Oedema | Health Professional | Concerta (Methylphenidate (Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | Neo-Synephrine (Phenylephrine Hydrochloride) | SS | | NASAL |
| NASAL | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/27/04ISR Number: 4369418-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20040504699
 Age:10 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------------------|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hypertension Pulmonary Oedema | Health Professional | Concerta (Methylphenidate Hydrochloride)Sustai ned Release Tablets | PS | | ORAL |
| 54 MG, 1 IN 1 DY, ORAL | | | | Neo-Synephrine (Phenylphrine Hydrochloride) | SS | | NASAL |

Date:05/27/04ISR Number: 4370101-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040503465
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|-----------------------------------|---|------|--------------|-------|
| Other | | Cholestasis Hepatitis Rash Scaly Urticaria | Foreign Health Professional | Concerta(Methylpheni date Hydrochloride)Sustai ned Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |

Date:05/28/04ISR Number: 4366761-5Report Type:Expedited (15-DaCompany Report #PHBS2004BR06639
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------|---------------|----------|------|----------------------------|-------|
| Other | | Paralysis | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| 1 tablet/d | 21600MIN | | | | | | |

Date:05/28/04ISR Number: 4366764-0Report Type:Expedited (15-DaCompany Report #PHEH2004US05626
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------|---------------|---------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | | Overdose | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:05/28/04ISR Number: 4367404-7Report Type:Direct Company Report #CTU 219727
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------|----------|------|--------------|-------|
| Hospitalization - 54 MG QD ORAL Initial or Prolonged | | Atrial Fibrillation | | Concerta | PS | | ORAL |
| | | Blood Pressure Diastolic Decreased | | Zyrtec | C | | |
| | | Cardiac Failure Congestive Cardiomyopathy Drug Abuser Ejection Fraction Decreased Fall Heart Rate Increased Hypomagnesaemia Hypoxia Loss Of Consciousness Metabolic Acidosis Pulmonary Congestion Respiratory Acidosis Ventricular Hypokinesia | | Creatine | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/28/04ISR Number: 4370531-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040504718
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------|---|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Movement Disorder | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | Seroquel (Quetiapine Fumarate) | C | | |

Date:06/01/04ISR Number: 4367303-0Report Type:Expedited (15-DaCompany Report #PHBS2004BR06886
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|--------|---------------|-----------------------------|------|----------------------------|-------|
| Other | | Asthma | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| 1.5 DF/d | | | | Nasonex | C | | |
| UNK, QD | | | | Aerolin "Glaxo Wellcome" | C | | |
| UNK, QID | | | | Clenil | C | | |
| UNK, BID | | | | | | | |

Date:06/01/04ISR Number: 4370915-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040501520
 Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Hallucination, Auditory Hallucination, Visual Paranoia Thinking Abnormal | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Dipiperon
(Unspecified)
Pipamperone C

Date:06/02/04ISR Number: 4372116-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040300993
Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Anorexia Weight Decreased | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 DAY, ORAL | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | |
| 10 MG, IN 1 DAY; 15 MG, 2 IN 1 DAY | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/02/04ISR Number: 4372225-5Report Type:Expedited (15-DaCompany Report #MK200405-0425-1
Age:24 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-----|-----------------------|---------------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged 60MG, DAILY | 6 | MON | Foreign Literature | Methylphenidate Hcl Tabs, Usp 20mg | PS | | |

Date:06/04/04ISR Number: 4371829-3Report Type:Direct Company Report #CTU 220139
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|----|---------------|--|------|--------------|-------|
| 1 TAB BID ORAL | | | | Methylphenidate 10 Mg 00406-1122-10 | PS | | ORAL |

Date:06/04/04ISR Number: 4374198-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040506500
Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|---------------|--|------|--------------|-------|
| Other ORAL | | | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| | | | | Lamictal (Lamotrigine) | C | | |

Date:06/08/04ISR Number: 4377851-5Report Type:Expedited (15-DaCompany Report #BE-JNJFOC-20040500353
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|-------------------|------------------------------|------|--------------|-------|
| Other | | | Foreign Health | Concerta (Methylphenidate | | | |

Suicidal Ideation

Professional

Hydrochloride)

Unspecified

PS

ORAL

36 MG, IN 1

DAY, ORAL

Date:06/10/04ISR Number: 4378820-1Report Type:Expedited (15-DaCompany Report #CEL-2004-01183-SLO

Age:40 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------|-----------------------------|---|------|--------------|-------|
| Disability | | Blindness Transient | Foreign Health Professional | Methylphenidate (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10MG THREE | | | | | | | |
| TIMES DAILY, | | | | | | | |
| ORALLY | | | | | | | |

Date:06/10/04ISR Number: 4385322-5Report Type:Direct

Company Report #USP 56655

Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------------------|------|--------------|-------|
| TABLET | | Medication Error | | Adderall 10 Mg | PS | | |
| TABLET | | | | Methylphenidate 10 Mg | SS | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/14/04ISR Number: 4379969-XReport Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040601564
Age:46 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|---|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Condition Aggravated Drug Level Below Therapeutic Grand Mal Convulsion | Foreign Health Professional Company | Concerta (Methylphenidate Hydrochloride) Sustained | | | ORAL |
| 54 MG, 1 IN 1 DAY, ORAL | | Oral Intake Reduced | Representative | | | PS | |
| | | Petit Mal Epilepsy Sleep Disorder Treatment Noncompliance | | Divalproex Sodium (Valproate Semisodium) Lamotrigine (Lamotrigine) | | | |
| | | | | | C | | |
| | | | | | C | | |

Date:06/15/04ISR Number: 4381800-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040304599
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blindness Transient Colour Blindness | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | | | ORAL |
| 54 MG, 1 IN 1 DAY, ORAL | | | | | | PS | |

Date:06/15/04ISR Number: 4382204-XReport Type:Expedited (15-DaCompany Report #2004037749
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|---|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Gastrointestinal Disorder | Health Professional Company Representative | Zoloft (Sertraline) Methylphenidate Hydrochloride (Methylphenidate Hydrochloride) | | | |
| | | | | | PS | | |
| | | | | | SS | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------|---|------|--------------|-------|
| Dose Other | | Suicidal Ideation | Consumer | Metadate Cd Capsules 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 10 MG, TWICE | | | | | | | |
| DAILY, ROUTE | | | | | | | |
| PO | | | | | | | |
| | | | | Depo Provera (Medroxyprogesterone Acetate) | C | | |
| | | | | Effexor (Venlafaxine Hydrochloride) | C | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------------------|---------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hypertension Pulmonary Oedema | Health Professional Other | Neo-Synephrine (Phenylephrine Hydrochloride) | PS | | NASAL |
| NASAL | | | | | | | |
| | | | | Concerta | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Methylphenidate Hydrochloride) SS ORAL
 54 MG, QD,
 ORAL

Date:06/17/04ISR Number: 4379409-0Report Type:Expedited (15-DaCompany Report #PHEH2004US06099
 Age:56 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|-----------|-----------------------------|---------------|------------|------|-------------------------|-------|
| Hospitalization - Initial or Prolonged | 30 mg, QD | Dysuria Pelvic Deformity | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 20 mg, QD | | | | Ritalin-Sr | SS | | ORAL |
| 10 mg, UNK | | | | Lexapro | C | | |

Date:06/17/04ISR Number: 4381209-2Report Type:Direct Company Report #CTU 221010
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|--------------|--|---------------|---------------------------------------|------|--------------|-------|
| Life-Threatening | 54 MG QD X 3 | Drug Interaction Hypertension Pulmonary Oedema | | Concerta 54 Mg. Mcneil | PS | Mc Neil | |
| 3 NASAL | | | | Neosynephrine 1% Nasal Spray Bayer | SS | Bayer | NASAL |
| SPRAYS | | | | | | | |

Date:06/18/04ISR Number: 4383574-9Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040601564
 Age:46 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|----------------|------------------------------|------|--------------|-------|
| Other | | Anticonvulsant Drug Level Below Therapeutic | Foreign Health | Concerta (Methylphenidate | | | |

| | | | | | |
|---------------|---|---|---|--------|------|
| 54 MG, 1 IN 1 | Excessive Exercise Grand Mal Convulsion Insomnia | Professional Company Representative | Hydrochloride) Sustained Release Tablets | PS | ORAL |
| DAY, ORAL | Medication Error | | | | |
| | Petit Mal Epilepsy Somnolence Treatment Noncompliance | | Divalproex Sodium (Valproate Semisodium)) Lamotrigine (Lamotrigine) | C C | |

Date:06/21/04ISR Number: 4383922-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040302004
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose Other | | Abnormal Behaviour Aggression Drug Ineffective Food Craving Suicidal Ideation | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:06/21/04ISR Number: 4397233-XReport Type:Periodic Company Report #USA-2004-0013440
Age:47 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------|-------------------|---------------------------------|------|--------------|-------|
| Dose Other | | Polysubstance Abuse | Consumer Other | Oxycontin Tablets (Oxycodone | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hydrochloride) PS
 Morphine Sulfate
 (Similar To Nda
 19-516) (Morphine
 Sulfate) SS
 Ritalin
 (Methylphenidate
 Hydrochloride) SS
 Codeine (Codeine) SS

Date:06/22/04ISR Number: 4383170-3Report Type:Direct
 Age:6 YR Gender:Male I/FU:I

Company Report #CTU 221221

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| 18 MG PO QAM | | Hallucination, Auditory | | Methylphenidate Er | PS | | ORAL |
| | | Insomnia Irritability Sleep Talking | | Guanfacine | C | | |

Date:06/22/04ISR Number: 4385130-5Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20040602728
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression Suicide Attempt | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:06/23/04ISR Number: 4383185-5Report Type:Expedited (15-DaCompany Report #PHFR2004GB02495
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Cardiac Murmur | | Ritaline | PS | Novartis Sector: Pharma | |

Date:06/23/04ISR Number: 4386271-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040603060
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Medication Error Overdose | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | ORAL |
| 54 MG, 1 IN 1 DAY, ORAL | | | | | | | |

Date:06/24/04ISR Number: 4388674-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040603003
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|--|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Pressure Increased Heart Rate Increased Nasal Congestion | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |
| Phenylephrine Hydrochloride Nasal | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Spray (Phenylephrine Hydrochloride) Spray SS

NASAL

NASAL

Date:06/24/04ISR Number: 4388686-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040603068

Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Disease Recurrence Herpes Ophthalmic | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | |

Date:06/28/04ISR Number: 4385340-7Report Type:Expedited (15-DaCompany Report #PHBS2004JP08068

Age:36 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-----------------------------------|---------------|---------|------|-------------------------|-------|
| Dose | | | | | | | |
| Death | | Death Drug Withdrawal Syndrome | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 1095 DAY | | Joint Stiffness | | | | | |

Date:06/28/04ISR Number: 4385839-3Report Type:Expedited (15-DaCompany Report #PHBS2004NL08230

Age:42 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|---------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Abortion Spontaneous Depression Dry Mouth | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:06/28/04ISR Number: 4386816-9Report Type:Direct Company Report #CTU 221695

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Concerta 18 Mgs | PS | | ORAL |
| 18 MGS TWICE | | | | | | | |

DAIL ORAL
Confusional State
Memory Impairment
Zoloft
C
Date:06/28/04ISR Number: 4389486-9Report Type:Expedited (15-DaCompany Report #DK-JNJFOC-20040304590
Age:13 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--|-----------------------------------|--|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged | Blood Pressure Increased Henoch-Schonlein Purpura | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, IN 1 DAY, ORAL | | | | | | |

Date:06/29/04ISR Number: 4388089-XReport Type:Direct Company Report #CTU 221758
Age: Gender:Male I/FU:I

| Outcome | PT |
|---|--|
| Hospitalization - Initial or Prolonged | Abnormal Behaviour Affective Disorder Bipolar Disorder Intentional Self-Injury Social Avoidant Behaviour |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Suicide Attempt

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------------|-----------------|------|--------------|-------|
| 36 MG ORAL | | | Concerta 36 Mg. | PS | | ORAL |
| 25 MG ORAL | | | Zoloft 25 Mg | SS | | ORAL |

Date:06/30/04ISR Number: 4389476-6Report Type:Expedited (15-DaCompany Report #NO-JNJFOC-20040604900
 Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------------|---|------|--------------|-------|
| Dose Other | | Chest Pain | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) Unspecified | PS | | ORAL |

SEE IMAGE

Date:06/30/04ISR Number: 4415346-0Report Type:Periodic Company Report #2003021340
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------|---------------|---|----------|--------------|-------|
| Dose Other | | Agitation Convulsion | Consumer | Zoloft (Sertraline) Methylphenidate Hydrochloride (Methylphenidate Hydrochloride) | PS SS | | |

Date:06/30/04ISR Number: 4415719-6Report Type:Periodic Company Report #2004014632
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|---|----------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Aggression Depression Suicidal Ideation | Consumer | Zoloft (Sertraline) Methylphenidate Hydrochloride (Methylphenidate Hydrochloride) | PS SS | | |

Date:07/01/04ISR Number: 4391901-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040605147

Age:6 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination, Visual | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

SEE IMAGE

Date:07/01/04ISR Number: 4393566-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040604066

Age:15 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|-----------------------------|-------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Eye Movement Disorder | Foreign Health Professional | Risperdal (Risperidone) Unspecified | PS | | |

1 MG, 1 IN 1

DAY

50 MG, 2 IN 1

DAY

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

54 MG

Concerta Xl
(Methylphenidate
Hydrochloride) SS

Date:07/02/04ISR Number: 4389456-0Report Type:Expedited (15-DaCompany Report #PHNU2004DE02303
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|------------------|------|----------------------------|-------|
| Death | | Death | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Unknown | | Poisoning Deliberate | | | | | |
| Unknown | | | | Asa | C | | ORAL |
| Unknown | | | | Furosemide | C | | ORAL |
| Unknown | | | | Haldol "Janssen" | C | | ORAL |
| Unknown | | | | Digitoxin | C | | ORAL |

Date:07/02/04ISR Number: 4389475-4Report Type:Expedited (15-DaCompany Report #PHFR2004GB02075
Age:40 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------------------|---------------------|----------|------|----------------------------|-------|
| Other | | Blindness Transient | Health Professional | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, TID | | | | | | | |

Date:07/02/04ISR Number: 4392542-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040406592
Age:44 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Gastrointestinal Obstruction Gastrointestinal Perforation | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release | | | |

54 MG, 1 IN 1
 DAY, ORAL
 Date:07/02/04ISR Number: 4392604-XReport Type:Expedited (15-DaCompany Report #HQWYE647924JUN04
 Age:36 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------------|---|---------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Enuresis Feeling Abnormal Formication | Foreign Consumer Other | Efexor (Venlafaxine Hydrochloride) | PS | | ORAL |
| 150 MG 1X PER 1 DAY ORAL | | General Physical Health Deterioration Insomnia Weight Decreased | | Ritalin (Methylphenidate Hydrochloride) Ativan (Lorazepam) | SS C | | |

Date:07/02/04ISR Number: 4392692-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040606160
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------|----------|-------------|-------------------|--|------|--------------|-------|
| Other | | Tachycardia | Foreign Health | Risperdal (Risperidone) | PS | | ORAL |
| 3 MG, IN 1 DAY, ORAL | | | Professional | Concerta (Methylphenidate Hydrochloride) | | | |

Freedom Of Information (FOI) Report

Sustained Release
Tablets SS ORAL

SEE IMAGE

Date:07/02/04ISR Number: 4392698-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040605857

Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------------|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Diplopia Strabismus | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

18 MG, IN 1

DAY, ORAL

Date:07/07/04ISR Number: 4394262-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040405591

Age:21 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------------|------------------------------------|---|------|--------------|-------|
| Other | | Hypertension Palpitations | Consumer Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Released Tablets | PS | | ORAL |

54 MG, 1 IN 1

DAY, ORAL

Date:07/07/04ISR Number: 4394264-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040406333

Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|------------------------|---|------|--------------|-------|
| Other | | Blood Pressure Increased Chest Pain Dilatation Atrial Dizziness | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/07/04ISR Number: 4395764-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040608216
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Social Avoidant Behaviour | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | PS | | |
| UNKNOWN | UNKNOWN | | | | | | |

Date:07/08/04ISR Number: 4392046-7Report Type:Expedited (15-DaCompany Report #PHBS2004JP08725
 Age:52 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|---------|------|-------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Aggression Gait Disturbance Parkinson'S Disease | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:07/08/04ISR Number: 4393027-XReport Type:Expedited (15-DaCompany Report #DK-GLAXOSMITHKLINE-B0337688A
 Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|--------------------------|-------|-----------------|-------|
| Dose | | | | | | | |
| Hospitalization - RESPIRATORY Initial or Prolonged (INHALATION) 2PUFF per day 5MG Three times per day 2 DAY | | Acute Psychosis Agitation Twice Anxiety Confusional State Drug Interaction Hyperhidrosis Hyperventilation Social Avoidant Behaviour Tremor | | Seretide Methylphenidate | PS SS | Glaxosmithkline | ORAL |

Date:07/08/04ISR Number: 4394099-9Report Type:Direct Company Report #CTU 222406
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----|---------------|-----------------------------------|------|--------------|-------|
| Disability Required 1 DAY | | Tic | | Methylphenidate 10 Mg Novartis | PS | Novartis | |
| Intervention to Prevent Permanent Impairment/Damage | | | | | | | |

Date:07/08/04ISR Number: 4394140-3Report Type:Direct Company Report #CTU 222435
 Age:41 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|-------------------------|------|--------------|-------|
| Other | | Insomnia Migraine | | Methylphenidate 10mg | PS | | |

Date:07/08/04ISR Number: 4395831-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040206433
 Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----------------------------------|---------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Near Drowning Suicide Attempt | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablet | PS | | ORAL |

18 MG, 1 IN 1

DAY, ORAL

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/09/04ISR Number: 4396478-2Report Type:Expedited (15-DaCompany Report #PT-JNJFOC-20040607708
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|-----------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Electrooculogram Abnormal Maculopathy Retinal Disorder Retinopathy | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, ORAL | | | | | | | |

Date:07/12/04ISR Number: 4394728-XReport Type:Expedited (15-DaCompany Report #PHBS2004JP08725
 Age:52 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------------|---------|------|-------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Aggression Drug Dependence | Health Professional | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| Other | | Gait Disturbance Parkinson'S Disease | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| 50 DF, QD Tremor | | | | | | | |

Date:07/14/04ISR Number: 4400039-6Report Type:Expedited (15-DaCompany Report #NO-JNJFOC-20040604900
 Age:16 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|----------|--------------------------------------|-----------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Chest Pain Cold Sweat Dyspnoea | Foreign Health Professional | Concerta (Methyphenidate Hydrochloride) | PS | | ORAL |
| Other | | Vomiting | | | | | |
| 18 MG, 1 IN 1 DAY, ORAL | | | | | | | |

Date:07/14/04ISR Number: 4400046-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040605857
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|---|------------------------|-----------------------------------|--|----|------|
| Hospitalization - Initial or Prolonged | Diplopia Strabismus | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | ORAL |
| 18 MG, IN 1 | | | | | |
| DAY, ORAL | | | | | |

Date:07/14/04ISR Number: 4400049-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040700659
Age:13 YR Gender:Male I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--|--|--|------|--------------|-------|
| | | Diabetes Mellitus Insulin-Dependent | Foreign Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:07/14/04ISR Number: 4400052-9Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20040604519
Age:12 YR Gender:Male I/FU:I

| | | |
|------------------|---|------------------------------------|
| Outcome Other | PT Drug Interaction Gynaecomastia | Report Source Foreign Health |
|------------------|---|------------------------------------|

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Professional

| Dose | Duration | Product | Role | Manufacturer | Route |
|--------------|----------|---|------|--------------|-------|
| 0.5 MG, ORAL | | Risperdal (Risperidone) | PS | | ORAL |
| 54 MG, ORAL | | Concerta (Methylphenidate Hydrochloride) Unspecified | SS | | ORAL |

Date:07/15/04ISR Number: 4398924-7Report Type:Expedited (15-DaCompany Report #PHBS2003JP13732
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------------------|---------------|----------|------|----------------------------|-------|
| Life-Threatening Hospitalization - TRANSPLACENTAL | | Apnoea Cyanosis | | Ritalin | PS | Novartis Sector: Pharma | |
| Initial or Prolonged TRANSPLACENTAL | | Drug Exposure During Pregnancy | | Paxil | SS | | |
| TRANSPLACENTAL | | Irritability | | Rohypnol | SS | | |
| TRANSPLACENTAL | | Tremor | | Solanax | SS | | |

Date:07/15/04ISR Number: 4398925-9Report Type:Expedited (15-DaCompany Report #PHNU2004DE02413
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------|----------|------|----------------------------|-------|
| Other | | Hypothyroidism | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:07/15/04ISR Number: 4398926-0Report Type:Expedited (15-DaCompany Report #PHNU2004DE02414
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Hypothyroidism | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:07/15/04ISR Number: 4398928-4Report Type:Expedited (15-DaCompany Report #PHNU2004DE02412
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Hypothyroidism | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:07/19/04ISR Number: 4403904-9Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040701677
 Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Injury Asphyxiation Suicide Attempt | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

ORAL

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/20/04ISR Number: 4402017-XReport Type:Expedited (15-DaCompany Report #PHFR2003GB01311
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|------------|------|----------------------------|-------|
| Disability | 20160MIN | Cyanosis Echocardiogram Abnormal | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 20mg/day | | Livedo Reticularis Pain In Extremity | | Ritalin-Sr | SS | Novartis Sector: Pharma | |
| 40mg/day | 10080MIN | Peripheral Coldness | | Lactulose | C | | ORAL |
| 10-20ml/BID/P | | Poor Peripheral Circulation Raynaud'S Phenomenon Skin Discolouration Tachycardia Ventricular Septal Defect Ventricular Septal Defect Acquired | | | | | |

Date:07/20/04ISR Number: 4402018-1Report Type:Expedited (15-DaCompany Report #PHBS2004JP08725
Age:52 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|---------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | | Aggression Drug Dependence | Health Professional | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| Other | | Gait Disturbance Parkinson'S Disease | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| 50 DF, QD | | Tremor | | | | | |

Date:07/20/04ISR Number: 4404445-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040405349
Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Aggression Alcohol Poisoning | Consumer | Concerta (Methylphenidate Hydrochloride) | | | |

| | | | | |
|-----------|--|---|----|------|
| SEE IMAGE | Apathy Depression | Sustained Release Tablets | PS | ORAL |
| SEE IMAGE | Impulse-Control Disorder Weight Increased | Lexapro (Escitalopram Oxalate) (All Other Therapeutic Products) | SS | ORAL |

Date:07/20/04ISR Number: 4404706-XReport Type:Expedited (15-DaCompany Report #CEL-2004-00320-ROC(1)
 Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------|------------------------|---|------|--------------|-------|
| Dose Other Required Intervention to Prevent Permanent SEE IMAGE Impairment/Damage | | Grand Mal Convulsion | Health Professional | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/20/04ISR Number: 4404757-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040608216
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Anxiety Fear Listless Merycism | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | | | ORAL |
| 18 MG, 1 IN 1 | | | | | PS | | |
| DAY, ORAL | | Psychiatric Symptom Social Avoidant Behaviour | | | | | |

Date:07/22/04ISR Number: 4408175-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040702344
Age:21 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haematuria | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) | | | |
| 54 MG | | | | | PS | | |

Date:07/22/04ISR Number: 4408205-0Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040704183
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------------------|-----------------------------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haematuria Vasculitis Necrotising | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Unspecified | | | |
| 54 MG | | | | | PS | | |

Date:07/23/04ISR Number: 4405149-5Report Type:Expedited (15-DaCompany Report #PHNU2004DE01468
Age:11 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Aplastic Anaemia | | Ritaline | PS | Novartis Sector: | |

| | | | | | |
|----------|----|-----|---------------------------|--------|------|
| 15mg/day | 71 | DAY | Biopsy Bone Marrow | Pharma | ORAL |
| | | | Abnormal | | |
| | | | Haematocrit Decreased | | |
| | | | Haemoglobin Decreased | | |
| | | | Mean Cell Haemoglobin | | |
| | | | Mean Cell Volume Abnormal | | |
| | | | Pancytopenia | | |
| | | | Platelet Count Decreased | | |
| | | | Red Blood Cell Count | | |
| | | | Decreased | | |
| | | | Reticulocyte Percentage | | |
| | | | Decreased | | |
| | | | White Blood Cell Count | | |
| | | | Decreased | | |

Date:07/23/04ISR Number: 4405225-7Report Type:Expedited (15-DaCompany Report #PHNU2004DE02414
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Thyroid Stimulating Hormone Increased | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | | Hypothyroidism | | | | | |
| | | Laboratory Test | | | | | |
| | | Interference | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/23/04ISR Number: 4405226-9Report Type:Expedited (15-DaCompany Report #PHNU2004DE02412
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Thyroid Stimulating Hormone Increased Hypothyroidism | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:07/23/04ISR Number: 4408574-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040702720
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|---------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cardiac Disorder Exercise Tolerance Decreased Heart Rate Increased | Foreign Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 18 MG, IN 1 DAY, ORAL | | | | | | | |

Date:07/23/04ISR Number: 4408591-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040704248
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | C-Reactive Protein Increased Leukopenia Lymphopenia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |

Date:07/26/04ISR Number: 4408372-9Report Type:Direct Company Report #CTU 223564
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Disability
18MG QAM

Unevaluable Event

Concerta

PS

Date:07/27/04ISR Number: 4411206-XReport Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040704267
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Headache Pyrexia | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | | | PS |
| 18 MG, IN 1 DAY | | | | | | | |

Date:07/28/04ISR Number: 4413987-8Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040201665
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|-----------------------------------|---|------|--------------|------------|
| Other | | Anorexia Gynaecomastia Insomnia Weight Decreased | Foreign Health Professional | Concerta Xl (Methylphenidate Hydrochloride) Sustained Release Tablets | | | PS ORAL |
| 54 MG, ORAL | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/28/04ISR Number: 4440673-0Report Type:Periodic Company Report #USA040259420
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| | | Anger | Consumer | Strattera | | | |
| | | Anorexia | | (Atomoxetine | | | |
| | | Fatigue | | Hydrochloride) | PS | | |
| 40 MG DAY | | | | | | | |
| | | Personality Change | | Concerta(Methylpheni | | | |
| | | Sleep Disorder | | date Hydrochloride) | SS | | |
| | | Somnolence | | Vitamins | C | | |

Date:07/29/04ISR Number: 4411155-7Report Type:Expedited (15-DaCompany Report #PHBS2004JP08871
 Age:7 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------|---------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine | | Ritalin | PS | Novartis Sector: | |
| | | Phosphokinase Increased | | | | Pharma | ORAL |
| 1 mg/d | | | | | | | |

Date:07/29/04ISR Number: 4414277-XReport Type:Expedited (15-DaCompany Report #CEL-2004-01474-SLO
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | Foreign | Equasym 5mg | | | |
| Required | | | Health | (Methylphenidate | | | |
| Intervention to | | | Professional | Hydrochloride) | PS | | ORAL |
| 5 MG TWICE | | | | | | | |
| Prevent Permanent | | | | | | | |
| DAILY, PER | | | | | | | |
| Impairment/Damage | | | | | | | |
| ORAL | | | | | | | |

Date:07/29/04ISR Number: 4414598-0Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20040402217
 Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | |
|---------------|------------------|----------------|-------------------|----|------|
| Other | Anorexia | Foreign | Concerta | | |
| | Weight Decreased | Health | (Methylphenidate | | |
| | Weight Increased | Professional | Hydrochloride) | | |
| | | Company | Sustained Release | | |
| | | Representative | Tablets | PS | ORAL |
| 54 MG, 1 IN 1 | | | | | |
| DAY, ORAL | | | | | |

Date:07/29/04ISR Number: 4414939-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040704979
 Age:9 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-----------------|----------------|-------------------|------|--------------|-------|
| Dose | | | | | | |
| Duration | | | | | | |
| Hospitalization - | Choreoathetosis | Health | Concerta | | | |
| Initial or Prolonged | Euphoric Mood | Professional | (Methylphenidate | | | |
| | Insomnia | Company | Hydrochloride) | | | |
| | | Representative | Sustained Release | | | |
| | | | Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | |
| DAY, ORAL | | | | | | |

Date:07/29/04ISR Number: 4443825-9Report Type:Periodic Company Report #US-JNJFOC-20040400832
 Age:15 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | |
| Duration | | | | | | |
| Hospitalization - | Convulsion | Consumer | Risperdal | | | |
| Initial or Prolonged | | | (Risperidone) | | | |
| | | | Tablets | PS | | ORAL |
| 2 MG, 2 IN 1 | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

DAY, ORAL

Concerta
(Methylphenidate
Hydrochloride)
Unspecified SS

Date:07/30/04ISR Number: 4411684-6Report Type:Expedited (15-DaCompany Report #PHBS2004JP10015
Age:70 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|---------------------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Delirium Dizziness | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/d | | Tremor Vomiting | | Morphine Hydrochloride | C | | |

Date:07/30/04ISR Number: 4418089-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040503465
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | C-Reactive Protein Increased Cholestasis Hepatitis Rash Scaly | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

36 MG, IN 1

DAY, ORAL

Date:08/02/04ISR Number: 4413817-4Report Type:Direct Company Report #CTU 224076
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Methylphenidate | PS | | |
| 5 MG | | | | | | | |

Date:08/03/04ISR Number: 4414271-9Report Type:Expedited (15-DaCompany Report #PHFR2004GB02985
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|--------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Asthma | | Ritaline | PS | Novartis Sector: Pharma | |
| UNKNOWN | 5 mg, BID | | | | | | |

Date:08/03/04ISR Number: 4416161-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040605147
Age:6 YR Gender: I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased Hallucination, Visual Screaming Treatment Noncompliance | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

SEE IMAGE

Date:08/03/04ISR Number: 4416170-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040705611
Age: Gender:Female I/FU:I

| Outcome | PT | Report Source |
|---------|-----------------------|-----------------------------------|
| Other | Anaphylactic Reaction | Health Professional Company |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Representative

| Dose | Duration | Product | Role | Manufacturer | Route |
|-----------|----------|--|------|--------------|-------|
| SEE IMAGE | | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| | | Other Unspecified Medications (All Other Therapeutic Product) | C | | |

Date:08/04/04ISR Number: 4421560-0Report Type:Expedited (15-DaCompany Report #CEL-2004-01480-ROC
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|------------------------|---|------|--------------|-------|
| Dose Other Required Intervention to 10MG Prevent Permanent INCREASED TO Impairment/Damage 20MG DAILY, ROUTE PO | | Headache Optic Atrophy Optic Nerve Injury | Health Professional | Metadate Cd (Methylphenidate Hydrochloride) | PS | | ORAL |
| | | | | Strattera | C | | |

Date:08/04/04ISR Number: 4422858-2Report Type:Expedited (15-DaCompany Report #S04-USA-04485-01
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|------------------------|---------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged 10 MG QD PO Other 15 MG QD PO | | Abnormal Behaviour Alcoholism Apathy Belligerence | Health Professional | Lexapro (Escitalopram) | PS | | ORAL |
| | | | | Lexapro (Escitalopram) | SS | | ORAL |

135 MG QD

Depression
Disinhibition
Legal Problem

Concerta
(Methylphenidate
Hydrochloride) SS

Personality Change
Physical Assault
School Refusal
Thinking Abnormal
Weight Increased

Alcohol (Alcohol) SS

Date:08/05/04ISR Number: 4418124-1Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 224292

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|-----------------------------|------|--------------|-------|
| Dose Other | | Disturbance In Attention Feeling Abnormal | | Generic Ritalin Sr 20 Mg | PS | | ORAL |
| TID PO | | Psychomotor Hyperactivity Stress | | | | | |

Date:08/06/04ISR Number: 4417181-6Report Type:Expedited (15-DaCompany Report #PHBS2004JP10015
Age:70 YR Gender:Female I/FU:F

Outcome PT
Other Delirium
Dizziness

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Drug Toxicity Tremor Vomiting | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------------------|---------------------|------------------------|------|-------------------------|-------|
| 10 mg/d | 21600MIN | | Health Professional | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/d | 4320 MIN | | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| | | | | Morphine Hydrochloride | C | | |
| | | | | Durotep Janssen | C | | |

Date:08/06/04ISR Number: 4424339-9Report Type:Direct Company Report #CTU 2244425E
Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-----------------------|---------------|-------------------------------|------|--------------|-------|
| Disability | | Visual Acuity Reduced | | Strattera 80 Mgs Eli Lilly | PS | Eli Lilly | ORAL |
| 80 MGS DAILY | | | | | | | |
| ORAL | | | | Concerta | SS | | |

Date:08/09/04ISR Number: 4420654-3Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0507436A
Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|---------|------|-----------------|-------|
| UNKNOWN | | Hallucination 2 YR | | Paxil | PS | Glaxosmithkline | |
| UNKNOWN | | Mood Swings | | Ritalin | SS | | |

Date:08/09/04ISR Number: 4421006-2Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0333314A
Age:66 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | | | |
|---|---|------------------------|-----------|----|-----------------|------|
| Life-Threatening 10MG Twice per day | Blood Pressure Decreased Coagulopathy | Health Professional | Paxil | PS | Glaxosmithkline | ORAL |
| 3U Three times per day | Cyanosis Depressed Level Of Consciousness | | Ritalin | SS | | ORAL |
| 30MG Per day | Disseminated | | Tetramide | SS | | ORAL |
| 25MG Three times per day | Intravascular Coagulation | | Amoxan | SS | | ORAL |
| 1MG Per day | Empyema | | Depas | SS | | ORAL |
| 2MG Per day | Glossoptosis | | Rohypnol | SS | | ORAL |
| 2MG Three times per day | Hyperpyrexia Infection Multi-Organ Failure Myoclonus Myoglobinuria Neuroleptic Malignant Syndrome Respiratory Failure Serotonin Syndrome Shock Somnolence | | Sepazon | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/09/04ISR Number: 4424814-7Report Type:Expedited (15-DaCompany Report #PT-JNJFOC-20040801064
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------|-----------------------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression Suicidal Ideation | Foreign Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |

Date:08/12/04ISR Number: 4424399-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040603102
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|------------|----------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Arthritis | | Risperdal | PS | | |
| OROPHARINGEAL | 0.125mg in | Serum Sickness | | | | | |
| am/0.25mg at | | | | | | | |
| HS | 3 MON | | | Risperdal | SS | | |
| OROPHARINGEAL | | | 3 MON | | | | |
| | | | | Concerta | SS | | |
| | | | | Clonidine | C | | |
| | | | | Clonidine | C | | |
| | | | | Zyrtec | C | | |
| OROPHARINGEAL | | | 27 DAY | | | | |
| | | | | Pepcid | C | | |
| | | | | Nasonex | C | | |
| RESPIRATORY | | | | | | | |
| (INHALATION) | 50mcg | | 27 DAY | | | | |
| RESPIRATORY | | | | Flovent | C | | |
| (INHALATION) | 2 puffs as | | | | | | |
| needed | 27 DAY | | | | | | |

Date:08/13/04ISR Number: 4427903-6Report Type:Expedited (15-DaCompany Report #CEL-2004-01190-ROC
Age:24 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|-------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Suicidal Ideation | Consumer | Metadate Cd Capsules | | | |
| Required | | | Health | 10 Mg | | | |
| Intervention to | | | Professional | (Methylphenidate | | | |
| Prevent Permanent | | | | Hydrochloride) | PS | | ORAL |
| 10 MG, TWICE | | | | | | | |
| Impairment/Damage | | | | | | | |
| DAILY, ROUTE | | | | | | | |

PO

Depo Provera
(Medroxyprogesterone
Acetate) C
Effexor (Venlafaxine
Hydrochloride) C

Date:08/13/04ISR Number: 4428093-6Report Type:Expedited (15-DaCompany Report #2004052733
Age:47 YR Gender:Female I/FU:I

| Outcome | PT |
|----------------------|------------------------|
| Hospitalization - | Abnormal Behaviour |
| Initial or Prolonged | Agitation |
| Other | Anger |
| | Feeling Abnormal |
| | Homicidal Ideation |
| | Insomnia |
| | Marital Problem |
| | Paranoia |
| | Relationship Breakdown |
| | Thinking Abnormal |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | |
|------|----------|--|---------------|-----------------------------------|------|--------------|
| | | Treatment Noncompliance Victim Of Spousal Abuse | | | | |
| Dose | Duration | | Report Source | Product | Role | Manufacturer |
| | | | Consumer | Neurontin (Gabapentin) | PS | |
| ORAL | | | | Methylphenidate Hydrochloride | SS | |
| | | | | All Other Therapeutic Products | SS | |
| | | | | | | Route |
| | | | | | | ORAL |

Date:08/16/04ISR Number: 4426843-6Report Type:Expedited (15-DaCompany Report #PHBS2004CA10581
Age: Gender:Male I/FU:I

| | | | | | | | |
|---------|----------|--|---------------|---------|------|----------------------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Blood Thyroid Stimulating Hormone Increased Tri-Iodothyronine Increased | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:08/19/04ISR Number: 4430593-XReport Type:Direct Company Report #CTU 225264
Age: Gender:Female I/FU:I

| | | | | | | | |
|--------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| 20 MG - ONCE | | Pharmaceutical Product | | Methylphenidate | PS | | |
| 1/2 AT 4PM | | Complaint | | | | | |

Date:08/23/04ISR Number: 4431211-7Report Type:Direct Company Report #CTU 225422
Age:33 YR Gender:Male I/FU:I

| | | | | | | | |
|---------|----------|-----------|---------------|-----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Agitation | | Zoloft 50 | PS | | |
| DAILY | | Attention | | Concerta | 36 | SS | |
| DAILY | | | | | | | |

Deficit/Hyperactivity
Disorder
Emotional Disorder
Euphoric Mood
Feeling Abnormal
Impulse-Control Disorder
Insomnia
Libido Increased
Mood Swings
Palpitations
Paraphilia
Parent-Child Problem
Relationship Breakdown
Somnolence
Suicidal Ideation

Date:08/24/04ISR Number: 4431099-4Report Type:Expedited (15-DaCompany Report #PHBS2004JP10015

Age:75 YR Gender:Female I/FU:F

Outcome PT
Other Delirium
Depressed Level Of
Consciousness
Dizziness
Malaise

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---|---------------------|-----------------------------------|-------------|-------------------------|-------|
| | | Oxygen Saturation Decreased Somnolence | | | | | |
| 10 mg/d | | Speech Disorder Tremor | Health Professional | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/d | 5760 MIN | Vomiting | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| 25 mg/d | | | | Morphine Hydrochloride Durotep | C C | | |
| 80 mg/d | | | | Diovan | C | | ORAL |
| 150 mg/d | | | | Protecadin Loxonin Ganaton | C C C | | ORAL |
| 15 mg/d | | | | Rize | C | | ORAL |
| 15 mg/d | | | | Novamin | C | | ORAL |

Date:08/24/04ISR Number: 4431336-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040702721
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|--|---------------|-----------|------|--------------|-------|
| Hospitalization - OROPHARINGEAL | | Haematocrit Decreased | | Concerta | PS | | |
| Initial or Prolonged OROPHARINGEAL | | Haemoglobin Decreased | | Medikinet | C | | |
| Other | | Infectious Mononucleosis Lymphocyte Percentage Decreased Mean Cell Haemoglobin Concentration Decreased Monocyte Percentage Decreased Neutrophil Percentage Decreased White Blood Cell Count Decreased | | | | | |

Date:08/25/04ISR Number: 4431725-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20040504699

Age: Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|--|---------------|----------------|------|--------------|-------|
| Dose Duration | | | | | | |
| Hospitalization - OROPHARINGEAL | Drug Interaction | | Concerta | PS | | |
| Initial or Prolonged | Malignant Hypertension Pulmonary Oedema Tooth Extraction | | Neo-Synephrine | SS | | NASAL |

Date:08/25/04ISR Number: 4432286-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040702344

Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|---|---------------|----------|------|--------------|-------|
| Dose Duration | | | | | | |
| Other OROPHARINGEAL | Haematuria Haemorrhage Urinary Tract | | Concerta | PS | | |

Date:08/25/04ISR Number: 4432393-3Report Type:Expedited (15-DaCompany Report #JP-GLAXOSMITHKLINE-B0333314A

Age:66 YR Gender:Female I/FU:F

| Outcome | PT |
|------------------|--|
| Life-Threatening | Blood Pressure Decreased Coagulopathy |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|-----------|------|-----------------|-------|
| 10MG Twice | | Cyanosis Depressed Level Of Consciousness | Paxil | PS | Glaxosmithkline | ORAL |
| per day | | Disseminated | | | | |
| 3U Three | | Intravascular Coagulation | Ritalin | SS | | ORAL |
| times per day | | Empyema | | | | |
| 30MG Per day | | Glossoptosis | Tetramide | SS | | ORAL |
| 25MG Three | | Hyperpyrexia | Amoxan | SS | | ORAL |
| times per day | | Infection | | | | |
| 1MG Per day | | Multi-Organ Failure | Depas | SS | | ORAL |
| 2MG Per day | | Myoclonus | Rohypnol | SS | | ORAL |
| 2MG Three | | Myoglobinuria | Sepazon | SS | | ORAL |
| times per day | | Neuroleptic Malignant Syndrome | | | | |
| | | Respiratory Failure Serotonin Syndrome Shock Somnolence | | | | |

Date:08/25/04ISR Number: 4432533-6Report Type:Expedited (15-DaCompany Report #PHNU2004DE02413

Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|---------------|----------|------|----------------------------|-------|
| Other | | Blood Thyroid Stimulating Hormone Increased | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 15 mg/day | | Hypothyroidism | | | | | |

Date:08/25/04ISR Number: 4432679-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040702344

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haematuria | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:08/26/04ISR Number: 4433285-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040702720
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Heart Rate Increased | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:08/26/04ISR Number: 4454690-8Report Type:Periodic Company Report #WAES 0406USA02224
Age:69 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| 10 | | Disturbance In Attention | Consumer | Tab Zetia 10 Mg | PS | | ORAL |
| MG/DAILY/PO | | Drug Interaction | Health | | | | |
| 40 | | Psychomotor Hyperactivity | Professional | Tab Ritalin 40 Mg | SS | | ORAL |
| MG/DAILY/PO | | | | Celebrex | C | | |
| | | | | Zoloft | C | | |

Date:08/27/04ISR Number: 4436699-3Report Type:Direct Company Report #CTU 225815
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------------------|---------------|---------|------|--------------|-------|
| Other | | Pharmaceutical Product Complaint | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Somnolence

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---------------|-------------------------------|------|--------------|-------|
| 5 MG DLY | | | Ritalin Generic (Methylin) | PS | | |

Date:08/31/04ISR Number: 4437824-0Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040806637
Age:15 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Phobia | | Concerta | PS | | |
| OROPHARINGEAL | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:08/31/04ISR Number: 4438436-5Report Type:Expedited (15-DaCompany Report #PHBS2004NO11152
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------|------------------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia Muscle Fatigue | Health Professional | Ritalina | PS | Novartis Sector: Pharma | |
| UNKNOWN | | Weight Decreased | | | | | |

Date:08/31/04ISR Number: 4438437-7Report Type:Expedited (15-DaCompany Report #PHNU2004DE03040
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine Phosphokinase Abnormal | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 5 to 10mg/day | | | | | | | |

Date:08/31/04ISR Number: 4439194-0Report Type:Expedited (15-DaCompany Report #CEL-2004-01604-ROC
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blindness | Health | Metadate Cd Capsules | | | |
| Required | | Maculopathy | Professional | (Methylphenidate | | | |
| Intervention to | | Retinal Disorder | | Hydrochloride) | PS | | |
| Prevent Permanent | | | | | | | |
| Impairment/Damage | | | | | | | |

Date:09/02/04ISR Number: 4440298-7Report Type:Expedited (15-DaCompany Report #C04-T-137

Age:23 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dizziness | Consumer | Methylphenidate Hcl | | | |
| | | | | Tablets, Usp 10 Mg | PS | | |

Date:09/02/04ISR Number: 4441083-2Report Type:Direct Company Report #CTU 226183

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|----------------|---------------|--------------|------|--------------|-------|
| Dose | | | | | | | |
| Required | | Abdominal Pain | | Ritalin 5 Mg | PS | | ORAL |
| 5 MG BID ORAL | | | | | | | |
| Intervention to | | Cholelithiasis | | | | | |
| Prevent Permanent | | | | | | | |
| Impairment/Damage | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/02/04ISR Number: 4441084-4Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 226184

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|---------------|-------------------|---------------|----------|------|--------------|-------|
| Dose Required | 5-20 MG DAILY | Abdominal Pain | | Ritalin | PS | | ORAL |
| Intervention to | ORAL | Cholelithiasis | | | | | |
| Prevent Permanent | 36MG DAILY | Impairment/Damage | | Concerta | SS | | ORAL |
| ORAL | | | | | | | |

Date:09/03/04ISR Number: 4601412-3Report Type:Periodic
 Age:13 YR Gender:Male I/FU:I

Company Report #PHEH2004US03872

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------|--|------|--------------|-------|
| Dose | | Convulsion | Consumer | Ritalin(Methylphenidate Hydrochloride) | PS | | |
| Other | | | | | | | |

Date:09/07/04ISR Number: 4441616-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040704248
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------------------|--------------------|---------------|----------|------|--------------|-------|
| Dose | Hospitalization - | C-Reactive Protein | Health | Concerta | PS | | |
| OROPHARINGEAL | Initial or Prolonged | Increased | Professional | Concerta | SS | | |
| OROPHARINGEAL | Other | Granulocytopenia | | Concerta | SS | | |
| OROPHARINGEAL | | Lymphopenia | | | | | |

Date:09/07/04ISR Number: 4441712-3Report Type:Expedited (15-DaCompany Report #PHNU2004DE03099
 Age:25 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|----------|------|------------------|-------|
| Dose | | Hyperthyroidism | | Ritaline | PS | Novartis Sector: | |
| Other | | | | | | | |

| | | | | | | |
|-----------|----------------|--|--|------------|--------|----------------------------|
| Unknown | Sleep Disorder | | | | Pharma | ORAL |
| | | | | Ritaline | SS | Novartis Sector: Pharma |
| Unknown | | | | Ritalin-Sr | SS | ORAL |
| 1 tab/day | | | | | | |

Date:09/07/04ISR Number: 4441750-0Report Type:Expedited (15-DaCompany Report #PHNU2004DE03086
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-----------------|---------------|----------|------|----------------------------|-------|
| Other | | Hyperthyroidism | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 50 to 60 | | | | | | | |
| mg/day | | | | | | | |

Date:09/07/04ISR Number: 4442906-3Report Type:Direct Company Report #CTU 226386
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------|-------------------------------------|------|--------------|-------|
| Dose | | Drug Ineffective Pharmaceutical Product | | Ritalin Brand Name Med Necessary | PS | | ORAL |
| 20 MG 3 QID | | | | | | | |
| (PO) | | Complaint | | Xanax Brand Name Med Necessary | SS | | |
| 2 MG 3 BID | | | | | | | |
| HIGH DOSE | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/08/04ISR Number: 4443812-0Report Type:Expedited (15-DaCompany Report #PHBS2004IL11384
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------|-----------------------|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Hallucinations, Mixed | | Methylphenidate | PS | Novartis Sector: Pharma | |
| UNKNOWN | .3 mg/kg, QD | | | | | | |

Date:09/08/04ISR Number: 4443828-4Report Type:Expedited (15-DaCompany Report #PHBS2004IL11386
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------|---------------|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination | | Methylphenidate | PS | Novartis Sector: Pharma | |
| UNKNOWN | .3 mg/kg, QD | | | | | | |

Date:09/08/04ISR Number: 4443829-6Report Type:Expedited (15-DaCompany Report #PHBS2004IL11387
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|---------------|---------------------------------|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Hallucinations, Mixed Stress | | Methylphenidate | PS | Novartis Sector: Pharma | |
| UNKNOWN | .25 mg/kg, QD | | | | | | |

Date:09/08/04ISR Number: 4443847-8Report Type:Expedited (15-DaCompany Report #PHNU2004DE02817
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Abdominal Pain Upper Blood Creatine Phosphokinase Increased Blood Creatine Phosphokinase Mb Diarrhoea Nausea | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:09/08/04ISR Number: 4443849-1Report Type:Expedited (15-DaCompany Report #PHRM2004FR02704
Age:40 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------|---------------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Bradycardia | Health Professional | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 30 mg daily | | | | Zoloft | SS | | |
| | | | | Lithium | SS | | |

Date:09/10/04ISR Number: 4445603-3Report Type:Expedited (15-DaCompany Report #PHNU2004DE03154
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Vasculitic Rash | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Unknown | | | | | | | |

Date:09/10/04ISR Number: 4445729-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040502040
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | Health Professional | Concerta | PS | | |
| OROPHARINGEAL | | Condition Aggravated Weight Decreased | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/10/04ISR Number: 4445832-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040809695
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|---------------------------|----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | |
| Other | | | Cerebellar Infarction | | | | |
| OROPHARINGEAL | | | | Ritalin | SS | | |
| OROPHARINGEAL | | | Cerebral Artery Occlusion | | | | |

Date:09/10/04ISR Number: 4448389-1Report Type:Direct Company Report #CTU 226847
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|----|---|-------------------------------------|------|--------------|-------|
| Dose | | | | Ritalin Brand Name Med Necessary | PS | | ORAL |
| 20 MG 1 QID (PO) | | | Drug Ineffective Pharmaceutical Product Complaint | | | | |
| 2 MG 1 BID 3 QHS DOSE | | | | Xanax Brand Name Med Necessary | SS | | |

Date:09/13/04ISR Number: 4449142-5Report Type:Expedited (15-DaCompany Report #LBID00204003065
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----|---|--|----------|--------------|-------|
| Hospitalization - Initial or Prolonged | | | Literature Health Professional | Lithium Carbonate(Lithium Carbonate) | PS | | ORAL |
| PO, 300 MG QID PO | | | Abdominal Pain Atrioventricular Block First Degree Blood Thyroid Stimulating Hormone Decreased Chest Pain Conduction Disorder Diarrhoea Disorientation Dizziness | Methylphenidate (Methylphenidate Hydrochloride) Escitalopram (Escitalopram) Clonidine | SS SS | | |

Drug Level Above
Therapeutic
Electrocardiogram Qrs
Complex Prolonged
Fluid Intake Reduced
Hyperhidrosis
Hypotension
Mania
Oral Intake Reduced
Pallor
Palpitations
Tachyarrhythmia
Therapeutic Agent
Toxicity
Ventricular Extrasystoles
Ventricular Tachycardia
Vomiting
White Blood Cell Count
Increased

(Clonidine)

SS

Date:09/13/04ISR Number: 4449749-5Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 226852

Outcome PT
Aggression
Impulsive Behaviour
Pharmaceutical Product

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Complaint

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------|----------------------|------|--------------|-------|
| 20 MG SR | | | Ritalin - Brand Name | PS | | |
| TWICE TAB | | | | | | |
| DAILY | | | | | | |

Date:09/13/04ISR Number: 4449751-3Report Type:Direct Company Report #CTU 226853
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------------------|---------------|---------|------|--------------|-------|
| Dose | | No Adverse Drug Effect | | Ritalin | PS | | |
| 20 MG SR 2 | | | | | | | |
| TABS DAILY | | | | | | | |

Date:09/15/04ISR Number: 4449858-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040901057
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | Leukopenia | Health | Concerta | PS | | |
| Other | | Monocytosis | Professional | | | | |
| OROPHARINGEAL | | Neutropenia | | | | | |

Date:09/15/04ISR Number: 4449950-0Report Type:Expedited (15-DaCompany Report #PHNU2004DE02303
 Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|----------|------|------------------|-------|
| Dose | | Death | Health | Ritaline | PS | Novartis Sector: | |
| Death | | Overdose | Professional | | | Pharma | ORAL |
| Unknown | | Poisoning Deliberate | | Asa | C | | ORAL |
| Unknown | | | | | | | |

| | | | | | |
|---------|--|--|------------------|---|------|
| Unknown | | | Furosemide | C | ORAL |
| Unknown | | | Haldol "Janssen" | C | ORAL |
| Unknown | | | Digitoxin | C | ORAL |

Date:09/15/04ISR Number: 4449994-9Report Type:Expedited (15-DaCompany Report #PHBS2004JP11753
Age:25 YR Gender:Male I/FU:F

| Outcome Dose Other | Duration | PT Drug Abuser Theft | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|-------------|----------------------------|---------------|------------|------|----------------------------|-------|
| 40 mg/d | | | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 3 - 4 DF/d | | | | Ritaline | SS | Novartis Sector: Pharma | ORAL |
| INTRAVENOUS | 1 DF, QD to | | | Ritaline | SS | Novartis Sector: Pharma | |
| TID | | | | Ritaline | SS | Novartis Sector: Pharma | |
| INTRAVENOUS | 45 mg/day | | | Mianserin | C | | |
| UNKNOWN | 20 mg/d | | | Sulpiride | C | | |
| UNKNOWN | 300 mg/d | | | Fluoxetine | C | | ORAL |
| 3 DF/day | | | | Sulpiride | C | | |
| INTRAVENOUS | 60 mg/d | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/15/04ISR Number: 4450006-1Report Type:Expedited (15-DaCompany Report #PHBS2004JP10015
 Age:75 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-------------------------------------|---------------|---------------|------|----------------------------|-------|
| Death | | Death | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| Other | | Delirium | | | | | |
| 10 mg/d | | | | | | | |
| | | Depressed Level Of Consciousness | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| 20 mg/d | 5760 MIN | | | | | | |
| | | Dizziness | | Morphine | | | |
| | | Malaise | | Hydrochloride | C | | |
| | | Oxygen Saturation | | Durotep | C | | |
| 25 mg/d | | | | | | | |
| | | Decreased | | Diovan | C | | ORAL |
| 80 mg/d | | | | | | | |
| | | Somnolence | | Protecadin | C | | |
| | | Speech Disorder | | Loxonin | C | | |
| | | Tremor | | Ganaton | C | | ORAL |
| 150 mg/d | | | | | | | |
| | | Vomiting | | Rize | C | | ORAL |
| 15 mg/d | | | | | | | |
| | | | | Novamin | C | | ORAL |
| 15 mg/d | | | | | | | |

Date:09/15/04ISR Number: 4450027-9Report Type:Expedited (15-DaCompany Report #PHBS2004JP11891
 Age:33 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|------------------------|-----------|------|----------------------------|-------|
| Other | | Priapism | Health Professional | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | | | | Tegretol | SS | | ORAL |
| | | | | Akineton | SS | | ORAL |
| | | | | Erimin | SS | | ORAL |
| | | | | Wintermin | SS | | ORAL |
| | | | | Risperdal | SS | | ORAL |
| | | | | Depas | SS | | ORAL |
| | | | | Myslee | SS | | ORAL |

Date:09/15/04ISR Number: 4450029-2Report Type:Expedited (15-DaCompany Report #PHFR2004GB03398
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------------|---------------|-------------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Benign Intracranial Hypertension | | Ritaline | PS | Novartis Sector: Pharma | |
| UNKNOWN | 40mg/day | | | Antibiotics | C | | |
| UNKNOWN | | | | | | | |

Date:09/15/04ISR Number: 4450040-1Report Type:Expedited (15-DaCompany Report #PHNU2004DE03197
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------------|-----------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Strabismus | Health Professional | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Unknown | | | | Medikinet | SS | | ORAL |
| Unknown | | | | | | | |

Date:09/15/04ISR Number: 4451998-7Report Type:Direct Company Report #CTU 227206
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - PO [PRIOR TO Initial or Prolonged ADMISSION] | | Headache Vomiting | | Ritalin | PS | | ORAL |
| | | | | Albuterol | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/16/04ISR Number: 4451377-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040901570
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Vasoconstriction | | Concerta Xl | PS | | |
| OROPHARINGEAL | | | | Melatonin | C | | |
| UNKNOWN | | | | | | | |

Date:09/16/04ISR Number: 4451378-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040504699
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Acute Pulmonary Oedema | Health | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| Initial or Prolonged | | Anaesthetic Complication | Professional | Neo-Synephrine | SS | | NASAL |
| | | Cardiac | | Propofol | SS | | |
| | | Anaesthetic Complication | | Fentanyl | C | | |
| | | Pulmonary | | Midazolam | C | | |
| | | Drug Interaction | | Rocuronium | C | | |
| | | Malignant Hypertension | | | | | |
| | | Tachycardia | | | | | |

Date:09/16/04ISR Number: 4451379-6Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040704183
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haematuria | Health | Concerta Xl | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Vasculitis Necrotising | Professional | | | | |

Date:09/16/04ISR Number: 4452897-7Report Type:Expedited (15-DaCompany Report #2004029622
Age:52 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anticonvulsant Drug Level | Consumer | Dilantin Kapseals | | | |

| | | | | |
|---------------|----------------------------------|--|----|------|
| 300 MG (1 D), | Decreased | (Phenytoin Sodium) | PS | ORAL |
| ORAL | Anticonvulsant Drug Level | | | |
| 500 MG (1 D) | Increased Convulsion | Phenytoin (Phenytoin) | SS | |
| | Drug Effect Decreased | Methylphenidate Hydrochloride | | |
| | Epilepsy | (Methylphenidate Hydrochloride) | SS | |
| | Fatigue | Gabapentin (Gabapentin) | C | |
| | Ill-Defined Disorder | Clonazepam (Clonazepam) | C | |
| | Memory Impairment | Buspirone Hydrochloride | | |
| | Nervousness | (Buspirone Hydrochloride) | C | |
| | Pharmaceutical Product Complaint | Tamsulosin Hydrochloride | | |
| | Treatment Noncompliance | (Tamsulosin Hydrochloride) | C | |
| | | Enalapril Maleate (Enalapril Maleate) | C | |
| | | Yohimbine (Yohimbine) | C | |
| | | Axotal (Old Form) (Butalbital, Caffeine, | | |

Freedom Of Information (FOI) Report

Paracetamol) C
 Donepezil
 Hydrochloride
 (Donepezil
 Hydrochloride) C
 Lomotil (Atropine
 Sulfate,
 Diphenoxylate
 Hydrochloride) C

Date:09/16/04ISR Number: 4452910-7Report Type:Expedited (15-DaCompany Report #2004-DE-04634GD
 Age:10 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--|---------------|---|----------|--------------|-------|
| Dose Duration Hospitalization - Initial or Prolonged 1200 MG Required (TWICE Intervention to DAILY), Prevent Permanent Impairment/Damage 0.4 MG (TWICE DAILY) | Abdominal Pain Atrioventricular Block First Degree Chest Pain | Literature | Lithium Carbonate (Lithium Carbonate) | PS | | |
| 36 MG (ONCE DAILY), IN THE MORNING 10 MG (ONCE DAILY), 600 MG (ONCE DAILY) | Conduction Disorder Diarrhoea Disorientation Dizziness Drug Interaction Drug Level Increased Electrocardiogram Qrs Complex Prolonged Hyperhidrosis Hypotension Hypothyroidism Oral Intake Reduced Pallor Palpitations | | Clonidine (Clonidine) Methylphenidate (Methylphenidate) Escitalopram (Escitalopram) Oxcarbazine (Antiepileptics) Depakote (Valproate) | SS SS | | |

| | | | |
|---------------|---------------------------|-----------------|----|
| 1500 MG (ONE | Tachyarrhythmia | Semisodium) | SS |
| THIRD OF | Tachycardia | | |
| DAILY DOSE IN | Therapeutic Agent | | |
| THE MORNING | Toxicity | | |
| AND TWO | Ventricular Extrasystoles | | |
| | Ventricular Tachycardia | Levothyroxine | |
| | Vomiting | (Levothyroxine) | SS |
| | White Blood Cell Count | | |
| | Increased | | |

Date:09/17/04ISR Number: 4451971-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903736
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|----------|------|--------------|-------|
| Other | | Apraxia | | Concerta | PS | | |
| OROPHARINGEAL | | Asthenia | | Concerta | SS | | |
| OROPHARINGEAL | | Brain Neoplasm | | | | | |
| | | Cerebral Cyst | | | | | |
| | | Hypoaesthesia | | | | | |

Date:09/17/04ISR Number: 4452383-4Report Type:Expedited (15-DaCompany Report #PHBS2004JP10015
Age:75 YR Gender:Female I/FU:F

| | |
|---------|--------------------|
| Outcome | PT |
| Death | Death |
| Other | Delirium |
| | Depressed Level Of |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---|---------------|--------------------------------------|-------------|----------------------------|-------|
| 10 mg/d | | Consciousness Dizziness Malaise Oxygen Saturation Decreased Somnolence | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/d | 5760 MIN | Speech Disorder Tremor Vomiting | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| 25 mg/d | | | | Morphine Hydrochloride Durotep | C C | | |
| 80 mg/d | | | | Diovan | C | | ORAL |
| 150 mg/d | | | | Protecadin Loxonin Ganaton | C C C | | ORAL |
| 15 mg/d | | | | Rize | C | | ORAL |
| 15 mg/d | | | | Novamin | C | | ORAL |

Date:09/17/04ISR Number: 4452384-6Report Type:Expedited (15-DaCompany Report #PHFR2004GB03398
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------------------|---------------|-------------|------|----------------------------|-------|
| Dose Other | | Benign Intracranial Hypertension | | Ritaline | PS | Novartis Sector: Pharma | |
| UNKNOWN | 40mg/day | | | Antibiotics | C | | |
| UNKNOWN | | | | | | | |

Date:09/17/04ISR Number: 4452385-8Report Type:Expedited (15-DaCompany Report #PHBS2004JP11753
Age:25 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|------------------|-------|
| Dose Other | | Drug Abuser | | Ritaline | PS | Novartis Sector: | |

| | | | | | | |
|-------------|------------------|--|------------|----|----------------------------|------|
| 40 mg/d | Medication Error | | | | Pharma | ORAL |
| | Theft | | Ritaline | SS | Novartis Sector: Pharma | ORAL |
| 3 - 4 DF/d | | | Ritaline | SS | Novartis Sector: Pharma | |
| INTRAVENOUS | 1 DF, QD to | | | | | |
| TID | | | Ritaline | SS | Novartis Sector: Pharma | |
| INTRAVENOUS | 45 mg/day | | | | | |
| UNKNOWN | 20 mg/d | | Mianserin | C | | |
| UNKNOWN | 300 mg/d | | Sulpiride | C | | |
| 3 DF/day | | | Fluoxetine | C | | ORAL |
| INTRAVENOUS | 60 mg/d | | Sulpiride | C | | |

Date:09/17/04ISR Number: 4452387-1Report Type:Expedited (15-DaCompany Report #PHBS2004JP11891
Age:33 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|---------------|-----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Priapism | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | | | | Tegretol | SS | | ORAL |
| | | | | Akineton | SS | | ORAL |
| | | | | Erimin | SS | | ORAL |
| | | | | Wintermin | SS | | ORAL |
| | | | | Risperdal | SS | | ORAL |
| | | | | Depas | SS | | ORAL |
| | | | | Myslee | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/17/04ISR Number: 4452388-3Report Type:Expedited (15-DaCompany Report #PHNU2004DE03197
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------|-----------|------|----------------------------|-------|
| Dose | | | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Other | | Strabismus | | | | | |
| Unknown | | | | Medikinet | SS | | ORAL |
| Unknown | | | | | | | |

Date:09/17/04ISR Number: 4452411-6Report Type:Expedited (15-DaCompany Report #PHNU2004DE02303
Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|------------------|------|----------------------------|-------|
| Dose | | | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Death | | Death Overdose | | | | | |
| Unknown | | Poisoning Deliberate | | Asa | C | | ORAL |
| Unknown | | | | Furosemide | C | | ORAL |
| Unknown | | | | Haldol "Janssen" | C | | ORAL |
| Unknown | | | | Digitoxin | C | | ORAL |
| Unknown | | | | | | | |

Date:09/17/04ISR Number: 4454414-4Report Type:Direct Company Report #CTU 227479
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|------------------|---------------|-------------------------------------|------|--------------|-------|
| Dose | | | | Ritalin Brand Name Med Necessary | PS | | ORAL |
| 20 MG 1 QID (PO) | | Drug Ineffective | | | | | |
| 2 MG 1 BID 3 QID PO | | | | Xanax Brand Name Med Necessary | SS | | ORAL |

Date:09/17/04ISR Number: 4454445-4Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 227450

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--------------------------|---------------|---------------------|------|--------------|-------|
| Dose Required | | Blood Pressure Increased | | Methylphenidate Sr | | | |
| Intervention to | | Condition Aggravated | | 20 Mg Geneva | PS | Geneva | ORAL |
| 20MG QID ORAL | | | | | | | |
| Prevent Permanent | | | | Hydrochlorothiazide | C | | |
| Impairment/Damage | | | | Etodolac | C | | |
| | | | | Wellbutrin | C | | |
| | | | | Lisinopril | C | | |
| | | | | Aciphex | C | | |

Date:09/17/04ISR Number: 4455545-5Report Type:Expedited (15-DaCompany Report #CEL-2004-01480-ROC
Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--------------------|---------------|----------------------|------|--------------|-------|
| Dose Required | | Headache | Health | Metadate Cd Capsules | | | |
| Intervention to | | Mydriasis | Professional | (Strength | | | |
| Prevent Permanent | | Optic Atrophy | | Unspecified) | | | |
| Impairment/Damage | | Visual Disturbance | | (Methylphenidate | | | |
| 10MG, | | | | Hydrochloride) | PS | | ORAL |
| INCREASED TO | | | | | | | |
| 20 MG THEN | | | | | | | |
| DECREASED TO | | | | | | | |
| 10MG, QAM, | | | | Strattera | C | | |
| | | | | Ddavp (Desmopressin) | C | | |
| | | | | Luvox (Fluvoxamine) | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Maleate) C

Date:09/20/04ISR Number: 4453340-4Report Type:Expedited (15-DaCompany Report #PHFR2004GB02985
Age:6 YR Gender:Male I/FU:F

| | | | | | | |
|---------|----------------------|---------------|----------|------|------------------|-------|
| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | |
| Other | Asthma | Health | Ritaline | PS | Novartis Sector: | |
| | Condition Aggravated | Professional | | | Pharma | |
| UNKNOWN | 5 mg, BID | | | | | |

Date:09/20/04ISR Number: 4453343-XReport Type:Expedited (15-DaCompany Report #PHBS2004BR12227
Age:10 YR Gender:Male I/FU:I

| | | | | | | |
|----------|-----------------|---------------|----------|------|------------------|-------|
| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | |
| Other | Hyperthyroidism | Consumer | Ritalina | PS | Novartis Sector: | |
| | | | | | Pharma | ORAL |
| 1 DF, QD | | | | | | |

Date:09/20/04ISR Number: 4453417-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040901570
Age:9 YR Gender:Male I/FU:I

| | | | | | | |
|---------------|------------------|---------------|-------------|------|--------------|-------|
| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | |
| Other | Vasoconstriction | Health | Concerta Xl | PS | | |
| OROPHARINGEAL | | Professional | Melatonin | C | | |
| UNKNOWN | | | | | | |

Date:09/20/04ISR Number: 4453418-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040504699
Age: Gender:Female I/FU:I

| | | | | | | |
|----------------------|------------------------|---------------|----------------|------|--------------|-------|
| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | |
| Hospitalization - | Acute Pulmonary Oedema | Health | Concerta | PS | | |
| OROPHARINGEAL | | | | | | |
| Initial or Prolonged | Drug Interaction | Professional | Neo-Synephrine | SS | | NASAL |
| | Malignant Hypertension | | Propofol | SS | | |
| | Tachycardia | | Fentanyl | C | | |

Tooth Extraction

Midazolam
Rocuronium

C
C

Date:09/20/04ISR Number: 4453419-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040704183

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|-------------|------|--------------|-------|
| Other | | Haematuria | Health | Concerta Xl | PS | | |
| OROPHARINGEAL | | | Professional | | | | |

Date:09/20/04ISR Number: 4453449-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040704248

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------------------|---------------|----------|------|--------------|-------|
| Hospitalization - | | C-Reactive Protein | Health | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| Initial or Prolonged | | Increased | Professional | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| Other | | Granulocytopenia | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Lymphopenia | | | | | |
| | | White Blood Cell Count | | | | | |
| | | Decreased | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/20/04ISR Number: 4453502-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040901057
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Monocytosis | Health | Concerta | PS | | |
| OROPHARINGEAL | | Neutropenia | Professional | | | | |
| | | White Blood Cell Count Decreased | | | | | |

Date:09/20/04ISR Number: 4453565-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903736
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | Consumer | Concerta | PS | | |
| OROPHARINGEAL | | Asthenia | | Concerta | SS | | |
| OROPHARINGEAL | | Brain Neoplasm Benign Cerebral Cyst Psychomotor Hyperactivity Sensory Loss | | | | | |

Date:09/20/04ISR Number: 4453577-4Report Type:Expedited (15-DaCompany Report #PHFR2004GB02985
 Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|--------|------------------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Asthma | Health Professional | Ritaline | PS | Novartis Sector: Pharma | |
| UNKNOWN | 5 mg, BID | | | | | | |

Date:09/20/04ISR Number: 4453581-6Report Type:Expedited (15-DaCompany Report #PHBS2004BR12227
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Hyperthyroidism | Consumer | Ritalina | PS | Novartis Sector: | |

1 DF, QD

Date:09/20/04ISR Number: 4454698-2Report Type:Direct Company Report #CTU 227583
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|--|------|--------------|-------|
| Dose | | Drug Ineffective Pharmaceutical Product Complaint | | Methylphenidate 20mg Mallinkrodt | PS | Mallinkrodt | ORAL |
| 20 MG QID | | | | | | | |
| ORAL | | | | Lamictal | C | | |

Date:09/20/04ISR Number: 4458826-4Report Type:Direct Company Report #CTU 227781
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|------------------|---------------|--------------------------------|------|----------------------------|-------|
| Dose | | Medication Error | | Methadone 40mg Pill Form | PS | Express Script Services | |
| Life-Threatening Other | | | | Metadate 40 Once Daily Oral | SS | | ORAL |
| | | | | Clonidine 1 At Bedtime Oral | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/21/04ISR Number: 4457241-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903580
 Age:46 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------|----------|------------------------|---------------|------------------------|------|--------------|-------|
| Death | | | Alcohol Use | Literature | Cyclobenzaprine | | | |
| Hospitalization - | | | Blood Disorder | Health | (Cyclobenzaprine | | | |
| Initial or Prolonged | | | Electrocardiogram Qrs | Professional | Hydrochloride) | | | |
| Other | | | Complex Prolonged | | Tablets | PS | | ORAL |
| ORAL | | | | | | | | |
| | | | Heart Rate Increased | | Ibuprofen | | | |
| ORAL | | | Multiple Drug Overdose | | (Ibuprofen) | SS | | ORAL |
| | | | | | | | | |
| | | | Respiratory Arrest | | Chlorzoxazone | | | |
| ORAL | | | Stupor | | (Chlorzoxazone)Tablets | SS | | ORAL |
| | | | | | | | | |
| | | | | | Methylphenidate | | | |
| ORAL | | | | | (Methylphenidate | SS | | ORAL |
| | | | | | Hydrochloride) | | | |
| | | | | | Diphenhydramine | | | |
| ORAL | | | | | (Diphenhydramine) | SS | | ORAL |
| | | | | | | | | |
| | | | | | Haloperidol | | | |
| ORAL | | | | | (Haloperidol) | SS | | |
| | | | | | Cephalexin | | | |
| ORAL | | | | | (Cefalexin) | SS | | ORAL |
| | | | | | | | | |
| | | | | | Naproxen (Naproxen) | SS | | ORAL |
| ORAL | | | | | | | | |
| | | | | | Ethanol (Ethanol) | SS | | ORAL |
| ORAL | | | | | | | | |

Date:09/22/04ISR Number: 4455612-6Report Type:Expedited (15-DaCompany Report #PHBS2004JP11891
 Age:33 YR Gender:Male I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------|----------|----------|---------------|-----------|------|------------------|-------|
| Other | | | Pain | Health | Ritaline | PS | Novartis Sector: | |
| | | | Priapism | Professional | | | Pharma | ORAL |
| | | | | | Tegretol | SS | | ORAL |
| | | | | | Akineton | SS | | ORAL |
| | | | | | Erimin | SS | | ORAL |
| | | | | | Wintermin | SS | | ORAL |

| | | |
|-----------|----|------|
| Risperdal | SS | ORAL |
| Depas | SS | ORAL |
| Myslee | SS | ORAL |
| Serenzin | SS | |

Date:09/22/04ISR Number: 4455616-3Report Type:Expedited (15-DaCompany Report #PHEH2004US09879
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination, Auditory | | Ritalin La | PS | Novartis Sector: Pharma | |

Date:09/22/04ISR Number: 4455617-5Report Type:Expedited (15-DaCompany Report #PHFR2004GB03500
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-------------|---------------|-----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Neutropenia | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, QID | | | | | | | |
| 10 mg, QD | | | | Strattera | SS | | ORAL |
| 40 mg, QD | | | | Strattera | SS | | ORAL |
| 2mg/nocte | 895 DAY | | | Melatonin | C | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/22/04ISR Number: 4457736-6Report Type:Expedited (15-DaCompany Report #2004-DE-04634GD
 Age:10 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--|---------------|---|------|--------------|-------|
| Dose Hospitalization - Initial or Prolonged Other 1200 MG TWICE DAILY | Abdominal Pain Atrioventricular Block First Degree Chest Pain | Literature | Lithium Carbonate (Lithium Carbonate) (Lithium Carbonate) | PS | | |
| 0.4 MG (TWICE DAILY) | Diarrhoea Disorientation Dizziness Drug Interaction | | Clonidine (Clonidine) (Clonidine-Hcl) | SS | | |
| 36 MG (ONCE DAILY) (IN THE MORNING) | Hyperhidrosis Hypotension Hypothyroidism Oral Intake Reduced | | Methylphenidate (Methylphenidate) | SS | | |
| 10 MG (ONCE DAILY) | Pallor Palpitations Rhythm Idioventricular | | Escitalopram (Escitalopram) | SS | | |
| 600 MG (ONCE DAILY) | Therapeutic Agent Toxicity Ventricular Extrasystoles | | Oxcarbazine (Antiepileptics) | SS | | |
| SEE IMAGE | Ventricular Tachycardia Vomiting | | Depakote (Valproate Semisodium) | SS | | |
| 0.05 MG (ONCE DAILY) | White Blood Cell Count Increased | | Levothyroxine (Levothyroxine) | SS | | |

Date:09/22/04ISR Number: 4458057-8Report Type:Expedited (15-DaCompany Report #A01200404339
 Age:33 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--|--|--|--------------|-------|
| Hospitalization - Initial or Prolonged | | Po2 Increased Priapism Surgical Procedure Repeated | Foreign Literature Health Professional Other | Zolpidem Tartrate Depas - (Etizolam) - Unknown - Unit Dose : Unknown Ritalin - (Methylphenidate Hydrochloride) - Unknown - Unit Dose : Unknown Akineton - (Biperiden Hydrochloride) - Unknown - Unit Dose : Unknown (Nimetazepam) - Unknown - Unit Dose : Unknown Wintermin - (Chlorpromazine Hydrochloride) - Unknown - Unit Dose : Unknown Tegretol - (Carbamazepine) - Unknown - Unit Dose : Unknown Risperdal - (Risperidone) - U Nknown - Unit Dose : | PS SS SS SS SS SS SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Unknown SS
 Serenizin -
 (Diazepam) - Unknown
 - Unit Dose :
 Unknown SS

Date:09/23/04ISR Number: 4456977-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040504699
 Age: Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-------------------------|---------------|----------------|------|--------------|-------|
| Dose Duration | | | | | | |
| Life-Threatening | Acute Pulmonary Oedema | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | |
| Hospitalization - | Bradycardia | | Propofol | SS | | |
| Initial or Prolonged | Drug Interaction | | Fentanyl | C | | |
| | Malignant Hypertension | | Rocuronium | C | | |
| | Procedural Complication | | Midazolam | C | | |
| | Ventricular Tachycardia | | Neo-Synephrine | I | | NASAL |

1%, two to

three sprays,

nasal

Date:09/24/04ISR Number: 4458044-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040604067
 Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|--------------|---------------|----------|------|--------------|-------|
| Dose Duration | | | | | | |
| Other | Hypertension | | Concerta | PS | | |
| OROPHARINGEAL | 219 DAY | | | | | |

Date:09/24/04ISR Number: 4458045-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040704267
 Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---------------|----------|------|--------------|-------|
| Dose Duration | | | | | | |
| Hospitalization - | Headache | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | |
| Initial or Prolonged | Pyrexia | | | | | |

Date:09/24/04ISR Number: 4462023-6Report Type:Direct
Age:13 YR Gender:Male I/FU:I

Company Report #CTU 228022

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Methylphenidate | PS | | ORAL |
| 15 MG PO BID | | Pharmaceutical Product Complaint | | | | | |

Date:09/24/04ISR Number: 4462079-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903580
Age:46 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|---|------|--------------|-------|
| Death | | Blood Disorder | Literature | Cyclobenzaprine | | | |
| Hospitalization - Initial or Prolonged | | Electrocardiogram Qrs Complex Prolonged | Health Professional | (Cyclobenzaprine Hydrochloride) | | | |
| Other | | Heart Rate Increased | | Tablet | PS | | ORAL |
| ORAL | | Multiple Drug Overdose Respiratory Arrest | | Ibuprofen (Ibuprofen) | SS | | ORAL |
| ORAL | | Stupor | | Chlorzoxazone (Chlorzoxazone) Tablets | SS | | ORAL |
| ORAL | | | | Methylphenidate (Methylphenidate Hydrochloride) | SS | | ORAL |
| | | | | Haloperidol | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | |
|------|--------------------------------------|----|------|
| ORAL | (Haloperidol) | SS | ORAL |
| ORAL | Diphenhydramine (Diphenhydramine) | SS | ORAL |
| ORAL | Cephalexin (Cefalexin) | SS | ORAL |
| ORAL | Naproxen (Naproxen) | SS | ORAL |
| ORAL | Methanol (Ethanol) | SS | ORAL |

Date:09/24/04ISR Number: 4462401-5Report Type:Expedited (15-DaCompany Report #A01200404339
Age:33 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|--------------------|---------------|--|------|--------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - | Blood Ph Decreased | Literature | (Zolpidem Tartrate) | PS | | |
| Initial or Prolonged | Pco2 Decreased | Health | Depas (Etizolam) | SS | | |
| | Priapism | Professional | Ritalin (Methyphenidate Hydrochloride) | SS | | |
| | | | Winternin (Chlorpromazine Hydrochloride) | SS | | |
| | | | Tegretol (Carbamazepine) | SS | | |
| | | | Serenzin (Diazepam) | SS | | |
| | | | Nimetazepam | SS | | |
| | | | Akineton (Biperiden Hydrochloride) | C | | |
| | | | Risperdal (Risperidone) | C | | |

Date:09/27/04ISR Number: 4459444-4Report Type:Expedited (15-DaCompany Report #PHBS2004BR10427
Age:4 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------------------|---------------|------------|------|----------------------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - | Abdominal Pain Upper | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| Initial or Prolonged | Apathy | | | | | |
| 10 mg, QD | 168 DAY | | | | | |
| Other | Crying | | Ritalin La | SS | | ORAL |

Depressed Mood
Headache
Meningitis

Date:09/28/04ISR Number: 4461216-1Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20040906864
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | | Concerta | PS | | |
| UNKNOWN | | Chest Pain Insomnia Nightmare Psychomotor Retardation | | | | | |

Date:09/28/04ISR Number: 4461332-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040701677
Age:18 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Suicide Attempt | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/28/04ISR Number: 4461333-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040907804
Age:29 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|----|---|----------|------|--------------|-------|
| Hospitalization - OROPHARINGEAL | | | Chest Discomfort | Concerta | PS | | |
| Initial or Prolonged | | | Feeling Hot Heart Rate Increased Hyperhidrosis Nausea Skin Warm Vomiting | Xenical | SS | | |

Date:09/29/04ISR Number: 4461738-3Report Type:Expedited (15-DaCompany Report #PHBS2004CA10581
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|--|---------|------|----------------------------|-------|
| Other | | | Blood Thyroid Stimulating Hormone Increased Tri-Iodothyronine Increased | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:09/30/04ISR Number: 4462980-8Report Type:Expedited (15-DaCompany Report #PHBS2004JP10015
Age:75 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|----|-------------------------------------|--------------------------------------|--------|----------------------------|-------|
| Death Other 10 mg/d | | | Death Delirium | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/d | 5760 MIN | | Depressed Level Of Consciousness | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| 25 mg/d | | | Dialysis Dizziness Malaise | Morphine Hydrochloride Durotep | C C | | |
| 80 mg/d | | | Oxygen Saturation | Diovan | C | | ORAL |
| | | | Decreased Somnolence | Protecadin Loxonin | C C | | |

| | | | | |
|----------|-----------------|---------|---|------|
| 150 mg/d | Speech Disorder | Ganaton | C | ORAL |
| | Tremor | Rize | C | ORAL |
| 15 mg/d | Vomiting | Novamin | C | ORAL |
| 15 mg/d | | | | |

Date:09/30/04ISR Number: 4463320-0Report Type:Expedited (15-DaCompany Report #PHBS2004JP08725
Age:52 YR Gender:Male I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------------------|---------------|----------|------|------------------|-------|
| Dose Duration | | | | | | |
| Hospitalization - | Aggression | Health | Ritalin | PS | Novartis Sector: | |
| Initial or Prolonged | Back Disorder | Professional | | | Pharma | ORAL |
| Other | Delusion Of Grandeur | | Ritalin | SS | Novartis Sector: | |
| | Drug Dependence | | | | Pharma | ORAL |
| 50 DF, QD | Gait Disturbance | | Serenace | C | | |
| | Parkinson'S Disease | | Cercine | C | | |
| | Tremor | | Lexotan | C | | |

Date:09/30/04ISR Number: 4463321-2Report Type:Expedited (15-DaCompany Report #PHNU2004DE00618
Age: Gender:Male I/FU:F

| Outcome | PT |
|---------|---|
| Other | Blood Creatinine Increased Creatinine Renal |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|------------|----------|--|------------------------|----------|------|----------------------------|-------|
| | | Clearance Decreased Haematuria Proteinuria Tubulointerstitial | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | Nephritis | Health Professional | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, BID | | | | | | | |

Date:09/30/04ISR Number: 4463620-4Report Type:Expedited (15-DaCompany Report #C04-T-137
Age:23 YR Gender:Female I/FU:F

| | | | | | | | |
|---------|----------|-------------------------|---------------|---|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Dizziness | Consumer | Methylphenidate Hci Tablets, Usp 10 Mg | PS | | |
| Other | | Hypotonia Somnolence | | Ortho-Cyclen | SS | | |

Date:10/01/04ISR Number: 4463787-8Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040900021
Age: Gender:Male I/FU:F

| | | | | | | | |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Neutropenia | | Concerta | PS | | |
| Other | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| OROPHARINGEAL | | | | | | | |

Date:10/01/04ISR Number: 4463788-XReport Type:Expedited (15-DaCompany Report #NL-JNJFOC-20040907060
Age: Gender:Male I/FU:I

| | | | | | | | |
|------------------------------|----------|------------------------|---------------|----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | Hospitalisation | | Concerta | PS | | |
| Hospitalization - UNKNOWN | | No Adverse Drug Effect | | | | | |
| Initial or Prolonged | | | | | | | |

Date:10/01/04ISR Number: 4465343-4Report Type:Direct Company Report #CTU 228503
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | | Methylphenidate Hcl | PS | | ORAL |
| 20 MG BID PO | | Disturbance In Attention | | Celebrex | C | | |
| | | Insomnia | | Lorazepam | C | | |
| | | Pharmaceutical Product | | Provigil | C | | |
| | | Complaint | | | | | |

Date:10/01/04ISR Number: 4465795-XReport Type:Direct Company Report #CTU 228573
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | | Ritalin | PS | | |
| | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |
| | | Tic | | | | | |

Date:10/04/04ISR Number: 4464718-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040908454
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-------------|---------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Visual Field Defect | | Concerta | PS | | |
| UNKNOWN | 36mg in the | | | | | | |

morning and
 18mg in the
 afternoon

Freedom Of Information (FOI) Report

Melatonin C

UNKNOWN

Date:10/05/04ISR Number: 4465926-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040909656

Age:21 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|-------------------------------|------|--------------|-------|
| Death | | Completed Suicide | | Pseudoephedrine Hydrochloride | PS | | |
| OROPHARINGEAL | | Multiple Drug Overdose | | | | | |
| OROPHARINGEAL | | | | Methylphenidate | SS | | |
| OROPHARINGEAL | | | | Aspirin | SS | | |

Date:10/05/04ISR Number: 4466163-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908271

Age:17 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Death | | Drug Abuser | | Concerta | PS | | |
| OROPHARINGEAL | | Overdose | | | | | |

Date:10/05/04ISR Number: 4516207-9Report Type:Periodic Company Report #NSADSS2003024795

Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---------------------------------|------|--------------|-------|
| Other | | Abdominal Pain | Consumer | Concerta | | | |
| | | Anorexia | Health | (Methylphenidate Hydrochloride) | | | |
| | | Weight Decreased | Professional | Sustained Release Tablets | PS | | ORAL |

18 MG, 1 IN 1

DAY, ORAL; 36

MG, 1 IN 1

DAY, ORAL

Qvar (Beclometasone
Dipropionate) C
Albuterol
(Salbutamol) C
Motrin (Ibuprofen) C
Claritin
(Loratadine) C

Date:10/05/04ISR Number: 4516211-0Report Type:Periodic Company Report #US-JNJFOC-20040406074
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---|--|------|--------------|-------|
| Dose Other | | Convulsion | Health Professional Company Representative | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 27 MG, 1 IN 1 | | | | | | | |

DAY, ORAL

Date:10/05/04ISR Number: 4516214-6Report Type:Periodic Company Report #US-JNJFOC-20040203753
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------------------|---------------|--|------|--------------|-------|
| Dose Other | | Aggression Anorexia Insomnia | Consumer | Concerta (Methylphenidate Hydrochloride) | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

18 MG, 1 IN 1
 DAY, ORAL;
 54 MG, 1 IN 1
 DAY, ORAL

Sustained Release
 Tablets PS ORAL

Cyproheptadine
 (Cyproheptadine) C

Date:10/05/04ISR Number: 4516219-5Report Type:Periodic Company Report #US-JNJFOC-20040200252
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|------------------------|--|------|--------------|-------|
| Dose Other | | Convulsion Stress | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL | | | | | | | |

Date:10/05/04ISR Number: 4516221-3Report Type:Periodic Company Report #US-JNJFOC-20031006767
 Age:6 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|--|------|--------------|-------|
| Dose Other | | Aggression | Consumer | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| ORAL; 45 MG, | | | | | | | |

ORAL

Date:10/05/04ISR Number: 4516223-7Report Type:Periodic Company Report #US-JNJFOC-20031001158
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|------------------------|--|------|--------------|-------|
| Dose Other | | Aggression Anxiety | Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | ORAL |
| 36 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL; | | | | | | | |
| 54 MG, 1 IN 1 | | | | | | | |
| DAY, ORAL | | | | | | | |

Date:10/05/04ISR Number: 4516224-9Report Type:Periodic Company Report #US-JNJFOC-20030706262
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|------------------------------------|--|------|--------------|-------|
| Dose Other | | Convulsion | Consumer Health Professional | Concerta (Methylphenidate Hydrochloride) Sustained Release Tablets | PS | | |
| 54 MG, 1 IN 1 | | | | | | | |
| DAY | | | | | | | |
| | | | | Imipramine (Imipramine) | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/05/04ISR Number: 4516697-1Report Type:Periodic Company Report #PHEH2004US08250
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|--|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypertension | Health Professional Company Representative | Ritalin La (Methylphenidate Hydrochloride) Extended Release Capsules | PS | | |

20 UNK,

Date:10/05/04ISR Number: 4516700-9Report Type:Periodic Company Report #PHEH2004US09321
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Consumer | Ritalin La (Methylphenidate Hydrochloride) Extended Release Capsules | PS | | ORAL |
| | | | | Depakote (Valproate Semisodium) | C | | |
| | | | | Klonopin | C | | |

20 MG, QD,
 ORAL

Date:10/07/04ISR Number: 4468306-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040909429
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine | | Concerta | PS | | |
| OROPHARINGEAL | | Phosphokinase Increased Myalgia | | | | | |

Date:10/07/04ISR Number: 4468526-2Report Type:Expedited (15-DaCompany Report #PHNU2004DE03396
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Amnesia | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 10 mg/day | | | | | | | |

Date:10/08/04ISR Number: 4469710-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041000166
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypoglycaemia | | Concerta | PS | | |
| OROPHARINGEAL 3 WK | | | | | | | |
| Therapeutic Response | | | | | | | |
| Unexpected | | | | | | | |

Date:10/08/04ISR Number: 4472103-7Report Type:Expedited (15-DaCompany Report #2004029622
Age:52 YR Gender:Male I/FU:F

| Outcome | PT |
|---------|-----------------------|
| Other | Convulsion |
| | Diarrhoea |
| | Drug Effect Decreased |
| | Drug Level Decreased |
| | Drug Level Increased |
| | Fatigue |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Pharmaceutical Product | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|--|------|--------------|-------|
| | | Memory Impairment Nervousness Pharmaceutical Product | Consumer | Dilantin Kapseals (Phenytoin Sodium) | PS | | ORAL |
| 300 MG (1 D), | | Complaint Treatment Noncompliance | | | | | |
| ORAL | | | | Phenytoin (Phenytoin) | SS | | |
| 500 MG (1 D) | | | | Methylphenidate Hydrochloride (Methylphenidate Hydrochloride) | SS | | ORAL |
| ORAL | | | | Gabapentin (Gabapentin) | C | | |
| | | | | Clonazepam (Clonazepam) | C | | |
| | | | | Buspirone Hydrochloride (Buspirone Hydrochloride) | C | | |
| | | | | Tamsulosin Hydrochloride (Tamsulosin Hydrochloride) | C | | |
| | | | | Enalapril Maleate (Enalapril Maleate) | C | | |
| | | | | Yohimbine (Yohimbine) | C | | |
| | | | | Axotal (Old Form) (Butalbital, Caffeine, Paracetamol) | C | | |
| | | | | Donepezil Hydrochloride (Donepezil Hydrochloride) | C | | |
| | | | | Lomotil (Atropine Sulfate, Diphenoxylate Hydrochloride) | C | | |
| | | | | Rofecoxib (Rofecoxib) | C | | |

Date:10/11/04ISR Number: 4470844-9Report Type:Expedited (15-DaCompany Report #PHBS2004JP11891
Age:33 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-----------|------|------------------|-------|
| Dose | | | Health | Ritaline | PS | Novartis Sector: | |
| Other | | Pain Priapism | Professional | | | Pharma | ORAL |
| | | | | Tegretol | SS | | ORAL |
| | | | | Akineton | SS | | ORAL |
| | | | | Erimin | SS | | ORAL |
| | | | | Wintermin | SS | | ORAL |
| | | | | Risperdal | SS | | ORAL |
| | | | | Depas | SS | | ORAL |
| | | | | Myslee | SS | | ORAL |
| | | | | Serenzin | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/11/04ISR Number: 4470845-0Report Type:Expedited (15-DaCompany Report #PHRM2004FR02704
Age:40 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-------------|---------------------|-----------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Bradycardia | Health Professional | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 30 mg daily | | | | Zoloft | SS | | ORAL |
| | | | | Teralithe | SS | | ORAL |
| | | | | Seresta | C | | ORAL |

Date:10/11/04ISR Number: 4470846-2Report Type:Expedited (15-DaCompany Report #PHNU2004DE03197
Age:11 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------|---------------------|-----------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Strabismus | Health Professional | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/day | | | | Medikinet | SS | | ORAL |
| Unknown | | | | | | | |

Date:10/12/04ISR Number: 4471608-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041001012
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - OROPHARINGEAL | | Dyskinesia | | Concerta | PS | | |
| Initial or Prolonged | | Feeling Drunk Tremor | | Zyprexa | C | | |

Date:10/12/04ISR Number: 4471609-4Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20040906864
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Health Professional | Concerta | PS | | |
| OROPHARINGEAL | | Anorexia | | | | | |

Anxiety
 Chest Pain
 Headache
 Insomnia
 Nightmare
 Psychomotor Retardation
 Tremor

Date:10/13/04ISR Number: 4473082-9Report Type:Expedited (15-DaCompany Report #PHEH2004US09879

Age: Gender: I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------------|------------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination, Auditory | Health Professional | Ritalin La | PS | Novartis Sector: Pharma | |

Date:10/13/04ISR Number: 4473096-9Report Type:Expedited (15-DaCompany Report #PHFR2004GB03500

Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------------------|---------------|-------------|------|-------------------------|-------|
| Dose | | | | | | | |
| Other | | Insomnia Neutropenia | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, QID | | | | Ritaline | SS | Novartis Sector: Pharma | |
| 36 mg, QD | | | | Atomoxetine | C | | ORAL |
| 10 - 40mg QD | 63360MIN | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/18/04ISR Number: 4477314-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040909429
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine | Health | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Phosphokinase Increased | Professional | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Myalgia | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | | | Polamidon | C | | |
| OROPHARINGEAL | | | | | | | |

Date:10/18/04ISR Number: 4477315-4Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041002525
 Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Subclavian Vein | Health | Concerta | PS | | |
| OROPHARINGEAL | | 4 MON | | | | | |
| | | Thrombosis | Professional | | | | |

Date:10/18/04ISR Number: 4477334-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041002117
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Developmental Delay | | Concerta | PS | | |
| INTRA-UTERINE | | | | | | | |
| | | Drug Exposure During Pregnancy | | | | | |

Date:10/18/04ISR Number: 4477582-7Report Type:Expedited (15-DaCompany Report #PHNU2004DE03396
 Age:15 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Amnesia | Health | Ritaline | PS | Novartis Sector: | |
| | | Concussion | Professional | | | Pharma | ORAL |
| 10 mg/day | | | | | | | |

Date:10/18/04ISR Number: 4678420-XReport Type:Direct Company Report #CTU 239856
 Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Insomnia | | Ritalin | PS | | |
| | | Psychomotor Hyperactivity | | | | | |

Date:10/19/04ISR Number: 4478641-5Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040606738
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Brain Neoplasm | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Convulsion | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Haemangioma | | | | | |

Date:10/20/04ISR Number: 4479365-0Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20041004939
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Diabetes Mellitus | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/21/04ISR Number: 4481386-9Report Type:Expedited (15-DaCompany Report #PHEH2004US11102

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 mg, TID | | | | | | | |
| 25 mg, UNK | | | | Paxil | SS | | ORAL |

Date:10/21/04ISR Number: 4483547-1Report Type:Direct Company Report #CTU 230198

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion Pharmaceutical Product Complaint Tic | | Ritalin | PS | | |

Date:10/22/04ISR Number: 4482604-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20041004002

Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour 3 DAY Aggression Disinhibition | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:10/22/04ISR Number: 4482687-0Report Type:Expedited (15-DaCompany Report #PHBS2004JP13956

Age:74 YR Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Endocrine Ophthalmopathy Hyperthyroidism | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 30 mg/day | | | | | | | |
| 10 mg/day | | | | Paxil | SS | | ORAL |

Date:10/22/04ISR Number: 4482688-2Report Type:Expedited (15-DaCompany Report #PHRM2004FR03125
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------------------------------|---------------|-------------|------|----------------------------|-------|
| Dose | | | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Other | | Drug Interaction Tachycardia | | | | | |
| 50 mg/day | | | | Paracetamol | SS | | ORAL |
| 500 mg/day | | | | | | | |

Date:10/22/04ISR Number: 4483854-2Report Type:Direct Company Report #CTU 230232
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | Adderall Xr 30 Mg | | | |
| Required | | Medication Error | | Rite Aid | PS | Rite Aid | ORAL |
| Intervention to | | | | | | | |
| 1 DAILY | | | | | | | |
| Prevent Permanent | | | | | | | |
| ORAL | | | | Concerta 36 Mg | | | |
| Impairment/Damage | | | | Rite Aid | SS | Rite Aid | ORAL |
| 1 DAILY | | | | | | | |
| ORAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/22/04ISR Number: 4483855-4Report Type:Direct
 Age: Gender:Female I/FU:I

Company Report #CTU 230231

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------|---------------|----------------|------|--------------|-------|
| Dose Required | 1 DAILY | Medication Error | | Concerta 36 Mg | PS | | ORAL |
| Intervention to ORAL Prevent Permanent Impairment/Damage | | | | | | | |

Date:10/22/04ISR Number: 4483869-4Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 230332

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------------|------------------|---------------|---------|------|--------------|-------|
| Dose | 10 MG ONCE | Drug Ineffective | | Ritalin | PS | | ORAL |
| (PO) TID Pharmaceutical Product Complaint | | | | | | | |

Date:10/26/04ISR Number: 4485747-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040700659
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|---------------|-------------------|---------------|----------|------|--------------|-------|
| Dose | OROPHARINGEAL | Diabetes Mellitus | Health | Concerta | PS | | |
| Insulin-Dependent Professional | | | | | | | |

Date:10/26/04ISR Number: 4485780-1Report Type:Expedited (15-DaCompany Report #PHBS2004JP13956
 Age:74 YR Gender:Unknown I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|-----------|--------------------------|---------------|---------|------|-------------------------|-------|
| Dose | 30 mg/day | Endocrine Ophthalmopathy | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| Eye Pain | | | | | | | |

10 mg/day Hyperthyroidism Paxil SS ORAL
 Tonsillar Disorder

Date:10/27/04 ISR Number: 4486839-5 Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903736
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------------|----------|---------------------------|---------------|----------|------|--------------|-------|
| Hospitalization - OROPHARINGEAL | | Brain Neoplasm | | Concerta | PS | | |
| Initial or Prolonged OROPHARINGEAL | | Cerebral Cyst | | Concerta | SS | | |
| Other OROPHARINGEAL | | Facial Paresis | | Concerta | SS | | |
| OROPHARINGEAL | | Fall | | Concerta | SS | | |
| | | Ganglioneuroma | | | | | |
| | | Headache | | | | | |
| | | Hemiparesis | | | | | |
| | | Periorbital Haematoma | | | | | |
| | | Peroneal Nerve Palsy | | | | | |
| | | Psychomotor Hyperactivity | | | | | |
| | | Simple Partial Seizures | | | | | |
| | | Tongue Atrophy | | | | | |

Date:10/28/04 ISR Number: 4488541-2 Report Type:Direct Company Report #CTU 230659
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|----------------------|------|--------------|-------|
| Other | | Drug Ineffective | | Ritalin 10 Mg 2 1/2 | | | |
| | | Pharmaceutical Product | | Complaint | PS | | |
| | | | | Ritalin 10 Mg 2 Tabs | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Q 7 Pm

SS

Date:10/28/04ISR Number: 4488543-6Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 230658

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | Ritalin 10 Mg | PS | | ORAL |
| Other | | Drug Ineffective | | Clondine 0.1 Mg | SS | | |
| 25/25/25/PO | | | | | | | |
| 0.1 MG 4X | | | | | | | |
| /DAY | | | | | | | |

Date:10/29/04ISR Number: 4489174-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040901057
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | |
| Other | | Monocytosis | | | | | |
| OROPHARINGEAL | | Neutropenia | | | | | |

Date:10/29/04ISR Number: 4489175-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041006981
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | |
| Other | | Hospitalisation | | | | | |
| OROPHARINGEAL | | | | | | | |

Date:10/29/04ISR Number: 4491919-4Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 230810

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|--------------------------------------|---------------|-----------------------|------|--------------|-------|
| Dose | | | | Methylphenidate 20 Mg | PS | | ORAL |
| Life-Threatening Disability | | Disorientation Lacunar Infarction | | | | | |
| 20 MG 2 TIMES | | | | | | | |

Speech Disorder

PER DA ORAL
 150 MG 2
 TIMES PER DA
 ORAL
 Wellbutrin 150 Mg SS ORAL
 Celexa C
 Trazadone C
 Luvox C

Date:11/01/04ISR Number: 4491812-7Report Type:Expedited (15-DaCompany Report #CEL-2004-01867-ROC
 Age:21 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|--------------------------------|---|------|--------------|-------|
| Death | | Completed Suicide | Literature Health Professional | Methylphenidate (Methylphenidate Hydrochloride) | PS | | ORAL |
| PO | | | | Aspirin (Acetylsalicylic Acid) | SS | | |
| | | | | Pseudoephedrine (Pseudoephedrine) | SS | | |

Date:11/02/04ISR Number: 4490443-2Report Type:Expedited (15-DaCompany Report #PHFR2004GB03999
 Age:15 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|----------------------|---------------|----------|------|-------------------------|-------|
| Other | | Hepatitis C Positive | | Ritaline | PS | Novartis Sector: Pharma | |
| | 30 mg/day | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/02/04ISR Number: 4490663-7Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0443660A
 Age:51 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------|-------------------|------|-----------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia | | Combivir | PS | Glaxosmithkline | ORAL |
| | | Diarrhoea | | Lithium Carbonate | SS | Glaxosmithkline | ORAL |
| 900MG Per day | | | | | | | |
| | | Drug Interaction | | Bactrim | SS | Glaxosmithkline | |
| | | Nausea | | Concerta | SS | | |
| 54MG per day | | | | | | | |
| | | Therapeutic Agent | | Sustiva | SS | | |
| | | Toxicity | | Zocor | SS | | ORAL |
| 80MG Per day | | | | | | | |
| | | Vomiting | | Zyprexa | C | | |
| 2.5MG Per day | | | | | | | |

Date:11/03/04ISR Number: 4491516-0Report Type:Expedited (15-DaCompany Report #PHBS2004DE14649
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Petechiae | | Ritalin | PS | Novartis Sector: Pharma | |
| | | Schamberg'S Disease | | | | | |
| UNKNOWN | | | | | | | |

Date:11/04/04ISR Number: 4495136-3Report Type:Expedited (15-DaCompany Report #2004-DE-05401GD
 Age:21 YR Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Completed Suicide | Literature | Acetylsalicylic Acid | PS | | ORAL |
| PO | | | | | | | |
| | | Multiple Drug Overdose | | Pseudoephedrine Hcl (Pseudoephedrine) | SS | | ORAL |
| PO | | | | | | | |
| | | | | Methylphenidate (Methylphenidate) | SS | | ORAL |
| PO | | | | | | | |

Date:11/04/04ISR Number: 4497409-7Report Type:Expedited (15-DaCompany Report #2004062831
Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | No Adverse Drug Effect | Consumer | Neurontin (Gabapentin) | PS | | |
| | | | | Oxycocet (Oxycodone Hydrochloride, Paracetamol) | SS | | |
| | | | | Paroxetine Hydrochloride (Paroxetine Hydrochloride) | SS | | |
| | | | | Rofecoxib (Rofecoxib) | SS | | |
| | | | | Methylphenidate Hydrochloride (Methylphenidate Hydrochloride) | SS | | |
| | | | | Fentanyl (Fentanyl) | SS | | |

Date:11/05/04ISR Number: 4493985-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908710
Age:46 YR Gender:Male I/FU:I

| | |
|---------|--|
| Outcome | PT |
| Death | Blood Test Abnormal Completed Suicide Electrocardiogram Qrs Complex Shortened |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Heart Rate Increased Intentional Misuse Respiratory Arrest | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|-----------------|------|--------------|-------|
| OROPHARINGEAL | | | | Haldol | PS | | |
| OROPHARINGEAL | | | | Diphenhydramine | SS | | |
| OROPHARINGEAL | | | | Cyclobenzaprine | SS | | |
| | | | | Ibuprofen | SS | | |
| | | | | Cephalexin | SS | | |
| | | | | Naproxen | SS | | |
| | | | | Chlorzoxazone | SS | | |
| | | | | Methylphenidate | SS | | |
| | | | | Ethanol | SS | | |

Date:11/08/04ISR Number: 4495524-5Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040606738
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|----------|------|--------------|-------|
| Other | | Brain Neoplasm | | Concerta | PS | | |
| OROPHARINGEAL | | Cerebrovascular | | Concerta | SS | | |
| OROPHARINGEAL | | Arteriovenous Malformation Convulsion | | | | | |

Date:11/08/04ISR Number: 4495864-XReport Type:Expedited (15-DaCompany Report #PHBS2004JP14746
Age:37 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------------------------|---------------|---------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | | Confusional State Drug Dependence | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:11/08/04ISR Number: 4496194-2Report Type:Direct Company Report #CTU 231437
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | Neutropenia | | Concerta | PS | | ORAL |
| 36 MG (2) PO | | | | | | | |
| QD | | | | | | | |

Date:11/08/04ISR Number: 4496410-7Report Type:Direct Company Report #CTU 231456
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | Dystonia | | Concerta | PS | | |
| Other | | Heart Rate Increased | | | | | |
| 72 MGM | | Pain | | | | | |
| | | Tremor | | | | | |

Date:11/08/04ISR Number: 4497561-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041008038
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|--------------|------------------------|---------------|----------|------|--------------|-------|
| Dose | | Atrioventricular Block | | Concerta | PS | | |
| Other | | Second Degree | | Concerta | SS | | |
| OROPHARINGEAL | | Electrocardiogram Qt | | Concerta | SS | | |
| OROPHARINGEAL | 36mg+18mg so | Prolonged | | | | | |
| dosage could | | Heart Rate Decreased | | | | | |
| be adjusted | | Heart Rate Increased | | | | | |
| at home as | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

needed.

Date:11/08/04ISR Number: 4497562-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041008611
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|-----------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | Growth Retardation | Concerta | PS | | |
| OROPHARINGEAL | | | Protein Urine Present | | | | |

Date:11/08/04ISR Number: 4497658-8Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20040908783
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | Agitation | Concerta | PS | | |
| OROPHARINGEAL | | | 1 DAY | | | | |
| | | | Anxiety | | | | |
| | | | Dyskinesia | | | | |
| | | | Logorrhoea | | | | |

Date:11/08/04ISR Number: 4497659-XReport Type:Expedited (15-DaCompany Report #CA-JNJFOC-20041008010
 Age:37 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | Gastrointestinal | Concerta | PS | | |
| OROPHARINGEAL | | | Haemorrhage | Imovane | C | | |
| | | | Haematochezia | | | | |

Date:11/09/04ISR Number: 4496564-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040909656
 Age:21 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | | Agitation | Pseudoephedrine | | | |

| | | | |
|---------------|---------------------------|-----------------|----|
| OROPHARINGEAL | Blood Bicarbonate | Hydrochloride | PS |
| OROPHARINGEAL | Decreased | Methylphenidate | SS |
| OROPHARINGEAL | Blood Calcium Increased | Aspirin | SS |
| | Blood Chloride Decreased | | |
| | Blood Creatine | | |
| | Phosphokinase Increased | | |
| | Blood Creatinine | | |
| | Increased | | |
| | Blood Potassium Increased | | |
| | Blood Sodium Increased | | |
| | Body Temperature | | |
| | Increased | | |
| | Cardiac Arrest | | |
| | Grand Mal Convulsion | | |
| | Muscle Rigidity | | |
| | Therapeutic Agent | | |
| | Toxicity | | |
| | Therapy Non-Responder | | |

Date:11/09/04ISR Number: 4496570-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040502040
Age: Gender:Male I/FU:I

Outcome PT
Other Aggression
Condition Aggravated
Physical Assault

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | |
|---------------|----------|---|---------------|----------|------|--------------|
| | | Psychomotor Hyperactivity Weight Decreased | | | | |
| Dose | Duration | | Report Source | Product | Role | Manufacturer |
| | | | | Concerta | PS | |
| OROPHARINGEAL | | | | Concerta | SS | |
| OROPHARINGEAL | | | | | | |

Date:11/09/04ISR Number: 4496571-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20041100335
Age: Gender:Female I/FU:I

| | | | | | | | |
|---------------|----------|---|---------------|----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Cough | | Concerta | PS | | |
| OROPHARINGEAL | | Decreased Appetite Headache Hypotonia Insomnia Nasopharyngitis Psychomotor Hyperactivity Upper Respiratory Tract Infection Weight Decreased | | | | | |

Date:11/09/04ISR Number: 4498015-0Report Type:Direct Company Report #CTU 231604
Age: Gender:Female I/FU:I

| | | | | | | | |
|---------------|----------|-----------------------|---------------|---------------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Attention | | Ritalin 15 Mg | PS | | |
| 15MG 2X A DAY | | Deficit/Hyperactivity | | Ritalin 10 Mg | SS | | |
| 10 MG 2X A | | Disorder | | | | | |
| DAY | | Drug Ineffective | | | | | |

Date:11/10/04ISR Number: 4497285-2Report Type:Expedited (15-DaCompany Report #PHFR2004GB03632
Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Asthenia | | Ritaline | PS | Novartis Sector: Pharma | |
| 10 mg, BID | | Cerebral Ischaemia | | | | | |
| | | Headache | | Ritaline | SS | Novartis Sector: Pharma | ORAL |
| 35mg/day | | Paraesthesia | | | | | |

Date:11/10/04ISR Number: 4499151-5Report Type:Direct Company Report #CTU 231680
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| BID | | Drug Ineffective | | Tegretol 200 Mg Bid | PS | | |
| | | Pharmaceutical Product | | Ritalin 5 Mg Bid | SS | | |
| BID | | Complaint | | | | | |

Date:11/11/04ISR Number: 4499118-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040908271
Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Cardiac Arrest | Health | Concerta | PS | | |
| OROPHARINGEAL | | Drug Abuser | Professional | Methylphenidate | SS | | |
| OROPHARINGEAL | | Overdose | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/11/04ISR Number: 4499120-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041101316
Age:16 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------------|----------------------|---------------|----------|------|--------------|-------|
| Hospitalization - | | Heart Rate Increased | | Concerta | PS | | |
| OROPHARINGEAL | Took three | | | | | | |
| Initial or Prolonged | | Intentional Misuse | | | | | |
| doses | | | | | | | |
| Other | | Overdose | | | | | |
| (unspecified) | | Self-Medication | | | | | |

Date:11/11/04ISR Number: 4499121-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041101406
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|----------|------|--------------|-------|
| Other | | Bone Development Abnormal | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Growth Retardation | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:11/12/04ISR Number: 4499540-9Report Type:Expedited (15-DaCompany Report #PHBS2004SE14980
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------|---------------|-----------|------|----------------------------|-------|
| Other | | Atrial Fibrillation | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | | | | Levaxin | C | | |
| | | | | Symbicort | C | | |
| | | | | Sparkal | C | | |

Date:11/12/04ISR Number: 4500519-9Report Type:Direct Company Report #CTU 231841
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|------------------|------|--------------|-------|
| Dose | | Drug Ineffective | | Ritalin Sr 20 Mg | | | |

ORAL 20MG
 2-BID
 20MG 1 -
 AFTER PM
 Pharmaceutical Product
 Complaint
 2-Bid
 Ritalin 20 Mg
 1-After Pm
 PS
 SS

Date:11/12/04ISR Number: 4500784-8Report Type:Direct
 Age:18 YR Gender:Female I/FU:I
 Company Report #CTU 231827

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-----------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety | | Ritalin Generic 5mg | | | |
| | | Dyspnoea | | 1 Tid | PS | | |
| 5MG 1TID | | Urticaria | | | | | |

Date:11/15/04ISR Number: 4500602-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040502040
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | Health | Concerta | PS | | |
| OROPHARINGEAL | | Condition Aggravated | Professional | Concerta | SS | | |
| OROPHARINGEAL | | Homicidal Ideation | | Strattera | C | | |
| OROPHARINGEAL | | Weight Decreased | | Strattera | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/16/04ISR Number: 4501849-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041103309

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper | | Concerta | PS | | |
| OROPHARINGEAL | | Dyspnoea | | | | | |

Date:11/16/04ISR Number: 4502081-3Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20041007782

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Thrombocytopenic Purpura | | Concerta | PS | | |
| UNKNOWN | | | | | | | |
| Initial or Prolonged | | | | | | | |

Date:11/16/04ISR Number: 4502929-2Report Type:Direct Company Report #CTU 232187

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | | Adderall Extended | | | |
| 10 MG 1X | | Crying | | Release 10mg | PS | | |
| DAILY | | Headache | | | | | |
| | | Irritability | | Concerta Extended | | | |
| 27MG 1X DAILY | | Mood Altered | | Release 27mg | SS | | |
| | | Pallor | | | | | |
| | | Thirst | | | | | |

Date:11/17/04ISR Number: 4503016-XReport Type:Expedited (15-DaCompany Report #PHBS2004CH15298

Age:36 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--------------------|---------------|---------|------|------------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Arterial Occlusive | | Ritalin | PS | Novartis Sector: | |

Initial or Prolonged
INTRA-ARTERIAL 40 mg,

Disease

Pharma

Blood Creatine

ONCE/SINGLE

Phosphokinase Increased
C-Reactive Protein
Increased
Finger Amputation
Hypoaesthesia
Livedo Reticularis
Lividity
Medication Error
Mobility Decreased
Necrosis
Oedema Peripheral
Pain In Extremity
Pallor
Peripheral Coldness
Peripheral Ischaemia
White Blood Cell Count
Increased

Date:11/17/04ISR Number: 4504361-4Report Type:Direct
Age:9 YR Gender:Male I/FU:I

Company Report #CTU 232271

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Generic Ritalin 5 Mg | PS | | ORAL |
| 2 AM, 2 NOON, | | Pharmaceutical Product | | | | | |
| 2 PM PO/DAILY | | Complaint | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/17/04ISR Number: 4504374-2Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 232284

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Ritalin 10 Mg | PS | | |
| RITALIN | | Drug Ineffective | | | | | |
| 25/25/25/20 | | Impulsive Behaviour | | Clonidine 0.1 Mg | SS | | |
| CLONIDINE 0.1 | | Pharmaceutical Product | | | | | |
| MG 4X / DAY | | Complaint | | | | | |
| | | Psychomotor Hyperactivity | | | | | |

Date:11/17/04ISR Number: 4504377-8Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 232286

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Ritalin 10 Mg 2 1/2 | | | |
| | | Drug Ineffective | | Tabs Tid | PS | | |
| | | Impulsive Behaviour | | Ritalin 10 Mg 2 Tabs | | | |
| | | Pharmaceutical Product | | Q 7 Pm | SS | | |
| | | Complaint | | | | | |
| | | Psychomotor Hyperactivity | | | | | |

Date:11/19/04ISR Number: 4505938-2Report Type:Expedited (15-DaCompany Report #PHBS2004JP14746
Age:37 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------|---------------|-----------|------|------------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Aggression | Health | Ritalin | PS | Novartis Sector: | |
| Initial or Prolonged | | Confusional State | Professional | | | Pharma | ORAL |
| 60 mg/day | | Crying | | Depromel | C | | ORAL |
| 50 mg/d | 640 DAY | Depressed Level Of | | Tetramide | C | | ORAL |
| 30 mg/day | 627 DAY | Consciousness | | Lexotan | C | | ORAL |
| 15 mg/d | 627 DAY | | | | | | |

| | | | | |
|----------|----------------------|-------------|---|------|
| 0.5 mg/d | Drug Dependence | Halcion | C | ORAL |
| | Intentional Misuse | Silece | C | ORAL |
| 4 mg/d | Therapeutic Agent | Vegetamin A | C | ORAL |
| 1 DF/d | Toxicity Vomiting | | | |

Date:11/19/04ISR Number: 4505959-XReport Type:Expedited (15-DaCompany Report #PHBS2004JP13956
Age:74 YR Gender:Unknown I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------------|---------------|------------------|------|------------------|-------|
| Dose | | Eye Pain | | Ritalin | PS | Novartis Sector: | ORAL |
| Other | | Hyperthyroidism | | | | Pharma | |
| 30 mg/day | | Inflammation | | Ritalin | SS | Novartis Sector: | ORAL |
| | | Oropharyngeal Swelling | | | | Pharma | |
| 20 mg/day | | Pharyngolaryngeal Pain | | Paxil | SS | | ORAL |
| 10 mg/day | | Pyrexia | | Digoxin "Sandoz" | C | | |
| | | Tonsillar Disorder | | Vasolan | C | | |
| | | Tonsillar Hypertrophy | | Famotidine | C | | |
| | | | | Hypen | C | | |

Date:11/19/04ISR Number: 4509525-1Report Type:Expedited (15-DaCompany Report #CEL-2004-01986-ROC
Age:9 YR Gender:Male I/FU:I

Outcome
Required
Intervention to
Prevent Permanent

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Impairment/Damage

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|---|------|--------------|-------|
| 10MG ONCE PO | | Dyspnoea Vision Blurred Wheezing | Consumer | Metadate Cd Capsules 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:11/19/04ISR Number: 4512875-6Report Type:Direct Company Report #CTU 232529
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---|---------------|-----------------|------|--------------|-------|
| Other 5 MG PO TID | | Drug Ineffective Pharmaceutical Product Complaint | | Generic Ritalin | PS | | ORAL |

Date:11/22/04ISR Number: 4506523-9Report Type:Periodic Company Report #DE-JNJFOC-20041006981
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|----------|------|--------------|-------|
| OROPHARINGEAL | | Self-Medication | | Concerta | PS | | |

Date:11/22/04ISR Number: 4507058-XReport Type:Expedited (15-DaCompany Report #US-MERCK-0411USA03084
Age:51 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|---|----------------------|------------------|----------------------|
| UNKNOWN | | Asthenia Diarrhoea Drug Interaction Nausea | | Zocor Combivir Lithium Carbonate Zyprexa | PS SS SS SS | Merck & Co., Inc | ORAL ORAL ORAL |
| UNKNOWN | | Therapeutic Agent | | Bactrim | SS | | |

UNKNOWN Toxicity Sustiva SS
UNKNOWN Vomiting Concerta SS

Date:11/22/04ISR Number: 4508976-9Report Type:Direct Company Report #CTU 232608
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|----------|------|--------------|-------|
| Hospitalization - 40 MG ONCE A Initial or Prolonged DAY ORAL | | Agitation Convulsion Mental Status Changes | | Metadate | PS | Celltech | ORAL |

Date:11/22/04ISR Number: 4678444-2Report Type:Direct Company Report #CTU 241173
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|------------|------|--------------|-------|
| Dose | | Headache Pharmaceutical Product Complaint | | Ritalin Sr | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/23/04ISR Number: 4507774-XReport Type:Expedited (15-DaCompany Report #CA-JNJFOC-20041103919

Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depressed Mood | | Concerta | PS | | |
| | | Suicidal Ideation | | | | | |

Date:11/23/04ISR Number: 4507846-XReport Type:Expedited (15-DaCompany Report #IE-JNJFOC-20041103335

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Concerta | PS | | |
| OROPHARINGEAL | | 1 DAY | | | | | |
| | | Suicide Attempt | | | | | |

Date:11/23/04ISR Number: 4507847-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20041104644

Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Eosinophilia | | Concerta | PS | | |
| UNKNOWN | | | | | | | |

Date:11/23/04ISR Number: 4507848-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041104893

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Accommodation Disorder | | Concerta | PS | | |
| OROPHARINGEAL | | Angle Closure Glaucoma | | Biaxin | C | | |
| | | Treatment Noncompliance | | Plaquenil | C | | |
| | | Vision Blurred | | Timoptic | C | | |

Date:11/24/04ISR Number: 4509680-3Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20041103335

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Concerta | PS | | |
| OROPHARINGEAL | | 1 DAY | | | | | |
| | | Suicide Attempt | | | | | |

Date:11/24/04ISR Number: 4509681-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20041104644
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Eosinophilia | | Concerta | PS | | |
| UNKNOWN | | | | | | | |

Date:11/24/04ISR Number: 4509682-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041104893
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Accommodation Disorder | | Concerta | PS | | |
| OROPHARINGEAL | | Angle Closure Glaucoma | | Biaxin | C | | |
| | | Vision Blurred | | Plaquenil | C | | |
| | | | | Timoptic | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/24/04ISR Number: 4509718-3Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20041103919
 Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depressed Mood Depression Suicidal Ideation | | Concerta | PS | | |

Date:11/24/04ISR Number: 4510046-0Report Type:Expedited (15-DaCompany Report #PHRM2004FR03414
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Drug Ineffective | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 5 mg, BID | | Hypertonia Loss Of Consciousness | | | | | |

Date:11/24/04ISR Number: 4512916-6Report Type:Direct Company Report #CTU 232995
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|---------------|------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| 20 MG 5X A | | Abnormal Behaviour Agitation | | Ritalin (Methylphenidate) | PS | | |
| DAY | | Disturbance In Attention | | | | | |
| 10 MG 1X A | | Drug Effect Decreased Drug Tolerance Decreased | | Ritalin (Methylphenidate) | SS | | |
| DAY | | Feeling Abnormal Negativism | | | | | |

Date:11/26/04ISR Number: 4515332-6Report Type:Expedited (15-DaCompany Report #HQWYE740903AUG04
 Age:55 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------|---|------|--------------|-------|
| SEE IMAGE | | Agitation Alopecia Anhedonia Anxiety | Consumer | Effexor (Venlafaxine Hydrochloride, Capsule Extended Release) | PS | | |
| 500 MG | | Confusional State Crying | | Depakote (Valproate Semisodium) | SS | | |
| SIX (5 MG) | | Depression Diarrhoea Disease Recurrence | | Dexedrine (Dexamfetamine Sulfate) | SS | | |
| TABS MORNING AND AFTERNOON | | Disturbance In Attention Drug Withdrawal Syndrome | | | | | |
| 100 MG 3 X PER 1 DAY, ORAL | | Fatigue Headache Hyperhidrosis Irritability Middle Insomnia | | Effexor (Venlafaxine Hydrochloride, Tablet) | SS | | ORAL |
| SEE IMAGE | | Mood Swings | | Geodon (Ziprasidone) | SS | | |
| 0.5 MG IN THE AFTERNOON, 1 MG HS | | Overdose Panic Attack Serotonin Syndrome Social Avoidant Behaviour Suicidal Ideation | | Klonopin (Clonazepam) | SS | | |
| SEE IMAGE | | | | Remeron (Mirtazapine) | SS | | |
| | | | | Ritalin (Methylphenidate Hydrochloride) | SS | | |

Other
OROPHARINGEAL

Condition Aggravated

Concerta

PS

Depression
Irritability

Date:11/29/04ISR Number: 4511955-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20041106157
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | | Concerta | PS | | |
| OROPHARINGEAL | | Pain In Extremity | | | | | |

Date:11/30/04ISR Number: 4518279-4Report Type:Expedited (15-DaCompany Report #MK200411-0248-1
Age:22 YR Gender:Male I/FU:I

| Outcome | PT |
|----------------------|---------------------------|
| Hospitalization - | Agitation |
| Initial or Prolonged | Aspartate |
| | Aminotransferase |
| | Increased |
| | Blood Bilirubin Increased |
| | Blood Creatine |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Phosphokinase Increased Disturbance In Attention Dyskinesia Heart Rate Increased | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---|---------------|---|------|--------------|-------|
| 20MG, TID | 14 YR | Logorrhoea Nausea Tremor | Literature | Methylphenidate Hcl Tabs, Usp 20mg. | PS | | |
| 20MG, 20MG BID | | | | Dextroamphetamine Mixed Salts, Usp 20mg | SS | | |
| | | | | Escitalopram | C | | |

Date:12/01/04ISR Number: 4514866-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041105442
Age: Gender:Male I/FU:I

| Outcome Dose Other OROPHARINGEAL | Duration | PT Abnormal Behaviour 1 DAY Bruxism Formication Hallucination Hallucination, Visual Heart Rate Increased Movement Disorder Muscle Twitching Mydriasis Paranoia Screaming Self Injurious Behaviour Tremor | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|----------|------|--------------|-------|
| | | | Consumer | Concerta | PS | | |

Date:12/01/04ISR Number: 4516244-4Report Type:Direct Company Report #CTU 233316
Age: Gender:Male I/FU:I

| Outcome Dose Other 10 MG PO Q 4 | Duration | PT Drug Ineffective | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------------|---------------|---------------|------|--------------|-------|
| | | | | Ritalin 10 Mg | PS | | ORAL |

Date:12/02/04ISR Number: 4516466-2Report Type:Expedited (15-DaCompany Report #PHBS2004JP13956
 Age:74 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|------------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Eye Pain | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 30 mg/d | | Hyperthyroidism | | | | | |
| | | Inflammation | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| UNK, UNK | | Oropharyngeal Swelling | | | | | |
| | | Pharyngolaryngeal Pain | | Paxil | C | | ORAL |
| 30 mg/d | | | | | | | |
| | | Pyrexia | | Digoxin | C | | |
| | | Tonsillar Disorder | | Vasolan | C | | |
| 2 DF/d | | | | | | | |
| | | Tonsillar Hypertrophy | | Famotidine | C | | |
| 400 mg/d | | | | Hypen | C | | |

Date:12/02/04ISR Number: 4516467-4Report Type:Expedited (15-DaCompany Report #PHBS2004DE14649
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Petechiae | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | | Schamberg'S Disease | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/02/04ISR Number: 4516468-6Report Type:Expedited (15-DaCompany Report #PHBS2004JP15644
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---------------------------|---------------|---------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | | Ritalin | PS | Novartis Sector: | |
| | | Calculus Ureteric | | | | Pharma | ORAL |
| 70 to 80 | | | | | | | |
| tablets | 1440 MIN | Gastrointestinal Disorder | | | | | |
| | | Intentional Misuse | | | | | |
| | | Suicide Attempt | | | | | |

Date:12/03/04ISR Number: 4517848-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041200001
Age:4 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Accidental Overdose | | Concertra | PS | | |
| OROPHARINGEAL | | No Adverse Drug Effect | | | | | |

Date:12/03/04ISR Number: 4519745-8Report Type:Direct Company Report #CTU 233546
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| | | Drug Ineffective | | Ritalin Sr (Name | | | |
| | | Pharmaceutical Product | | Brand) | PS | | ORAL |
| 20 MG 2 TAB | | | | | | | |
| | | Complaint | | | | | |
| PO Q AM | | | | | | | |

Date:12/06/04ISR Number: 4519139-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041106847
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Optic Neuritis | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| Initial or Prolonged | | | | | | | |

Date:12/06/04ISR Number: 4519667-2Report Type:Expedited (15-DaCompany Report #PHNR2004AU01418
Age:8 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Urticaria Wheezing | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/day | | | | | | | |

Date:12/06/04ISR Number: 4520872-XReport Type:Direct Company Report #CTU 233720
Age:25 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|---------------|------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Erectile Dysfunction Libido Decreased | | Concerta 100 Mg One Daily | PS | | ORAL |
| ONE QD PO | | | | | | | |

Date:12/06/04ISR Number: 4520910-4Report Type:Expedited (15-DaCompany Report #L04-USA-07403-28
Age:58 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--------------------------------------|---|----------------|--------------|-------|
| Dose | | | | | | | |
| Death | | Completed Suicide Multiple Drug Overdose | Literature Health Professional | Citalopram Risperidone (Risperidone) Methylphenidate | PS SS SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/07/04ISR Number: 4519790-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041105801
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Deafness | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:12/07/04ISR Number: 4519994-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041105442
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | 1 DAY | | | | | |
| | | Bruxism | | | | | |
| | | Dyskinesia | | | | | |
| | | Formication | | | | | |
| | | Hallucinations, Mixed | | | | | |
| | | Heart Rate Increased | | | | | |
| | | Intentional Self-Injury | | | | | |
| | | Muscle Twitching | | | | | |
| | | Mydriasis | | | | | |
| | | Paranoia | | | | | |
| | | Personality Change | | | | | |
| | | Tremor | | | | | |

Date:12/07/04ISR Number: 4519995-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041201121
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | | | Lamictal | C | | |
| | | | | Seroquel | C | | |

Date:12/07/04ISR Number: 4522140-9Report Type:Expedited (15-DaCompany Report #CEL-2004-01867-ROC
 Age:21 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--------------------------------|---|------|--------------|-------|
| Death | | Blood Bicarbonate Decreased | Literature Health Professional | Methylphenidate Tablets (Unspecified) (Methylphenidate Hydrochloride) | PS | | ORAL |
| PO | | Blood Potassium Increased | | Aspirin (Acetylsalicylic Acid) | SS | | ORAL |
| PO | | Cardiac Arrest Completed Suicide | | | | | |
| PO | | Grand Mal Convulsion Intentional Misuse | | Pseudoephedrine (Pseudoephedrine) | SS | | ORAL |
| PO | | Therapeutic Agent | | Diet Solution | SS | | ORAL |
| PO | | Toxicity | | | | | |

Date:12/07/04ISR Number: 4523196-XReport Type:Direct Company Report #CTU 233738
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|---------------|-------------------------|------|--------------|-------|
| Dose | | Drug Ineffective | | Ritalin Sr (Brand Name) | PS | | ORAL |
| 20 MG 2 TAB | | Pharmaceutical Product | | | | | |
| PO QAM | | Complaint | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/08/04ISR Number: 4521127-XReport Type:Expedited (15-DaCompany Report #US-ROCHE-387925
 Age:29 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|----|---|----------|------|--------------|-------|
| Hospitalization - UNKNOWN | | | Chest Discomfort | Xenical | PS | Roche | |
| Initial or Prolonged | | | Hyperhidrosis Nausea Skin Warm Tachycardia Vomiting | Concerta | SS | | ORAL |

Date:12/08/04ISR Number: 4523236-8Report Type:Direct Company Report #CTU 233929
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|----|---|---------|------|--------------|-------|
| 10 MG 1 1/2 QID | | | Abnormal Behaviour Pharmaceutical Product Complaint | Ritalin | PS | | |

Date:12/09/04ISR Number: 4521840-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041008038
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--------------|----|------------------------------|----------|------|--------------|-------|
| Hospitalization - OROPHARINGEAL | | | Arrhythmia | Concerta | PS | | |
| Initial or Prolonged OROPHARINGEAL | | | Atrioventricular Block | Concerta | SS | | |
| Other OROPHARINGEAL | 36mg+18mg so | | Second Degree Bradycardia | Concerta | SS | | |
| dosage could be adjusted at home as needed. | | | | | | | |
| | | | Electrocardiogram Qt | | | | |
| | | | Prolonged | | | | |
| | | | Heart Rate Decreased | | | | |

Heart Rate Increased

Date:12/09/04ISR Number: 4523398-2Report Type:Direct Company Report #CTU 234028
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|------------------------|---------------|------|--------------|-------|
| Dose | | | | Ritalin 10 Mg | PS | | |
| RITALIN 25 MG | | | Drug Ineffective | | | | |
| (OA,12P, | | | Pharmaceutical Product | | | | |
| 20MG) | | | Complaint | | | | |

Date:12/10/04ISR Number: 4523062-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041200135
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------|---------------|----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | |
| Other | | | | Ritalin | SS | | |
| OROPHARINGEAL | | 6 YR | | | | | |
| OROPHARINGEAL | | 6 YR | | | | | |

Date:12/10/04ISR Number: 4523063-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20041200468
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|----------------------|----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | |
| Other | | | | | | | |
| UNKNOWN | | | Bruxism | | | | |
| | | | Dyskinesia | | | | |
| | | | Hallucination | | | | |
| | | | Heart Rate Increased | | | | |
| | | | Muscle Contracture | | | | |
| | | | Posture Abnormal | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/10/04ISR Number: 4679547-9Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 243013

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--|---------------|-----------------|------|--------------|-------|
| 10 MG PO @ 3:00PM | | Drug Effect Decreased Therapeutic Response Unexpected With Drug Substitution | | Methylphenidate | PS | | ORAL |

Date:12/13/04ISR Number: 4526166-0Report Type:Direct
Age:15 YR Gender:Male I/FU:I

Company Report #CTU 234127

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------|----------|---|---------------|-------------------------|------|--------------|-------|
| 20 MG 2 TAB PO QAM | | Drug Ineffective Pharmaceutical Product Complaint | | Ritalin Sr (Name Brand) | PS | | ORAL |

Date:12/14/04ISR Number: 4526725-5Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20041201336
Age:15 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|---------------|--------------------|---------|--------------|-------|
| OROPHARINGEAL UNKNOWN | | Abdominal Pain 233 DAY Aggression | | Concerta Zyrlex | PS C | | |
| UNKNOWN | | Anorexia | | Seretide Diskus | C | | |
| UNKNOWN | | Suicidal Ideation | | Seretide Diskus | C | | |

Date:12/14/04ISR Number: 4527317-4Report Type:Direct
Age:11 YR Gender:Male I/FU:I

Company Report #CTU 234265

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|------|----------|------------------|---------------|------------------|------|--------------|-------|
| | | | Drug Ineffective | | Adderall Xr 20mg | PS | | |
| ONCE DAILY | | | | | Concerta 27mg | SS | | |
| ONCE DAILY | | | | | | | | |

Date:12/14/04ISR Number: 4528888-4Report Type:Expedited (15-DaCompany Report #CEL-2004-02101-SLO
Age:8 YR Gender:Female I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------|----------|---|-----------------------------|---|------|--------------|-------|
| Other Required Intervention to Prevent Permanent Impairment/Damage | | | Skin Discolouration Trance Tremor | Foreign Health Professional | Equasym 5mg (Methylphenidate Hydrochloride) | PS | | |

Date:12/14/04ISR Number: 4529701-1Report Type:Expedited (15-DaCompany Report #MK200412-0247-1
Age:12 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|------|----------|---|---------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | | Aphasia Cerebral Arteritis Cerebral Artery Occlusion Cerebral Artery Stenosis Cerebral Infarction Cerebrovascular Accident Hemiparesis Xanthochromia | Literature | Methylphenidate Hcl Tabs, Usp (Strength Unk) | PS | | |
| 10 MG, TWICE DAILY | | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/15/04ISR Number: 4527201-6Report Type:Expedited (15-DaCompany Report #PHBS2004CH15298
 Age:36 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|---------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged INTRA-ARTERIAL | 40 mg, | | | Ritalin | PS | Novartis Sector: Pharma | |
| ONCE/SINGLE | | Blood Creatine Phosphokinase Increased C-Reactive Protein Increased Extremity Necrosis Finger Amputation Hypoaesthesia Livedo Reticularis Lividity Medication Error Mobility Decreased Necrosis Oedema Peripheral Pain In Extremity Pallor Peripheral Coldness Peripheral Ischaemia Vasospasm White Blood Cell Count Increased | | | | | |

Date:12/15/04ISR Number: 4527213-2Report Type:Expedited (15-DaCompany Report #PHRM2004FR03632
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------|------|----------------------------|-------|
| Other | | | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | | Antinuclear Antibody Positive Cutaneous Lupus Erythematosis | | | | | |

Date:12/15/04ISR Number: 4527565-3Report Type:Expedited (15-DaCompany Report #PHNU2004DE04132
 Age:33 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Lichen Planus | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/day | | | | | | | |

Date:12/16/04ISR Number: 4528625-3Report Type:Expedited (15-DaCompany Report #PHBS2004JP16546
 Age:40 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-----------------------|---------------|---------------------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged UNKNOWN | | Aggression Anxiety | | Ritalin | PS | Novartis Sector: Pharma | |
| | | Apathy | | Clomipramine | SS | | |
| | | Emotional Distress | | Sulpiride | SS | | |
| | | Excitability | | Psychiatric Therapy | C | | |
| | | Fatigue | | | | | |
| | | Irritability | | | | | |
| | | Suicidal Ideation | | | | | |
| | | Suicide Attempt | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/16/04ISR Number: 4528656-3Report Type:Expedited (15-DaCompany Report #PHBS2004JP16550
 Age:22 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|-----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged UNKNOWN | | Anxiety Irritability | | Ritalin | PS | Novartis Sector: Pharma | |
| | | Personality Disorder Suicide Attempt | | Triazolam | C | | |

Date:12/16/04ISR Number: 4530347-XReport Type:Direct Company Report #CTU 234448
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|-------------------------------------|---------------|------------------|------|--------------|-------|
| ONE TABLET, TID | | Agitation | | Ritalin 16mg Po | PS | | ORAL |
| ONE TAB, TID | | Pharmaceutical Product Complaint | | Ritalin 20 Mg Po | SS | | ORAL |
| ONE TAB, HS | | | | Buspar 10mg Po | SS | | ORAL |
| 0.1 MG | | | | Catapres | SS | | |

Date:12/17/04ISR Number: 4530562-5Report Type:Direct Company Report #CTU 234566
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------------------|---------------|---------------|------|--------------|-------|
| Life-Threatening DAILY | | Abnormal Behaviour | | Prozac 15mg | PS | | |
| Hospitalization - DAILY Initial or Prolonged | | Suicidal Ideation | | Concerta 35mg | SS | | |

Date:12/20/04ISR Number: 4531857-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041201688
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Other | | Deafness Neurosensory | | Concerta | PS | | |
| OROPHARINGEAL | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | Ritalin | C | | |

Date:12/20/04ISR Number: 4531858-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041202130
 Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Other | | Leukocytosis | | Concerta | PS | | |
| OROPHARINGEAL | | Thrombocytopenia | | Oralvac | C | | |
| UNKNOWN | | | | | | | |

Date:12/20/04ISR Number: 4531859-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041202143
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Other | | Abdominal Discomfort | | Concerta | PS | | |
| OROPHARINGEAL | | Asthenia | | Concerta | SS | | |
| OROPHARINGEAL | | Hypoaesthesia | | Concerta | SS | | |
| OROPHARINGEAL | | Sleep Disorder | | Concerta | SS | | |
| OROPHARINGEAL | | Tic | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/20/04ISR Number: 4531860-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041204347
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Coma Convulsion Drug Abuser | | Concerta | PS | | NASAL |

Date:12/20/04ISR Number: 4536911-6Report Type:Expedited (15-DaCompany Report #MK200401-0144-2
 Age:48 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|--------------------------------------|--|----------------|--------------|-------|
| Hospitalization - Initial or Prolonged 10 MG, TID 600 MG/DAY FOR THREE WEEKS PRIOR TO EVENT 10 MG/DAY FOR FOUR WEEKS PRIOR TO EVENT | | Back Pain Convulsion Depressed Level Of Consciousness Drug Withdrawal Syndrome Insomnia Muscle Spasms Overdose Postictal State Self-Medication Serotonin Syndrome | Literature Health Professional | Methylphenidate Hcl Tabs, Usp 10mg Venlafaxine Zolpidem | PS SS SS | | |

Date:12/21/04ISR Number: 4532656-7Report Type:Expedited (15-DaCompany Report #PHBS2004JP14746
 Age:37 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---------------------------------|---------------|---------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged 60 mg/day | | Aggression Confusional State | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

| | | | | | | |
|-----------|-----|-----|----------------------------------|-------------|---|------|
| 50 mg/d | 640 | DAY | Depressed Level Of Consciousness | Depromel | C | ORAL |
| 30 mg/day | 627 | DAY | Drug Dependence | Tetramide | C | ORAL |
| 15 mg/d | 627 | DAY | Intentional Misuse | Lexotan | C | ORAL |
| 0.5 mg/d | | | Therapeutic Agent | Halcion | C | ORAL |
| 4 mg/d | | | Toxicity | Silece | C | ORAL |
| 1 DF/d | | | | Vegetamin A | C | ORAL |

Date:12/21/04ISR Number: 4532664-6Report Type:Expedited (15-DaCompany Report #PHEH2004US13049
Age: Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|------------|------|----------------------------|-------|
| Other | | Loss Of Consciousness | | Ritalin La | PS | Novartis Sector: Pharma | |

Date:12/21/04ISR Number: 4532695-6Report Type:Expedited (15-DaCompany Report #PHBS2004BE16960
Age:48 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|----------|------|----------------------------|-------|
| Life-Threatening Hospitalization - 1440 MIN Initial or Prolonged | | Anuria Blood Creatine Phosphokinase Increased Disinhibition Haemodialysis Intentional Misuse Renal Failure Acute Rhabdomyolysis Self Mutilation | | Ritaline | PS | Novartis Sector: Pharma | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/21/04ISR Number: 4532696-8Report Type:Expedited (15-DaCompany Report #PHEH2004US13313
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | | | | | | | |

Date:12/21/04ISR Number: 4533553-3Report Type:Expedited (15-DaCompany Report #PHNU2004DE03580
Age:4 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|-----------|----------|---------------------------------------|--------------------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | 5 mg, BID | 50400MIN | Alanine Aminotransferase Increased | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| Other | | | Aspartate Aminotransferase | Antineoplastic Agents | SS | | |
| UNKNOWN | | | | | | | |
| UNKNOWN | Unknown | | Increased | Methotrexat | C | | |
| Attention Deficit/Hyperactivity Disorder Blood Bilirubin Increased Blood Creatine Phosphokinase Increased Drug Effect Decreased Drug Ineffective Gamma-Glutamyltransferase Increased Transaminases Increased Vomiting Weight Decreased | | | | | | | |

Date:12/21/04ISR Number: 4537874-XReport Type:Expedited (15-DaCompany Report #MK200412-0170-1
Age:17 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|----|----------------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | | Literature Health | Methylphenidate Hcl | PS | Usp | |
| Intentional Misuse Overdose | | | | | | | |

Date:12/21/04ISR Number: 4537903-3Report Type:Expedited (15-DaCompany Report #MK200412-0173-1
Age:58 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|--------------------------------------|--|----------------|--------------|-------|
| Death | | Completed Suicide Intentional Misuse | Literature Health Professional | Methylphenidate Hcl Citalopram Risperidone | PS SS SS | Usp | |

Date:12/22/04ISR Number: 4534208-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041205340
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------|---------------|----------------------|----------|--------------|-------|
| Hospitalization - OROPHARINGEAL Initial or Prolonged OROPHARINGEAL | | Aggression | | Concerta Concerta | PS SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/22/04ISR Number: 4535956-XReport Type:Direct
 Age: Gender:Female I/FU:I

Company Report #CTU 234929

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| 5 M, 3 TABS | | Abdominal Pain Upper | | Generic Ritalin | PS | | ORAL |
| PO TID | | Depressed Level Of Consciousness Disorientation Disturbance In Attention Dizziness Drug Effect Decreased Educational Problem Headache Pharmaceutical Product Complaint | | | | | |

Date:12/22/04ISR Number: 4539362-3Report Type:Expedited (15-DaCompany Report #MK200412-0296-1
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------------------|------------------------|---------------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged 20 MG, DAILY | | Cerebellar Syndrome Paraesthesia | Foreign Literature | Methylphenidate Hcl Tabs, Usp 20mg | PS | | |
| | | | Health Professional | | | | |

Date:12/22/04ISR Number: 4539385-4Report Type:Expedited (15-DaCompany Report #2004AP03091
 Age:54 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------------------|------------------------|---------|------|--------------|-------|
| Death 250 MG DAILY | | Abnormal Behaviour | Foreign | Iressa | PS | | ORAL |
| Hospitalization - PO Initial or Prolonged 6 MG DAILY RC | | Delirium Incoherent | Health Professional | Seniran | SS | | |
| 10 MG DAILY | | Lung Adenocarcinoma | Other | Ritalin | SS | | ORAL |

| | | | | | |
|---------------|---------------------|-----------------|----|--|------|
| PO | Malignant Neoplasm | | | | |
| | Progression | Tryptanol | | | |
| | Mental Disorder | | | | |
| | Pain | /Aus/ | SS | | ORAL |
| 10 MG DAILY | | | | | |
| | Respiratory Arrest | | | | |
| PO | | | | | |
| | Respiratory Failure | Horizon | SS | | ORAL |
| 5 MG DAILY PO | | | | | |
| | Vomiting | Silece | SS | | ORAL |
| 1 MG DAILY PO | | | | | |
| | | Voltaren | C | | |
| | | Cerocral | C | | |
| | | Pariet | C | | |
| | | Rinderon | C | | |
| | | Depas | C | | |
| | | Blopress | C | | |
| | | Norvasc | C | | |
| | | Carboplatin | C | | |
| | | Taxol | C | | |
| | | Radiotherapy | C | | |
| | | Durotep Janssen | C | | |
| | | Anpec Dainippon | C | | |

Date:12/23/04ISR Number: 4536556-8Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20041204305
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Other | | Erectile Dysfunction | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/23/04ISR Number: 4537196-7Report Type:Expedited (15-DaCompany Report #PHEH2004US13049
Age:7 YR Gender:Unknown I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Loss Of Consciousness | | Ritalin La | PS | Novartis Sector: Pharma | |
| 20 mg, QD | | | | | | | |

Date:12/27/04ISR Number: 4538627-9Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20041103919
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depressed Mood | | Concerta | PS | | |
| OROPHARINGEAL Suicidal Ideation | | | | | | | |

Date:12/28/04ISR Number: 4539288-5Report Type:Expedited (15-DaCompany Report #PHBS2004JP03369
Age:25 Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged UNKNOWN | | Chorea | | Ritalin | PS | Novartis Sector: Pharma | |
| Imipramine C | | | | | | | |
| Pemoline C | | | | | | | |

Date:12/28/04ISR Number: 4539294-0Report Type:Expedited (15-DaCompany Report #PHBS2004JP17256
Age:72 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Pancytopenia | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| UNK, UNK | | | | | | | |
| Seroquel SS | | | | | | | |
| Tecipul C | | | | | | | |
| Sepazon C | | | | | | | |
| Amoban C | | | | | | | |

Date:12/28/04ISR Number: 4539718-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041105056
Age:48 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|----------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | | | | | |
| OROPHARINGEAL | | | Condition Aggravated | Concerta | PS | | |
| | | | Depression | | | | |

Date:12/28/04ISR Number: 4539783-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041204158
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|--------------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | | | | | |
| OROPHARINGEAL | | | Cerebrovascular Disorder | Concerta | PS | | |
| | | | Hallucination | | | | |

Date:12/28/04ISR Number: 4541013-9Report Type:Expedited (15-DaCompany Report #CEL-2004-02187-SLO
Age:5 YR Gender:Male I/FU:I

Outcome
Other
Required
Intervention to
Prevent Permanent

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Impairment/Damage

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------|-----------------------------|--|------|--------------|-------|
| 25MG, TWICE | | Neutropenia | Foreign Health Professional | Equasym (Strength Unspecified) (Methylphenidate Hydrochloride) | PS | | |
| DAILY, ROUTE | | | | | | | |
| UNKNOWN | | | | | | | |

Date:12/28/04ISR Number: 4554624-1Report Type:Periodic Company Report #PHEH2004US11665
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------|---------------------|--|------|--------------|-------|
| Dose Other | | Psychotic Disorder | Health Professional | Ritalin La (Methylphenidate Hydrochloride) Extended Release Capsules | PS | | |

Date:12/28/04ISR Number: 4554626-5Report Type:Periodic Company Report #PHEH2004US12841
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--|---------------|--|------|--------------|-------|
| Dose Other | | Drug Withdrawal Syndrome Sleep Disorder | Consumer | Ritalin La (Methylphenidate Hydrochloride) Extended Release Capsules | PS | | ORAL |

50 MG, QD,

ORAL

| | | | |
|------------------------------------|----|--|--|
| Unspecified Medications For Adhd() | SS | | |
|------------------------------------|----|--|--|

Date:12/28/04ISR Number: 4554629-0Report Type:Periodic Company Report #PHEH2004US09321
Age:11 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|----------------------------------|---------------|--|--------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion Petit Mal Epilepsy | Consumer | Ritalin La (Methylphenidate Hydrochloride) Extended Release Capsules | PS | | ORAL |
| 20 MG, QD, ORAL | | | | Depakote (Valproate Semisodium) Klonopin (Clonazepam) | C C | | |

Date:01/03/05ISR Number: 4544168-5Report Type:Direct Company Report #CTU 235451
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|---|---------------|----------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Pharmaceutical Product Complaint | | Ritalin Sr (Name Brand) | PS | | ORAL |
| 20 MG 2 TAB PO Q AM | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/03/05ISR Number: 4545209-1Report Type:Direct
 Age:11 YR Gender:Male I/FU:I

Company Report #CTU 235472

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | Adderall Xr 20 Mg | PS | | |
| 1 DAILY | | Drug Ineffective | | Concerta 27 Mg | SS | | |
| 1 DAILY | | | | | | | |

Date:01/04/05ISR Number: 4543940-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041207073
 Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | |
| Other | | Transient Psychosis | | Singulair | C | | |
| OROPHARINGEAL | | | | Clarinox | C | | |
| | | | | Flonase | C | | |

Date:01/04/05ISR Number: 4545747-1Report Type:Direct
 Age: Gender:Male I/FU:I

Company Report #CTU 235597

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------------|---------------|---------------|------|--------------|-------|
| Dose | | | | Ritalin 10 Mg | PS | | ORAL |
| Other | | Drug Ineffective | | | | | |
| 10 MG PO Q 4 | | Pharmaceutical Product | | | | | |
| PRN | | Complaint | | | | | |

Date:01/05/05ISR Number: 4545272-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041207524
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | |
| Hospitalization - | | Intestinal Obstruction | | | | | |
| OROPHARINGEAL | | | | | | | |
| Initial or Prolonged | | | | | | | |

Date:01/07/05ISR Number: 4547171-4Report Type:Expedited (15-DaCompany Report #PHBS2004JP03369
Age:25 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--------|---------------|------------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged UNKNOWN | | Chorea | | Ritalin | PS | Novartis Sector: Pharma | |
| | | | | Imipramine | C | | |
| | | | | Pemoline | C | | |

Date:01/07/05ISR Number: 4547214-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041201688
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|-----------------------|---------------|--------------------|------|--------------|-------|
| Other OROPHARINGEAL | | Deafness Neurosensory | | Concerta | PS | | |
| OROPHARINGEAL | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | Ritalin | C | | |
| UNKNOWN | | | | Berotec Spray | C | | |
| UNKNOWN | | | | Symbiocord Inhaler | C | | |

Date:01/10/05ISR Number: 4549112-2Report Type:Expedited (15-DaCompany Report #PHEH2005US00508
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|---------|------|----------------------------|-------|
| Other | | Neurological Symptom | | Ritalin | PS | Novartis Sector: Pharma | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/10/05ISR Number: 4549113-4Report Type:Expedited (15-DaCompany Report #PHBS2004BR10729
 Age:6 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| 1 DF, QD | | Immune System Disorder | | | | | |
| | | Pharyngitis | | Ritalina | SS | Novartis Sector: Pharma | ORAL |
| 2 DF/day | | Pneumonia | | | | | |
| | | Pyrexia | | Ritalina | SS | Novartis Sector: Pharma | ORAL |
| 0.5 DF, QD | | | | | | | |
| | | | | Tegretol | C | | ORAL |
| 200 mg, BID | | | | | | | |
| | | | | Tegretol | C | | ORAL |
| 15 ml/d | | | | | | | |

Date:01/10/05ISR Number: 4566148-6Report Type:Direct Company Report #CTU 236077
 Age:51 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Headache | | Methylphenidate | PS | | ORAL |
| 10 MG 1/2 UP | | | | | | | |
| TO 6 X /D PO | | | | | | | |

Date:01/10/05ISR Number: 4566152-8Report Type:Direct Company Report #CTU 236079
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Disturbance In Attention | | Ritalin | PS | | |
| 30 MG AM AND | | | | | | | |
| PM | | Mood Swings | | | | | |

Date:01/10/05ISR Number: 4567646-1Report Type:Direct Company Report #CTU 236063
 Age: Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|----------------------------|------|--------------|-------|
| 20 MG | | Abnormal Behaviour Affective Disorder | | Ritalin Sr (Name Brand) | PS | | ORAL |
| AM-LUNCH- 4 | | Pharmaceutical Product | | | | | |
| PM ORALLY | | Complaint | | | | | |

Date:01/11/05ISR Number: 4549589-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20041200468
Age: Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|----------|------|--------------|-------|
| Other UNKNOWN | | Bruxism | Health | Concerta | PS | | |
| | | Dyskinesia Hallucination Heart Rate Increased Muscle Contracture Posture Abnormal | Professional | | | | |

Date:01/12/05ISR Number: 4563738-1Report Type:Direct Company Report #CTU 236492
Age:14 YR Gender:Male I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------|---------------|---------|------|--------------|-------|
| Hospitalization - 20 MG SR 2 Initial or Prolonged TABS DAILY | | Drug Ineffective | | Ritalin | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/12/05ISR Number: 4563820-9Report Type:Direct
Age:13 YR Gender:Male I/FU:I

Company Report #CTU 236263

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------------|----------|-------------------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Ritalin | PS | | ORAL |
| 75 MG PO BID/ ONGOING THERAPY | | Pharmaceutical Product Complaint | | | | | |

Date:01/12/05ISR Number: 4565067-9Report Type:Direct
Age:51 YR Gender:Female I/FU:I

Company Report #CTU 236305

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|----------|---------------|-----------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Headache | | Methylphenidate | PS | | ORAL |
| 10 MG PO 1/2 UP TO 6 X/D | | | | | | | |

Date:01/14/05ISR Number: 4552662-6Report Type:Expedited (15-DaCompany Report #PHEH2005US00555
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged 10 mg, UNK | | Abnormal Behaviour Aggression | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 40 mg, QD | | Bipolar Disorder | | Strattera | C | | |
| 0.5 mg, BID | | Fight In School | | Risperdal | C | | |

Date:01/14/05ISR Number: 4568862-5Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 236886

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Methylphenidate 20 | | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-------------|--------------|---------------|-----------|------|----------------------------|-------|
| Death | 20 mg, BID | Drug Abuser | | Ritalin | PS | Novartis Sector: Pharma | |
| | 200 mg, QHS | Overdose | | Clozapine | SS | | |
| | 50 mg, QD | Sudden Death | | Compazine | SS | | |
| | (50mg QAM) | | | Percocet | SS | | |
| | 1 mg, TID | | | Paxil | C | | |
| | | | | Ativan | C | | |

Date:01/19/05ISR Number: 4555851-XReport Type:Expedited (15-DaCompany Report #PHEH2004US04593
Age:72 YR Gender:Female I/FU:F

Date:01/20/05ISR Number: 4559976-4Report Type:Direct Company Report #CTU 237318
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|-----------|--|---------------|--------------------------|------|--------------|-------|
| ONE AT 630, | 10, 1 & 4 | Drug Effect Decreased Pharmaceutical Product Complaint | | Ritalin 20 Mg An 5 Mg | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/20/05ISR Number: 4559988-0Report Type:Direct
Age: Gender:Female I/FU:I

Company Report #CTU 237414

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------------|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| 10 MG 1 TID | | Abnormal Behaviour | | Ritalin | PS | | |
| 20 MG | | Anxiety | | Ritalin S.R. 20mg | SS | | |
| | | Crying | | | | | |
| | | Drug Intolerance | | | | | |
| | | Impulsive Behaviour | | | | | |

Date:01/21/05ISR Number: 4558673-9Report Type:Direct
Age: Gender: I/FU:I

Company Report #CTU 237641

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| | | Drug Effect Decreased | | Methylphenidate Hcl | PS | | |
| | | Pharmaceutical Product | | Ritalin | SS | | |
| | | Complaint | | | | | |

Date:01/21/05ISR Number: 4558674-0Report Type:Direct
Age: Gender: I/FU:I

Company Report #CTU 237642

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| | | Drug Effect Decreased | | Methylphenidate Hcl | PS | | |
| | | Pharmaceutical Product | | Ritalin | SS | | |
| | | Complaint | | | | | |

Date:01/21/05ISR Number: 4559213-0Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 237577

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------|----------|----------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| Required | | Anaemia | | Concerta 54 Mg | PS | | ORAL |
| 54 MG Q | | | | | | | |
| Intervention to | | Jaundice | | | | | |
| DAY ORAL | | | | | | | |

Prevent Permanent
10 MG Q DAY
Impairment/Damage
ORAL

Strattera 10 Mg SS ORAL

Date:01/21/05ISR Number: 4560726-6Report Type:Expedited (15-DaCompany Report #CEL-2005-00024-SLO
Age:25 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|-----------------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Agitation Intentional Misuse Suicide Attempt | Foreign Health Professional | Equasym 10mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| 100MG, ONCE, PO | | | | | | | |
| 20MG, ONCE, PO | | | | Cetirizine (Cetirizine) | SS | | ORAL |
| 1200MG, ONCE, PO | | | | Paracetamol (Paracetamol) | SS | | ORAL |
| 1600MG, ONCE, PO | | | | Ibuprofen (Ibuprofen) | SS | | ORAL |
| 2400 MG, ONCE, PO | | | | Ibuprofen (Ibuprofen) | SS | | ORAL |
| RECTAL | 2500 MG, | | | Paracetamol (Paracetamol) | SS | | |
| ONCE, RECTAL | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | |
|---------------------|-----------------------------|----|------|
| 400 MG, ONCE, PO | Rifun (Pantoprazole Sodium) | SS | ORAL |
| 8000MG, ONCE, PO | Cefalexin (Cefalexin) | SS | ORAL |

Date:01/21/05ISR Number: 4562891-3Report Type:Expedited (15-DaCompany Report #CAN-2005-0000232
Age:34 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------|---------------|--|------|--------------|-------|
| Death | | Blood Alcohol Increased | Foreign | Morphine | | | |
| Other | | Completed Suicide | Other | Sulfate(Morphine Sulfate) | PS | | |
| | | Dependence | | Codeine(Codeine) | | | |
| | | Drug Withdrawal Syndrome | | Other | SS | | |
| | | Injury Asphyxiation | | Ritalin(Methylphenidate Hydrochloride) | SS | | |
| | | Toxicologic Test Abnormal | | Acetaminophen(Paracetamol) | SS | | |
| | | | | Caffeine(Caffeine) | SS | | |
| | | | | Alcohol(Ethanol) | SS | | |

Date:01/24/05ISR Number: 4559085-4Report Type:Expedited (15-DaCompany Report #PHBS2005BR01169
Age:46 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|----------|------|-------------------------|-------|
| Other | | Self-Medication | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| | | Syncope | | | | | |

Date:01/24/05ISR Number: 4559311-1Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050103495
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Other
OROPHARINGEAL
Abdominal Pain Upper
5 MON
Bradycardia
Weight Decreased

Concerta PS

Date:01/24/05ISR Number: 4559312-3Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050103500
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Personality Disorder | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:01/25/05ISR Number: 4563104-9Report Type:Expedited (15-DaCompany Report #CAN-2005-0000232
Age:34 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------|--------------------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Completed Suicide | Foreign | Morphine Sulfate | | | |
| Other | | Dependence | Other | (Morphine Sulfate) | PS | | |
| | | Drug Withdrawal Syndrome | | Codeine (Codeine) | | | |
| | | Obstructive Airways | | Other | SS | | |
| | | Disorder | | Ritalin | | | |
| | | | | (Methylphenidate) | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hydrochloride) SS
 Acetaminophen
 (Paracetamol) SS
 Caffeine (Caffeine) SS
 Alcohol (Ethanol) SS

Date:01/26/05ISR Number: 4560887-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041106847
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----------------|---------------|----------|------|--------------|-------|
| Hospitalization - OROPHARINGEAL Initial or Prolonged | | Optic Neuritis | | Concerta | PS | | |

Date:01/26/05ISR Number: 4561214-3Report Type:Expedited (15-DaCompany Report #PHBS2005NO01113
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|---|---------------|---------|------|----------------------------|-------|
| Other 20 mg+20mg+10 mg | | Blood Pressure Increased Drug Ineffective Feeling Abnormal General Physical Condition Abnormal Pharmaceutical Product Complaint Renal Disorder | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:01/26/05ISR Number: 4561221-0Report Type:Expedited (15-DaCompany Report #PHBS2005BR01240
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---|---------------|----------|------|----------------------------|-------|
| Other 3 DF/day | | Body Height Increased Increased Appetite Weight Increased | | Ritalina | PS | Novartis Sector: Pharma | ORAL |

Date:01/27/05ISR Number: 4562535-0Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050103711
Age:19 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|--------------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | Drug Withdrawal Syndrome | Concerta | PS | | |
| OROPHARINGEAL | | | Mood Altered | | | | |
| | | | Road Traffic Accident | | | | |
| | | | Sudden Onset Of Sleep | | | | |

Date:01/27/05ISR Number: 4562536-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20041105442
Age: Gender:Male I/FU:I

| | |
|---------|-------------------------|
| Outcome | PT |
| Other | Abnormal Behaviour |
| | Aggression |
| | Bite |
| | Bruxism |
| | Dyskinesia |
| | Formication |
| | Hallucinations, Mixed |
| | Heart Rate Increased |
| | Intentional Self-Injury |
| | Muscle Twitching |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|---------------|----------|---|---------------|----------|------|--------------|-------|
| | | Mydriasis Paranoia Personality Change | Report Source | Product | Role | Manufacturer | Route |
| Dose | Duration | | | | | | |
| OROPHARINGEAL | | Screaming 1 DAY Tremor | | Concerta | PS | | |

Date:01/28/05ISR Number: 4563857-XReport Type:Expedited (15-DaCompany Report #PHBS2005BR01169
Age:46 YR Gender:Female I/FU:F

| | | | | | | | |
|---------|----------|---------|---------------|----------|------|----------------------------|-------|
| | | PT | Report Source | Product | Role | Manufacturer | Route |
| Outcome | Duration | | | | | | |
| Dose | | | | | | | |
| Other | | Syncope | | Ritalina | PS | Novartis Sector: Pharma | ORAL |

Date:01/28/05ISR Number: 4563858-1Report Type:Expedited (15-DaCompany Report #PHBS2005BR01240
Age:15 YR Gender:Male I/FU:F

| | | | | | | | |
|---------|----------|---|---------------|----------|------|----------------------------|-------|
| | | PT | Report Source | Product | Role | Manufacturer | Route |
| Outcome | Duration | | | | | | |
| Dose | | | | | | | |
| Other | | Body Height Increased Increased Appetite Weight Increased | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| | 3 DF/day | | | | | | |

Date:01/28/05ISR Number: 4563928-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050104165
Age:7 YR Gender:Male I/FU:I

| | | | | | | | |
|---------------|----------|----------------------------------|---------------|----------|------|--------------|-------|
| | | PT | Report Source | Product | Role | Manufacturer | Route |
| Outcome | Duration | | | | | | |
| Dose | | | | | | | |
| Other | | Osteochondrosis Osteonecrosis | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:01/28/05ISR Number: 4563929-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050104873
Age:16 YR Gender:Male I/FU:I

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|------|-------------|------------|---------------|-----------|------|--------------|-------|
| Other | | | Aggression | | Concerta | PS | | |
| UNKNOWN | | 2.5 tablets | Hepatitis | | | | | |
| of Concerta* | | | | | | | | |
| per day, one | | | | | | | | |
| in the | | | | | | | | |
| morning, one | | | | | | | | |
| UNKNOWN | | | | | Tegratol | C | | |
| UNKNOWN | | | | | Clozapine | C | | |
| UNKNOWN | | | | | Melatonin | C | | |
| UNKNOWN | | | | | Codeine | C | | |

Date:01/28/05ISR Number: 4563930-6Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040900021
Age: Gender:Male I/FU:F

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|------|----------|-------------|---------------|----------|------|--------------|-------|
| Other | | | Neutropenia | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | | |
| OROPHARINGEAL | | | | | | | | |

Date:01/28/05ISR Number: 4566484-3Report Type:Expedited (15-DaCompany Report #KII-2005-0014855
Age:27 YR Gender:Male I/FU:I

Outcome
Hospitalization -
Initial or Prolonged
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|-------------|---|--|--|------|--------------|-------|
| | | Agitation Bile Duct Obstruction Blood Pressure Diastolic Decreased | Study Health Professional Other | Oxycontin (Oxycodone Hydrochloride) Cr Tablet | PS | | |
| INTRAVENOUS | SEE TEXT | Cholecystitis Infective | | | | | |
| INTRAVENOUS | | Dehydration | | Cocaine (Cocaine) | SS | | |
| INTRAVENOUS | INTRAVENOUS | Dry Skin Dyskinesia Hyperpyrexia | | Methylphenidate (Methylphenidate) | SS | | |
| INTRAVENOUS | SEE TEXT | Lethargy | | | | | |
| INTRAVENOUS | | Liver Function Test Abnormal | | Acetaminophen W/Oxycodone | SS | | |
| INTRAVENOUS | SEE TEXT | Muscle Twitching | | | | | |
| INTRAVENOUS | | Pain Polysubstance Abuse Tachycardia Vomiting | | | | | |

Date:01/28/05ISR Number: 4575427-8Report Type:Direct Company Report #CTU 238478
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---|---------------|------------------------------|------|--------------|-------|
| Dose Other | | Drug Effect Decreased Pharmaceutical Product | | Ritalin (Methylphenidate) | PS | | ORAL |
| 15 MG PO BID | | Complaint | | | | | |

Date:01/31/05ISR Number: 4565039-4Report Type:Expedited (15-DaCompany Report #PHBS2005NL01519
Age: Gender:Male I/FU:I

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration Renal Failure Ritaline PS Novartis Sector: ORAL
Hospitalization - Initial or Prolonged 50 mg/d Pharma

Date:02/01/05ISR Number: 4567118-4Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20040304857
Age: Gender:Male I/FU:I

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration Haematuria Concerta PS
Other OROPHARINGEAL

Date:02/02/05ISR Number: 4567911-8Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050105128
Age:15 YR Gender:Male I/FU:I

Outcome PT Report Source Product Role Manufacturer Route
Dose Duration Anger Concerta PS
Death OROPHARINGEAL 14 MON
Completed Suicide
Injury Asphyxiation

Date:02/02/05ISR Number: 4571263-7Report Type:Expedited (15-DaCompany Report #MK200501-0177-1
Age:50 YR Gender:Female I/FU:I

Outcome PT
Other Abnormal Behaviour
Anger

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Convulsion Decreased Immune Responsiveness | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|-----------------------|--|----------------------------|--------------|-------|
| 100 MG, HS, PO 50MG IN 3 DOSES, TID | | Dysphoria Hypersomnia Nausea Overdose Somnolence Suicide Attempt Weight Increased | Foreign Literature | Pamelor 50 Mg Capsules Methylphenidate | PS SS | | ORAL |
| | | | | Fluoxetine Gabapentin Levetiracetam Midrin Pemoline Sumatriptan | C C C C C C | | |

Date:02/03/05ISR Number: 4571639-8Report Type:Direct Company Report #CTU 239105
Age: Gender:Male I/FU:I

| Outcome Dose Other | Duration | PT Pharmaceutical Product Complaint Therapeutic Response Decreased | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--|---------------|-----------------|------|--------------|-------|
| | | | | Methylphenidate | PS | | |

Date:02/03/05ISR Number: 4571714-8Report Type:Direct Company Report #CTU 239116
Age: Gender:Male I/FU:I

| Outcome Dose Other | Duration | PT Drug Ineffective Pharmaceutical Product Complaint | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|---------------|-----------------|------|--------------|-------|
| | | | | Methylphenidate | PS | | |

Date:02/03/05ISR Number: 4601309-9Report Type:Periodic Company Report #PHEH2004US11665
Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|------------------------|--|------|--------------|-------|
| Dose Other | | Psychotic Disorder | Health Professional | Ritalin La (Methylphenidate Hydrochloride) Extended Release Capsules | PS | | |

Date:02/03/05ISR Number: 4601312-9Report Type:Periodic Company Report #PHEH2004US12447
 Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---|--|------|--------------|-------|
| Dose Other | | Drug Abuser | Health Professional Company Representative | Ritalin (Methylphenidate Hydrochloride) Unknown | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/03/05ISR Number: 4601402-0Report Type:Periodic Company Report #PHEH2004US01330
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------|---------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hallucination | Consumer | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | |

40 MG

Date:02/03/05ISR Number: 4601404-4Report Type:Periodic Company Report #PHEH2004US01439
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|---|----------------------------------|--------------|-------|
| Dose Other | | Anxiety Confusional State Drug Abuser Fatigue Headache Lethargy | Consumer | Ritalin La(Methylphenidate Hydrochloride) Extended Release Capsules Accutane (Isotretinoin) Over The Counter Antihistamines (No Ingredients/Substances) | PS C C | | |

Date:02/03/05ISR Number: 4601406-8Report Type:Periodic Company Report #PHEH2004US02009
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------|------------------------|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Heart Rate Increased | Health Professional | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | |

Date:02/03/05ISR Number: 4601408-1Report Type:Periodic Company Report #PHEH2004US02260
 Age:71 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | | |
|-----------|---------------------------------|----------|---|--------|
| Other | Abdominal Pain Upper Depression | Consumer | Ritalin(Methylphenidate Hydrochloride) Tablet | PS |
| 60 MG, QD | | | Lexapro (Escitalopral Oxalate) Celexa (Citalopram Hydrobromide) | C C |

Date:02/03/05ISR Number: 4601410-XReport Type:Periodic Company Report #PHEH2004US02353
Age:18 YR Gender:Male I/FU:I

| | |
|----------------------|--------------------------------|
| Outcome | PT |
| Hospitalization - | Decreased Appetite |
| Initial or Prolonged | Depression |
| Other | Dissociative Identity Disorder |
| | Disturbance In Attention |
| | Learning Disorder |
| | Mental Impairment |
| | Nervousness |
| | Sleep Disorder |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Weight Decreased

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---------------|---|------|--------------|-------|
| 25 MG, BID, ORAL | | Consumer | Ritalin(Methylphenidate Hydrochloride) Tablet | PS | | ORAL |
| | | | Paxil (Paroxetine Hydrochloride) | C | | |

Date:02/03/05ISR Number: 4601414-7Report Type:Periodic Company Report #PHEH2004US04845
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------|--|---|-------------------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Hypertension | Health Professional Company Representative | Ritalin(Methylphenidate Hydrochloride) Vasotec (Enalapril Maleate) Lotrel (Amlodipine, Benazepril Hydrochloride) Hydrochlorothiazide (Hydrochlorothiazide) | PS C C C | | |

Date:02/03/05ISR Number: 4601421-4Report Type:Periodic Company Report #PHEH2004US08250
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|--|---|------|--------------|-------|
| Other | | Hypertension | Health Professional Company Representative | Ritalin La(Methylphenidate Hydrochloride) Extended Release Capsules | PS | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Health Professional | Ritalin(Methylphenidate Hydrochloride) | PS | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion Petit Mal Epilepsy | Consumer | Ritalin La(Methylphenidate Hydrochloride) Extended Release Capsules | PS | | ORAL |

20 MG, QD,

ORAL

Depakote (Valproate Semisodium) C
Klonopin (Clonazepam) C

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/04/05ISR Number: 4570146-6Report Type:Expedited (15-DaCompany Report #PHFR2005GB00763
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|---------------|-------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Rectal Haemorrhage | | Ritalin | PS | Novartis Sector: Pharma | |
| 45-65 mg/day | | | | Risperidone | C | | |

Date:02/04/05ISR Number: 4570358-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050106306
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Neutropenia | | Concerta | PS | | |
| OROPHARINGEAL | | 397 DAY | | | | | |

Date:02/04/05ISR Number: 4576175-0Report Type:Expedited (15-DaCompany Report #2004AP03091
Age:54 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Abnormal Behaviour | Foreign | Iressa | PS | | ORAL |
| 250 MG DAILY | | | | | | | |
| Hospitalization - | | Delirium | Health | | | | |
| PO | | | | | | | |
| Initial or Prolonged | | Malignant Neoplasm | Professional | Seniran | SS | | |
| 6 MG DAILY RC | | | | | | | |
| | | Progression | Other | Ritalin | SS | | ORAL |
| 10 MG DAILY | | | | | | | |
| | | Mental Disorder | | | | | |
| PO | | | | | | | |
| | | Non-Small Cell Lung | | Tryptanol | SS | | ORAL |
| 10 MG DAILY | | | | | | | |
| | | Cancer | | | | | |
| PO | | | | | | | |
| | | Pain | | Horizon | SS | | ORAL |
| 5 MG DAILY PO | | | | | | | |
| | | Respiratory Arrest | | Silece | SS | | ORAL |
| 1 MG DAILY PO | | | | | | | |
| | | Respiratory Failure | | Voltaren | C | | |
| | | Vomiting | | Cerocral | C | | |

| | | |
|--------------|-----------|-----------|
| Pariet | C | |
| Rinderon | C | |
| Depas | C | |
| Blopress | C | |
| Norvasc | C | |
| Carboplatin | C | |
| Taxol | C | |
| Radiotherapy | C | |
| Durotep | Janssen | C |
| Anpec | Dainippon | C |
| | | Janssen |
| | | Dainippon |

Date:02/08/05ISR Number: 4573699-7Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0527917A
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|---------|------|-----------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Paxil | PS | Glaxosmithkline | ORAL |
| | | | | Ritalin | SS | | |
| 20MG Three | | | | | | | |
| times per day | | | | | | | |

Date:02/08/05ISR Number: 4574951-1Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20041002525
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Subclavian Vein | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| 4 MON | | | | | | | |
| Thrombosis | | | | | | | |
| Thrombosis | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/08/05ISR Number: 4574952-3Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050103495
 Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | | Concerta | PS | | |
| OROPHARINGEAL | | 5 MON | | | | | |
| | | Anorexia | | | | | |
| | | Bradycardia | | | | | |
| | | Weight Decreased | | | | | |

Date:02/08/05ISR Number: 4577030-2Report Type:Expedited (15-DaCompany Report #CEL-2005-00094-ROC
 Age:32 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Gastrointestinal | Health | Methylphenidate 20 | | | |
| Initial or Prolonged | | Haemorrhage | Professional | Mg Er Tablets | | | |
| SEE IMAGE | | | | (Methylphenidate | PS | | |
| | | | | Hydrochloride) | | | |
| | | | | Amitriptyline | | | |
| | | | | (Amitriptyline) | C | | |
| | | | | Seroquel (Quetiapine | | | |
| | | | | Fumarate) | C | | |
| | | | | Depakote (Valproate | | | |
| | | | | Semisodium) | C | | |
| | | | | Lithium Er (Lithium) | C | | |

Date:02/08/05ISR Number: 4577626-8Report Type:Expedited (15-DaCompany Report #CEL-2005-00137-SLO
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|--------------|---------------|------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cardiomegaly | Foreign | Equasym | | | |
| Required | | | Consumer | (Methylphenidate | | | |
| Intervention to | | | | Hydrochloride) | PS | | |
| Prevent Permanent | | | | | | | |
| Impairment/Damage | | | | | | | |

Date:02/09/05ISR Number: 4575568-5Report Type:Expedited (15-DaCompany Report #PHBS2005IE01848
Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------------------------|---------------|------------------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | | Abnormal Behaviour Anger | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| Other UNKNOWN | | Convulsion Road Traffic Accident | | Valproate Sodium | C | | |

Date:02/09/05ISR Number: 4575673-3Report Type:Expedited (15-DaCompany Report #PHFR2005GB00752
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------|----------|---|---------------|-----------------|------|----------------------------|-------|
| Other 10 mg, BID | 11520MIN | Crying Hallucination, Visual Panic Reaction | | Methylphenidate | PS | Novartis Sector: Pharma | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/09/05ISR Number: 4577256-8Report Type:Expedited (15-DaCompany Report #2004AL000724
 Age:46 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|---|------|--------------|-------|
| Death | | Completed Suicide | Literature | Hydramine Cough | | | |
| Hospitalization - Initial or Prolonged | | Electrocardiogram Qrs Complex Prolonged Heart Rate Increased Multiple Drug Overdose | Health Professional | Syrup (Diphenhydramine Hydrochloride Cough Syrup) (Alpharma) | PS | Alpharma | ORAL |
| PO | | Respiratory Arrest Stupor | | Hydramine Elixir (Diphenhydramine Hydrochloride Elixir) (Alpharma) | SS | Alpharma | ORAL |
| PO | | | | Cyclobenzaprine | SS | | ORAL |
| PO | | | | Haloperidol | SS | | ORAL |
| PO | | | | Ibuprofen Oral Suspension Usp, 100 Mg/5 Ml (Otc) (Alpharma) | SS | Alpharma | ORAL |
| PO | | | | Ibuprofen Oral Suspension Usp, 100 Mg/5 Ml (Rx) (Alpharma) | SS | Alpharma | ORAL |
| PO | | | | Methylphenidate | SS | | ORAL |
| PO | | | | Cephalexin | SS | | ORAL |
| PO | | | | Naproxen | SS | | ORAL |
| PO | | | | Chlorzoxazone | SS | | ORAL |
| PO | | | | Ethanol | SS | | ORAL |

Date:02/09/05ISR Number: 4578254-0Report Type:Expedited (15-DaCompany Report #CEL-2004-01986-ROC
 Age:9 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--------------|----------------------------------|------------------------------|--|------|--------------|-------|
| Required Intervention to Prevent Permanent Impairment/Damage | 10MG ONCE PO | Diplopia Dyspnoea Wheezing | Consumer Health Professional | Metadate Cd Capsules 10 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:02/09/05ISR Number: 4578789-0Report Type:Direct Company Report #CTU 239971
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|-----------------------|------|--------------|-------|
| PO TID | | Agitation Euphoric Mood Pharmaceutical Product Complaint | | Ritalin Generic 10 Mg | PS | | ORAL |

Date:02/10/05ISR Number: 4577056-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050201578
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------|---------------|----------|------|--------------|-------|
| Other | | Optic Ischaemic Neuropathy | | Concerta | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/10/05ISR Number: 4577351-3Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0544815A
 Age:15 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----|--------------------------|---------|------|-----------------|-------|
| Dose Hospitalization - RESPIRATORY Initial or Prolonged (INHALATION) | | Blood Pressure Increased | Advair | PS | Glaxosmithkline | |
| | | Drug Interaction | | | | |
| | | Heart Rate Increased | Ritalin | SS | | |

Date:02/11/05ISR Number: 4578236-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050201579
 Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----|----------------------|-------------|------|--------------|-------|
| Dose Other OROPHARINGEAL | | Intraocular Pressure | Concerta | PS | | |
| | | Increased | Concerta | SS | | |
| | | | Paxil | C | | |
| | | | Nexium | C | | |
| | | | Allopurinol | C | | |
| | | | Verapamil | C | | |
| | | | Zyrtec | C | | |

Date:02/11/05ISR Number: 4578757-9Report Type:Expedited (15-DaCompany Report #PHBS2004JP17256
 Age:72 YR Gender:Female I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|---------|---------------------------|----------|------|----------------------------|-------|
| Dose Other 30 mg/d | | Anaemia Blood Alkaline | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| | | Phosphatase Increased | Rohypnol | SS | | ORAL |
| 2 mg/d | | Haemoglobin Decreased | Seroquel | SS | | ORAL |
| 30 mg/d | | Malaise | Tecipul | SS | | ORAL |
| 6 mg/d | 134 DAY | Pancytopenia | Sepazon | SS | | ORAL |
| 2 mg/d | 183 DAY | Platelet Count Decreased | Amoban | C | | |

Red Blood Cell Count
Decreased
White Blood Cell Count
Decreased

Date:02/11/05ISR Number: 4578758-0Report Type:Expedited (15-DaCompany Report #PHFR2005GB00791
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Crohn'S Disease | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:02/14/05ISR Number: 4580158-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050201578
Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Optic Ischaemic Neuropathy | | Concerta | PS | | |

Date:02/14/05ISR Number: 4588711-9Report Type:Direct Company Report #CTU 240307
Age: Gender:Male I/FU:I

| Outcome | PT |
|---|--|
| Hospitalization - Initial or Prolonged | Alcohol Withdrawal Syndrome Depression |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|---------------|--------------------|------|--------------|-------|
| ONE, DAILY | 9 DAY | Hyperhidrosis Mental Status Changes Pyrexia | | Concerta Tab 36 Mg | PS | | |
| ONE, DAILY | 9 DAY | Serotonin Syndrome Tremor | | Paxil Cr 75 Mg | SS | | |

Date:02/15/05ISR Number: 4587530-7Report Type:Expedited (15-DaCompany Report #C02-T-001
Age: Gender:Male I/FU:F

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|--------------------|----------|---|---------------|----------------------------------|------|--------------|-------|
| 1.5 TABLET, BID | | PT Pharmaceutical Product Complaint Sedation | Other | Methylphenidate Hydrochloride | PS | Usp | |

Date:02/15/05ISR Number: 4587532-0Report Type:Expedited (15-DaCompany Report #C03-T-061
Age: Gender: I/FU:F

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|------|----------|------------------------|------------------------|----------------------------------|------|--------------|-------|
| | | PT Drug Ineffective | Health Professional | Methylphenidate Hydrochloride | PS | Usp | |

Date:02/16/05ISR Number: 4583811-1Report Type:Expedited (15-DaCompany Report #PHBS2005GR02177
Age:15 YR Gender:Male I/FU:I

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|---------|------|----------------------------|-------|
| 10 mg/d | | Death Drowning Loss Of Consciousness | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:02/16/05ISR Number: 4583815-9Report Type:Expedited (15-DaCompany Report #PHBS2005NL02225
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Autism Depression | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 40 mg/d | | | | | | | |

Date:02/16/05ISR Number: 4583818-4Report Type:Expedited (15-DaCompany Report #PHFR2005GB00763
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--------------------|---------------|-------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Rectal Haemorrhage | | Ritalin | PS | Novartis Sector: Pharma | |
| 45-65 mg/day | | | | Risperidone | C | | |

Date:02/16/05ISR Number: 4588497-8Report Type:Direct Company Report #CTU 240608
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|---|---------------|----------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Conversion Disorder | | Methylphenidate Er (Concerta) | PS | | ORAL |
| 36 MG PO QAM (1 DOSE) | | Crying | | | | | |
| | | Insomnia | | Mirtazapine | C | | |
| | | Irritability | | Montelukast | C | | |
| | | Screaming | | Quetiapine | C | | |
| | | | | Budesonide | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/16/05ISR Number: 4588542-XReport Type:Direct
 Age:7 YR Gender:Male I/FU:I

Company Report #CTU 240609

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|----|---|--------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | Abnormal Behaviour Hallucination, Visual | Methylphenidate (Regular Release) | PS | | ORAL |
| 10 MG PO TID | | | Homicidal Ideation | | | | |
| (TITRATED UP | | | Paranoia | | | | |
| TO 30MG/DAY) | | | Suicidal Ideation | | | | |

Date:02/17/05ISR Number: 4585653-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050202892
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|----------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | Obsessive-Compulsive | Concerta | PS | | |
| UNKNOWN | | | Disorder | | | | |

Date:02/17/05ISR Number: 4585654-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050202902
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|----------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | Obsessive-Compulsive | Concerta | PS | | |
| UNKNOWN | | | Disorder | | | | |

Date:02/17/05ISR Number: 4585655-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050104165
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|-----------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | Osteochondrosis | Concerta | PS | | |
| OROPHARINGEAL | | | Osteonecrosis | | | | |

Date:02/18/05ISR Number: 4586972-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050202160
Age:2 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|---------------------|---------------|----------|------|--------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - | Accidental Exposure | | Concerta | PS | | |
| OROPHARINGEAL | The patient | | | | | |
| Initial or Prolonged | Fatigue | | | | | |
| took the drug | Headache | | | | | |
| by accident. | Insomnia | | | | | |
| | Overdose | | | | | |
| | Palpitations | | | | | |
| | Restlessness | | | | | |

Date:02/18/05ISR Number: 4586973-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050203419
Age:6 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | Duration | | | | | |
| Life-Threatening | Cerebrovascular Accident | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | |
| Other | Fall | | | | | |
| | Head Injury | | | | | |
| | Injury | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/22/05ISR Number: 4588453-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050104873
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|-------------|--------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Concerta | PS | | |
| UNKNOWN | 2.5 tablets | Hepatitis | | | | | |
| of Concerta* | | | | | | | |
| per day, one | | Homicidal Ideation | | | | | |
| in the | | Suicidal Ideation | | | | | |
| morning, one | | | | | | | |
| UNKNOWN | | | | Tegratol | C | | |
| UNKNOWN | | | | Clozapine | C | | |
| UNKNOWN | | | | Melatonin | C | | |
| UNKNOWN | | | | Codeine | C | | |

Date:02/22/05ISR Number: 4588509-1Report Type:Expedited (15-DaCompany Report #PHBS2005US02434
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|-----------|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Dizziness | | Methylphenidate | PS | Novartis Sector: Pharma | |
| UNKNOWN | 20 mg, | Erythema | | | | | |
| ONCE/SINGLE | | Headache | | | | | |
| | | Wheezing | | | | | |

Date:02/22/05ISR Number: 4588510-8Report Type:Expedited (15-DaCompany Report #PHBS2005US02435
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------|-----------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | | Methylphenidate | PS | Novartis Sector: | |

UNKNOWN 17.5 mg, Diplopia
 ONCE/SINGLE Pain In Extremity
 Visual Disturbance

Pharma

Date:02/22/05ISR Number: 4588512-1Report Type:Expedited (15-DaCompany Report #PHFR2005GB00886
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------------------------|---------------|--------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Confusional State Hallucination | | Ritalin | PS | Novartis Sector: Pharma | |
| 10mg/day | | | | | | | |
| | | Meningococcal Sepsis | | Concerta | C | | ORAL |
| 36mg/day | | | | Gabapentin | C | | ORAL |
| 175mg/day | | | | Paracetamol | C | | |
| | | | | Erythromycin | C | | |
| | | | | Morphine | C | | |
| | | | | Voltarol | C | | |

Date:02/22/05ISR Number: 4591873-0Report Type:Expedited (15-DaCompany Report #CEL-2005-00169-ROC
 Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|---|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abnormal Behaviour Aggression Anxiety Depression | Consumer | Metadate Cd Capsules 20 Mg (Methylphenidate Hydrochloride) | PS | | ORAL |
| Required Intervention to Prevent Permanent 20MG EVERY Impairment/Damage MORNING AND EVERY AFTERNOON, PER ORAL | | Drug Interaction Growth Retardation Medication Error Suicidal Ideation | | | | | |
| | | | | Saizen (Somatropin) | SS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Lexapro C

Date:02/23/05ISR Number: 4589565-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050203922
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|-----------|-------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Mood Swings | | Concerta | PS | | |
| OROPHARINGEAL | Two 27 mg | Suicidal Ideation | | | | | |
| tablets | | | | Insulin | C | | |

Date:02/24/05ISR Number: 4595974-2Report Type:Direct Company Report #CTU 241288
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | | Concerta | PS | Alza 36 | ORAL |
| 2 PO ORAL | | Dizziness | | | | | |
| | | Heart Rate Irregular | | | | | |

Date:02/25/05ISR Number: 4590838-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050203934
Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Tachycardia | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:02/25/05ISR Number: 4590839-4Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050203942
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Confusional State | | Concerta | PS | | |
| UNKNOWN | | | | | | | |

UNKNOWN Paracetamol C
 UNKNOWN Volterol C
 UNKNOWN Morphine C
 UNKNOWN Gabapentin C
 UNKNOWN Ritalin C

Date:02/25/05ISR Number: 4590840-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050204467
 Age:15 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--------------------------|---------------|----------|------|--------------|-------|
| Dose Duration Hospitalization - OROPHARINGEAL | Megakaryocytes Decreased | | Concerta | PS | | |
| Initial or Prolonged Other | Thrombocytopenia | | | | | |

Date:02/25/05ISR Number: 4590841-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050204516
 Age:9 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|--------------------------|---------------|----------|------|--------------|-------|
| Dose Duration Other OROPHARINGEAL | Cerebrovascular Accident | | Concerta | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/25/05ISR Number: 4590842-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050204933
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Concerta | PS | | |
| OROPHARINGEAL | | Agitation | | | | | |
| | | Hallucination | | | | | |

Date:02/25/05ISR Number: 4595391-5Report Type:Direct Company Report #CTU 241435
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----------------------|---------------|----------|----------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Grand Mal Convulsion | | Ritalin | 20 Mg PS | | ORAL |
| 20 MG BID | | | | | | | |
| Hospitalization - | | | | | | | |
| ORAL | | | | | | | |
| Initial or Prolonged | | | | Ultram | 50 Mg SS | | ORAL |
| 100 MG Q. 4-6 | | | | | | | |
| Disability | | | | | | | |
| HRS PRN ORAL | | | | | | | |
| | | | | Hctz | C | | |
| | | | | Paxil | C | | |
| | | | | Seroquel | C | | |

Date:02/28/05ISR Number: 4592252-2Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12757514
 Age:18 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------------|---------------|----------|------|---|-------|
| Dose | | | | | | | |
| Hospitalization - | | Thrombocytopenia | | Abilify | PS | Otsuka Pharmaceutical Company, Ltd. | ORAL |
| Initial or Prolonged | | | | | | | |
| Reduced to 15 | | | | | | | |
| mg/day in | | | | | | | |
| Nov-2004. | | | | | | | |
| | | | | Concerta | SS | | ORAL |
| | | | | Lexapro | C | | ORAL |

Date:02/28/05ISR Number: 4597573-5Report Type:Direct
Age:15 YR Gender:Male I/FU:I

Company Report #CTU 241614

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|----------|---|---------------|----------|------|--------------|-------|
| Hospitalization - ONCE DAILY | | Abnormal Behaviour | | Paxil | PS | | ORAL |
| Initial or Prolonged ORAL | | Affective Disorder | | | | | |
| ONCE DAILY | | Aggression | | Adderall | SS | | ORAL |
| ORAL | | Bipolar Disorder | | | | | |
| | | Educational Problem Mania Predisposition To Disease | | Concerta | SS | | |

Date:03/02/05ISR Number: 4599312-0Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 241786

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------|----------|---|---------------|------------------------------|------|--------------|-------|
| Other [SEVERAL YEARS] | | Drug Ineffective Pharmaceutical Product Complaint | | Methylphenidate (Generic) | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/02/05ISR Number: 4599350-8Report Type:Direct
Age:17 YR Gender:Male I/FU:I

Company Report #CTU 241845

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased | | Ritalin | PS | | |
| | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |

Date:03/02/05ISR Number: 4599355-7Report Type:Direct
Age: Gender:Male I/FU:I

Company Report #CTU 241855

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective | | Ritalin La | PS | | |
| 5 MG | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |

Date:03/03/05ISR Number: 4597578-4Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050107016
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | White Blood Cell Count | | Risperdal | PS | | |
| UNKNOWN | | Decreased | | Ritalin | SS | | |

Date:03/04/05ISR Number: 4598373-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050104165
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Osteochondrosis | | Concerta | PS | | |
| OROPHARINGEAL | | Osteonecrosis | | | | | |

Date:03/04/05ISR Number: 4598374-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050102571
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------|---------------|-----------|------|--------------|-------|
| Hospitalization - | | Anorexia | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| Initial or Prolonged | | Brain Damage | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| Other | | Headache | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Migraine | | Seroquel | C | | |
| | | Nausea | | Trazodone | C | | |
| At bedtime | | | | | | | |
| | | Pyrexia | | | | | |
| | | Urinary Retention | | | | | |
| | | Vomiting | | | | | |

Date:03/07/05ISR Number: 4599671-9Report Type:Expedited (15-DaCompany Report #PHNU2004DE03154
Age:7 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------------|---------------|----------|------|----------------------------|-------|
| Other | | Vasculitic Rash | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, BID | | | | | | | |

Date:03/07/05ISR Number: 4599705-1Report Type:Expedited (15-DaCompany Report #PHBS2005BE03214
Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------|---------------|---------|------|----------------------------|-------|
| Hospitalization - | | Drug Abuser | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| Initial or Prolonged | | Hyperthermia | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

20 DF, Methylenedioxyamphetamines SS ORAL
 ONCE/SINGLE

Date:03/07/05ISR Number: 4599706-3Report Type:Expedited (15-DaCompany Report #PHFR2005GB01055
 Age:93 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------|---------------|-----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged 20mg/day | | Inflammation | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 36mg/day | | Peritoneal Neoplasm | | Concerta | SS | | ORAL |
| 3-6mg nocte | | | | Melatonin | C | | ORAL |

Date:03/07/05ISR Number: 4599707-5Report Type:Expedited (15-DaCompany Report #PHNU2005DE01174
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|----------|------|----------------------------|-------|
| Other | | Raynaud'S Phenomenon | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:03/08/05ISR Number: 4601232-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050205843
 Age:8 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|----------|------|--------------|-------|
| OROPHARINGEAL | | Carotid Artery Occlusion | | Concerta | PS | | |
| | | Cerebral Artery Occlusion | | | | | |
| | | Cerebral Infarction | | | | | |

Date:03/08/05ISR Number: 4601233-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050206003
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Raynaud'S Phenomenon | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:03/08/05ISR Number: 4601234-3Report Type:Expedited (15-DaCompany Report #PT-JNJFOC-20050300016
Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Optic Discs Blurred | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:03/08/05ISR Number: 4601235-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20041204158
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Cerebrovascular Disorder | | Ritalin | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Hallucination | | | | | |
| | | Headache | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/08/05ISR Number: 4601423-8Report Type:Expedited (15-DaCompany Report #PHBS2005BE03214
 Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------------|---------------|------------------------------------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | | Drug Abuser Hyperthermia | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 DF, ONCE/SINGLE | | | | Methylenedioxyametham phetamine | SS | | ORAL |

Date:03/09/05ISR Number: 4602457-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20050301825
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|--|---------------|----------------------|------|--------------|-------|
| Other OROPHARINGEAL | | Abdominal Pain Upper | | Concerta | PS | | |
| OROPHARINGEAL | | Back Disorder | | Concerta | SS | | |
| | | Dizziness Hepatic Lesion Platelet Count Decreased White Blood Cell Count Decreased | | Estrogen Replacement | C | | |

Date:03/09/05ISR Number: 4602781-0Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050300285
 Age:93 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|---------------------|---------------|-----------|------|--------------|-------|
| Hospitalization - OROPHARINGEAL | | Peritoneal Neoplasm | | Concerta | PS | | |
| Initial or Prolonged UNKNOWN | | | | Ritalin | SS | | |
| OROPHARINGEAL | | | | Melatonin | C | | |
| OROPHARINGEAL | 3-6mg | | | Melatonin | C | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------|---------------|--|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | Foreign | Equasym 5mg | | | |
| Required | | Decreased Appetite | Health | (Methylphenidate | | | |
| Intervention to | | Grand Mal Convulsion | Professional | Hydrochloride) | PS | | ORAL |
| 10MG MORNING, Prevent Permanent 5MG Impairment/Damage LUNCHTIME, PO | | Trance | | | | | |
| | | Weight Decreased | | | | | |
| | | | | Becotide (Beclometasone Dipropionate) | C | | |
| | | | | Salbutamol Sulphate (Salbutamol Sulphate) | C | | |
| | | | | Symbicort Turbohaler (Symbicort "Astrazeneca") | C | | |

| Outcome | PT |
|---------|---|
| Other | Disturbance In Attention Dizziness Nausea Paraesthesia |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Pharmaceutical Product Complaint Somnolence | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---|---------------|---------|------|----------------------------|-------|
| UNK, UNK | | | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| | | | | Ritalin | SS | Novartis Sector: Pharma | ORAL |

Date:03/10/05ISR Number: 4603639-3Report Type:Expedited (15-DaCompany Report #PHBS2005BE03214
Age:16 YR Gender:Female I/FU:F

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------------|---------------|-----------------------------------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged UNK, UNK | | Drug Abuser Hyperthermia | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 DF, ONCE/SINGLE | 1440 MIN | Intentional Misuse | | Methylenedioxymetham phetamine | SS | | ORAL |

Date:03/11/05ISR Number: 4605137-XReport Type:Expedited (15-DaCompany Report #PHEH2005US02821
Age:55 YR Gender:Female I/FU:I

| Outcome Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|--------------------------|--------|----------------------------|-------|
| Life-Threatening Hospitalization - Initial or Prolonged INTRACAVERNOUS | | Abscess Limb Amputation Cellulitis | | Ritalin | PS | Novartis Sector: Pharma | |
| | | Confusional State Depressed Level Of Consciousness Dizziness Erythema Fall Hallucination Inflammation Mental Status Changes Osteomyelitis | | Budesonide Prednisone | C C | | |

Skin Ulcer
Sleep Apnoea Syndrome
Somnolence

Date:03/11/05ISR Number: 4608461-XReport Type:Direct
Age:72 YR Gender:Male I/FU:I

Company Report #CTU 242943

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|-------------------------------|---------------|---|--|--------------|-------|
| Dose Hospitalization - 5 MG PO BID Initial or Prolonged | Delirium Hallucination | | Methylphenidate Aspirin Atenolol Metolazone Simvastatin Loratadine Calcium Carbonate Docusate Na Furosemide Isosorbide Mononitrate Nitroglycerin Potassium Chloride Flunisolide Trazodone Hcl | PS C C C C C C C C C C C C C C | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Amiodarone Hcl
 (Geneva) C
 Sertraline Hcl C
 Ferrous Gluconate C
 Clotrimazole C

Date:03/11/05ISR Number: 4609060-6Report Type:Expedited (15-DaCompany Report #KII-2005-0015423
 Age:45 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|--|--|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Acute Respiratory Distress Syndrome Agitation Blood Glucose Increased Body Temperature | Study Health Professional Other | Oxycodone Hydrochloride (Similar To Nda 20-553)(Oxycodone Hydrochloride) | PS | | ORAL |
| ORAL | | Decreased Bowel Sounds Abnormal | | Loperamide (Loperamide) | SS | | ORAL |
| ORAL | | Coma Hypotension | | Valproic Acid (Valproic Acid) | SS | | ORAL |
| ORAL | | Miosis Overdose Respiratory Depression | | Acetaminophen W/Hydrocodone Bitartrate(Paracetam ol, Hydrocodone Bitartrate) | SS | | ORAL |
| ORAL | | | | Antiretroviral | SS | | ORAL |
| ORAL | | | | Aciclovir (Aciclovir) | SS | | ORAL |
| ORAL | | | | Other Anti-Asthmatics For Systemic Use | SS | | ORAL |
| ORAL | | | | Antifungals For Systemic Use | SS | | ORAL |
| ORAL | | | | Trazodone (Trazodone) | SS | | ORAL |

| | | | |
|------|---|----|------|
| ORAL | Antibiotics | SS | ORAL |
| ORAL | Antihistamines For Systemic Use | SS | ORAL |
| ORAL | Salicylates(Salicylates) | SS | ORAL |
| ORAL | Phenothiazine (Phenothiazine) | SS | ORAL |
| ORAL | Dhea(Prasterone) | SS | ORAL |
| ORAL | Proton Pump Inihibitor | SS | ORAL |
| ORAL | Methylphenidate (Methylphenidate) | SS | ORAL |
| ORAL | Multivitamins And Iron | SS | ORAL |
| ORAL | Acetylsalicylic Acid (Acetylsalicylic Acid) | SS | ORAL |

Date:03/11/05ISR Number: 4677966-8Report Type:Direct
Age: Gender:Female I/FU:I

Company Report #CTU 242655

Outcome PT
Other Abnormal Behaviour
Impulsive Behaviour
Pharmaceutical Product

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Complaint

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------------|----------|---------------|--|------|--------------|-------|
| 20 MG 8A, 10:30A, 1PM, 3:30 PM | | | Methylphenidate -Though Medicine Shoppe North Menomonie, Wi | PS | | |
| | | | Tegretol | C | | |
| | | | Insulin | C | | |

Date:03/11/05ISR Number: 4687538-7Report Type:Direct Company Report #CTU 242985
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------------|----------|--|---------------|-------------|------|--------------|-------|
| Dose Other 5MG PO | | Therapeutic Response | | Ritalin 5mg | PS | | ORAL |
| | | Unexpected With Drug Substitution Weight Decreased | | | | | |

Date:03/11/05ISR Number: 4687560-0Report Type:Direct Company Report #CTU 242971
Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|---|---------------|--------------------|------|--------------|-------|
| Dose Other 20MG BID PO | | Abnormal Behaviour | | Generic Ritalin Sr | PS | | ORAL |
| | | Disturbance In Attention Drug Effect Decreased Therapeutic Response Unexpected With Drug Substitution | | | | | |

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Amenorrhoea Drug Abuser Infertility Ovarian Failure | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:03/14/05ISR Number: 4609650-0Report Type:Direct Company Report #CTU 243091

Age:49 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|---------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Crying | | Concerta 36 Mg Alza | PS | Alza | ORAL |
| ORAL | | Depression Mental Disorder Movement Disorder Speech Disorder | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/14/05ISR Number: 4609860-2Report Type:Direct
 Age:7 YR Gender:Male I/FU:I

Company Report #CTU 243082

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|------------------------|---------------|--------------------|------|--------------|-------|
| Life-Threatening | | Emotional Disorder | | Methylphenidate 10 | | | |
| Other | | Feeling Cold | | Mg Able | PS | Able | ORAL |
| 1 TABLET | | Heart Rate Increased | | | | | |
| MORNING AND | | Mydriasis | | | | | |
| NOON | ORAL | Personality Change | | | | | |
| | | Pharmaceutical Product | | | | | |
| | | Complaint | | | | | |
| | | Respiratory Rate | | | | | |
| | | Increased | | | | | |
| | | Tremor | | | | | |

Date:03/15/05ISR Number: 4608581-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050300703
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Other | | Intentional Misuse | | Concerta | PS | | |
| OROPHARINGEAL | | Suicide Attempt | | Tofranil | SS | | |
| UNKNOWN | | | | | | | |

Date:03/15/05ISR Number: 4608582-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050301155
 Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Other | | Disinhibition | | Concerta | PS | | |
| OROPHARINGEAL | | Hypomania | | | | | |
| | | Irritability | | | | | |
| | | Motion Sickness | | | | | |

Date:03/15/05ISR Number: 4608612-7Report Type:Expedited (15-DaCompany Report #PHBS2004JP17256
 Age:72 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Anaemia | | Ritalin | PS | Novartis Sector: | |
| | | Blood Alkaline | | | | Pharma | ORAL |
| 30 mg/d | | | | | | | |
| | | Phosphatase Increased | | Rohypnol | SS | | ORAL |
| 2 mg/d | | | | | | | |
| | | Haemoglobin Decreased | | Seroquel | SS | | ORAL |
| 30 mg/d | | | | | | | |
| | 134 DAY | Malaise | | Tecipul | SS | | ORAL |
| 6 mg/d | | | | | | | |
| | 183 DAY | Pancytopenia | | Sepazon | SS | | ORAL |
| 2 mg/d | | | | | | | |
| | | Platelet Count Decreased | | Amoban | C | | |
| | | Red Blood Cell Count Decreased | | | | | |
| | | White Blood Cell Count Decreased | | | | | |

Date:03/15/05ISR Number: 4608613-9Report Type:Expedited (15-DaCompany Report #PHBS2005BE03214
 Age:16 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------|---------------|-----------------------------------|------|------------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Drug Abuser | | Ritalin | PS | Novartis Sector: | |
| Initial or Prolonged | | Hyperthermia | | | | Pharma | ORAL |
| UNK, UNK | | | | | | | |
| | | Poisoning | | Methylenedioxymetham phetamine | SS | | ORAL |
| 20 DF, | | | | | | | |
| ONCE/SINGLE | 1440 MIN | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/15/05ISR Number: 4608785-6Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050104873
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-------------------|---------------|-----------|------|--------------|-------|
| Life-Threatening | | Aggression | | Concerta | PS | | |
| UNKNOWN | | Hepatitis | | Tegratol | C | | |
| UNKNOWN | | Suicidal Ideation | | Tegratol | C | | |
| UNKNOWN | | | | Clozapine | C | | |
| UNKNOWN | | | | Melatonin | C | | |
| UNKNOWN | | | | Codeine | C | | |

Date:03/15/05ISR Number: 4608786-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050205843
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|----------|------|--------------|-------|
| Other | | Carotid Artery Occlusion | | Concerta | PS | | |
| OROPHARINGEAL | | Cerebral Artery Occlusion | | | | | |
| | | Cerebral Infarction | | | | | |

Date:03/16/05ISR Number: 4609755-4Report Type:Expedited (15-DaCompany Report #PHNU2005DE01277
 Age:14 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|--------------------------|---------------|----------|------|------------------|-------|
| Other | | Drug Withdrawal Syndrome | | Ritaline | PS | Novartis Sector: | |
| UNK, UNK | | Hallucination, Auditory | | | | Pharma | ORAL |

Date:03/16/05ISR Number: 4612683-1Report Type:Direct Company Report #CTU 243436
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----|----------------------|--------------|------|--------------|-------|
| Hospitalization - 36MG BID | | | Heart Rate Increased | Concert 36mg | PS | | ORAL |
| Initial or Prolonged ORAL | | | Hyperhidrosis | | | | |
| Required Intervention to Prevent Permanent Impairment/Damage | | | Hypertension | Lovastatin | C | | |

Date:03/17/05ISR Number: 4611155-8Report Type:Expedited (15-DaCompany Report #PHFR2005GB01199
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|--------------------------------|---------------------|------|----------------------------|-------|
| Other | | | Choking Dyspnoea Malaise | Ritalin | PS | Novartis Sector: Pharma | |
| 1/80000 | | | Shock | Adrenaline | SS | | |
| 2% | | | | Lignocaine | SS | | |
| | | | | Prednisolone | C | | |
| | | | | Sodium Cromoglicate | C | | |

Date:03/18/05ISR Number: 4612535-7Report Type:Expedited (15-DaCompany Report #PHBS2005IL03820
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|----|---------------|---------|------|----------------------------|-------|
| Disability Other 122 DAY | | | Aggression | Ritalin | PS | Novartis Sector: Pharma | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/18/05ISR Number: 4616433-4Report Type:Expedited (15-DaCompany Report #L04-USA-07403-28
Age:58 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------------|---------------|---------------------|------|--------------|-------|
| Death | | Abnormal Behaviour | Literature | Celexa (Citalopram | | | |
| Hospitalization - | | Cardiac Arrest | Health | Hydrobromide) | PS | | |
| Initial or Prolonged | | Completed Suicide | Professional | Risperidone | | | |
| | | Confusional State | | (Risperidone) | SS | | |
| | | Convulsion | | Methylphenidate | SS | | |
| | | Hypotension | | Rofecoxib | SS | | |
| | | Intentional Misuse | | Hydrochlorothiazide | SS | | |
| | | Respiratory Arrest | | Aspirin | | | |
| | | Stupor | | (Acetylsalicylic | | | |
| | | Ventricular Tachycardia | | Acid) | SS | | |

Date:03/22/05ISR Number: 4614787-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050303326
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|----------|------|--------------|-------|
| Other | | Ventricular Septal Defect | | Concerta | PS | | |
| OROPHARINGEAL | | Acquired | | | | | |

Date:03/22/05ISR Number: 4614818-3Report Type:Expedited (15-DaCompany Report #PHEH2005US02821
Age:55 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------|---------------|------------|------|------------------|-------|
| Life-Threatening | | Abscess Limb | | Ritalin | PS | Novartis Sector: | |
| Hospitalization - | | Amputation | | | | Pharma | |
| Initial or Prolonged | | Cellulitis | | Remicade | SS | | |
| INTRACAVERNOUS | | Confusional State | | Budesonide | C | | |
| | | Depressed Level Of | | Prednisone | C | | |
| | | Consciousness | | | | | |
| | | Dizziness | | | | | |
| | | Erythema | | | | | |
| | | Fall | | | | | |
| | | Hallucination | | | | | |
| | | Inflammation | | | | | |
| | | Leg Amputation | | | | | |

Mental Status Changes
Osteomyelitis
Skin Ulcer
Sleep Apnoea Syndrome
Somnolence

Date:03/23/05ISR Number: 4617040-XReport Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050104873

Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|-------------------|---------------|-----------|------|--------------|-------|
| Dose Duration | | | | | | |
| Life-Threatening | Aggression | | Concerta | PS | | |
| UNKNOWN | | | | | | |
| Other | Hepatitis | | Tegratol | C | | |
| UNKNOWN | | | | | | |
| | Suicidal Ideation | | Tegratol | C | | |
| UNKNOWN | | | | | | |
| | | | Clozapine | C | | |
| UNKNOWN | | | | | | |
| | | | Melatonin | C | | |
| UNKNOWN | | | | | | |
| | | | Codeine | C | | |
| UNKNOWN | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/24/05ISR Number: 4617490-1Report Type:Expedited (15-DaCompany Report #PT-JNJFOC-20050303361
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | | Concerta | PS | | |
| UNKNOWN | | | | | | | |

Date:03/24/05ISR Number: 4617491-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050304301
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypersensitivity | | Concerta | PS | | |
| OROPHARINGEAL | | | | Equasym | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:03/24/05ISR Number: 4617492-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050304484
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Nystagmus | | Concerta | PS | | |
| OROPHARINGEAL | | Road Traffic Accident | | Atomoxetine | C | | |
| | | | | Ritalin | C | | |

Date:03/24/05ISR Number: 4617493-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050304505
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression | | Concerta | PS | | |
| OROPHARINGEAL | | | | Zyrtec | C | | |
| | | | | Albuterol | C | | |
| | | | | Flovent | C | | |

Date:03/24/05ISR Number: 4617494-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050205843
Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Carotid Artery Occlusion | | Concerta | PS | | |
| OROPHARINGEAL | | Cerebral Artery Occlusion | | | | | |
| | | Cerebral Infarction | | | | | |
| | | Convulsion | | | | | |

Date:03/24/05ISR Number: 4617556-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050304887
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Diplopia | | Concerta | PS | | |
| OROPHARINGEAL | | Vision Blurred | | Concerta | SS | | |
| OROPHARINGEAL | | | | Albuterol | C | | |
| RESPIRATORY | | | | | | | |
| (INHALATION) | | | | | | | |

Date:03/25/05ISR Number: 4619110-9Report Type:Expedited (15-DaCompany Report #PHEH2005US02821
Age:55 YR Gender:Female I/FU:F

| | |
|----------------------|-------------------|
| Outcome | PT |
| Life-Threatening | Abscess Limb |
| Hospitalization - | Amputation |
| Initial or Prolonged | Cellulitis |
| | Confusional State |

Complaint

Date:03/31/05ISR Number: 4623782-2Report Type:Expedited (15-DaCompany Report #PHBS2005BE03214
 Age:16 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|------------|-----------------------------|---------------|-----------------------------------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | 20-30 mg/d | Drug Abuser Hyperthermia | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 DF, ONCE/SINGLE | 1440 MIN | Poisoning | | Methylenedioxymetham phetamine | SS | | ORAL |
| | | | | Yasmin | SS | | |

Date:04/01/05ISR Number: 4624969-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050305097
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Other OROPHARINGEAL | | Suicide Attempt | | Concerta | PS | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/01/05ISR Number: 4624970-1Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050305110
Age:12 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|--------------|---------------|----------|------|--------------|-------|
| Dose Hospitalization - OROPHARINGEAL Initial or Prolonged | Constipation | | Concerta | PS | | |

Date:04/01/05ISR Number: 4624971-3Report Type:Expedited (15-DaCompany Report #NL-JNJFOC-20050305784
Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---|---------------|---------------------|----------|--------------|-------|
| Dose Hospitalization - UNKNOWN Initial or Prolonged UNKNOWN | Apathy Blood Potassium Decreased Fatigue Motor Dysfunction | | Concerta Ritalin | PS SS | | |

Date:04/01/05ISR Number: 4625100-2Report Type:Expedited (15-DaCompany Report #PHBS2005US04460
Age:19 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|---|---------------|-----------------|------|----------------------------|-------|
| Dose Other 80-100 mg, ONCE/SINGLE | Intentional Misuse Self Injurious Behaviour Suicide Attempt | | Methylphenidate | PS | Novartis Sector: Pharma | ORAL |

Date:04/01/05ISR Number: 4627914-1Report Type:Expedited (15-DaCompany Report #8009590
Age:16 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---------------------|---------------|------------------|----------|--------------|--------------|
| Dose Hospitalization - 500 MG 2/D PO Initial or Prolonged 1000 MG 2/D | Aggression Anger | Consumer | Keppra Keppra | PS SS | | ORAL ORAL |

| | | | | | |
|---------------|--------------------------|------------|----|--|------|
| PO | Bipolar Disorder | | | | |
| 1500 MG /D PO | Convulsion | Keppra | SS | | ORAL |
| 500 MG 2/D PO | Depression | Keppra | SS | | ORAL |
| 25 MG 4/D PO | Hepatic Enzyme Increased | Ritalin | SS | | ORAL |
| | Homicidal Ideation | Ortho-Evra | C | | |
| | Intentional Self-Injury | | | | |
| | Suicide Attempt | | | | |
| | Viral Dna Test Positive | | | | |

Date:04/04/05ISR Number: 4626023-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050305794
Age:31 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Other | | Disturbance In Attention | | Concerta | PS | | |
| OROPHARINGEAL | | 2 WK | | | | | |
| | | Hypertension | | | | | |
| | | Pericarditis | | | | | |
| | | Pleural Effusion | | | | | |
| | | Restlessness | | | | | |
| | | Somnolence | | | | | |

Date:04/05/05ISR Number: 4630614-5Report Type:Direct Company Report #CTU 245318
Age: Gender:Male I/FU:I

| | |
|---------|-----------------------|
| Outcome | PT |
| Other | Abnormal Behaviour |
| | Attention |
| | Deficit/Hyperactivity |

| | |
|-----------|---|
| Pulmicort | C |
| Foradil | C |
| Claritin | C |
| Albuterol | C |
| Singulair | C |

Date:04/08/05ISR Number: 4630268-8Report Type:Expedited (15-DaCompany Report #PHFR2005GB00791
 Age:17 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|---------|------|----------------------------|-------|
| Other | | Crohn'S Disease | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:04/08/05ISR Number: 4630470-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050307504
 Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Other | | Headache | | Concerta | PS | | |
| OROPHARINGEAL | | 1 YR | | | | | |
| | | Weight Decreased | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/08/05ISR Number: 4630471-7Report Type:Periodic Company Report #US-JNJFOC-20050303326
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|----------|------|--------------|-------|
| | | Ventricular Septal Defect | | Concerta | PS | | |
| OROPHARINGEAL | | Acquired | | | | | |

Date:04/11/05ISR Number: 4632416-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050400305
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|----------|------|--------------|-------|
| | | Gaze Palsy | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:04/11/05ISR Number: 4632793-2Report Type:Direct Company Report #CTU 245737
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|---|---------------|--|------|--------------|-------|
| Life-Threatening | | Depressed Level Of Consciousness Fatigue | | Methylphenidate Hydrochloride 10 Mg Able | PS | Able | ORAL |
| 10 MG TWICE | | Feeling Cold | | | | | |
| DAILY ORAL | | Heart Rate Increased Mydriasis Pharmaceutical Product Complaint Respiratory Rate Increased | | Methylin 10 Mg Mallinckrodt | SS | Mallinckrodt | |

Date:04/11/05ISR Number: 4633583-7Report Type:Direct Company Report #CTU 245838
 Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|-------------------|------|--------------|-------|
| | | Drug Ineffective | | Ritalin (Generic) | PS | | |

Pharmaceutical Product

THERAPY

Complaint

DATES: 5 YRS

AGO & PRESENT

Date:04/12/05ISR Number: 4632863-9Report Type:Expedited (15-DaCompany Report #PHBS2005JP04568

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis Bullous | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 10 mg/d | 2880 MIN | | | | | | |
| 10 mg/d | 2880 MIN | | | Paxil | SS | | ORAL |

Date:04/12/05ISR Number: 4632895-0Report Type:Expedited (15-DaCompany Report #PHBS2005CA05022

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Weight Decreased | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 50-60 mg/d | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/12/05ISR Number: 4632914-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050203419

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|------------|--------|--------------------------|-----------|------|--------------|-------|
| Hospitalization - | | | Cerebrovascular Accident | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| Initial or Prolonged | | Injury | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| Disability | | | | Clonidine | C | | |
| OROPHARINGEAL | Nightly | | | | | | |
| OROPHARINGEAL | Nightly | | | Clonidine | C | | |
| OROPHARINGEAL | Nightly | | | | | | |
| OROPHARINGEAL | At bedtime | | | Clonidine | C | | |

Date:04/13/05ISR Number: 4634037-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050203934

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|---------------|----------|------|--------------|-------|
| Other | | | Syncope | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | | Tachycardia | | | | |

Date:04/13/05ISR Number: 4634054-4Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20050400693

Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|---------------|----------|------|--------------|-------|
| Other | | | Depression | Concerta | PS | | |
| OROPHARINGEAL | | | 58 DAY | | | | |

Date:04/13/05ISR Number: 4636195-4Report Type:Direct Company Report #CTU 246110

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|----|-----------------------|----------------------|------|--------------|-------|
| Other | | | Abnormal Behaviour | Ritalin Sr -Celltech | PS | Celltech | ORAL |
| 20 MG PO | | | Drug Effect Decreased | | | | |

Pharmaceutical Product
Complaint

Date:04/13/05ISR Number: 4636231-5Report Type:Direct Company Report #CTU 246101
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-------------------------------------|---------------|---------|------|--------------|-------|
| Dose | | Educational Problem | | Ritalin | PS | | |
| 5 MG BID | | Pharmaceutical Product Complaint | | | | | |

Date:04/14/05ISR Number: 4634923-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050205843
Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|----------|------|--------------|-------|
| Dose | | Carotid Artery Occlusion | | Concerta | PS | | |
| Other | | Cerebral Artery Occlusion | | | | | |
| OROPHARINGEAL | | Cerebral Infarction | | | | | |
| | | Convulsion | | | | | |
| | | Depressed Level Of Consciousness | | | | | |
| | | General Physical Health Deterioration | | | | | |
| | | Headache | | | | | |
| | | Somnolence | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/14/05ISR Number: 4634947-8Report Type:Expedited (15-DaCompany Report #PHBS2005JP04568
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Dermatitis Bullous | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 10 mg/d | 2880 MIN | | | | | | |
| 10 mg/d | 2880 MIN | | | Paxil | SS | | ORAL |

Date:04/14/05ISR Number: 4634949-1Report Type:Expedited (15-DaCompany Report #PHBS2005CA05022
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Weight Decreased | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 50-60 mg/d | | | | | | | |

Date:04/14/05ISR Number: 4634956-9Report Type:Expedited (15-DaCompany Report #PHBS2005IL04868
Age:19 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine Phosphokinase Increased | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 375 mg, | | | | | | | |
| ONCE/SINGLE | | | | | | | |

Date:04/14/05ISR Number: 4635092-8Report Type:Expedited (15-DaCompany Report #PHBS2005IL04868
Age:19 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine Phosphokinase Increased | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 375 mg, | | | | | | | |
| ONCE/SINGLE | | | | | | | |

Date:04/14/05ISR Number: 4638850-9Report Type:Direct
Age:12 YR Gender:Male I/FU:I

Company Report #CTU 246237

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|-------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | | | | | |
| 10 MG | 1 IN | | | Ritalin - Generic | PS | | ORAL |
| | | | | | | | |
| AM | 1 AT 12 | | | | | | |
| | | | | | | | |
| NOON | BY | | | | | | |
| | | | | | | | |
| MOUTH | | | | | | | |

Date:04/15/05ISR Number: 4636425-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050301155
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | | | | | |
| OROPHARINGEAL | | | | Concerta | PS | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
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| | | | | | | | |

Date:04/15/05ISR Number: 4639096-0Report Type:Direct
Age: Gender: I/FU:I

Company Report #CTU 246248

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |
| | | | | | | | |
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/18/05ISR Number: 4637513-3Report Type:Expedited (15-DaCompany Report #PHEH2005US03975
Age:52 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----|--|------------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged UNK, QD Other | 51840MIN | | Angioplasty Catheterisation Cardiac Chest Pain Coronary Artery Occlusion Stent Placement | Ritalin La | PS | Novartis Sector: Pharma | ORAL |

Date:04/18/05ISR Number: 4637561-3Report Type:Expedited (15-DaCompany Report #PHBS2005NL05243
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|--|--------------------------|----------|----------------------------|-------|
| Other | | | Drug Interaction Psychotic Disorder | Carbamazepine Ritalin | PS SS | Novartis Sector: Pharma | |

Date:04/18/05ISR Number: 4637853-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050201579
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|----|-----------------------------------|---|-----------------------|--------------|-------|
| Other OROPHARINGEAL | | | Intraocular Pressure Increased | Concerta Concerta | PS SS | | |
| | | | | Paxil Nexium Allopurinol Verapamil Zyrtec | C C C C C | | |

Date:04/18/05ISR Number: 4638730-9Report Type:Direct Company Report #CTU 246398
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Drug Effect Decreased
Pharmaceutical Product
Complaint
Speech Disorder
Tic

Ritalin

PS

Date:04/19/05ISR Number: 4639074-1Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050402745
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haemorrhage | | Concerta | PS | | |
| UNKNOWN | | | | | | | |

Date:04/20/05ISR Number: 4640049-7Report Type:Expedited (15-DaCompany Report #PHBS2005BR05556
Age:12 YR Gender:Male I/FU:I

| Outcome | PT |
|----------------------|--------------------------|
| Hospitalization - | Anorexia |
| Initial or Prolonged | Blood Pressure Decreased |
| | Blood Pressure |
| | Fluctuation |
| | Chromaturia |
| | Depressed Mood |
| | Depressive Symptom |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|----------|------|----------------------------|-------|
| | | Diarrhoea Hepatitis B Hypertension | | | | |
| 10 mg, QD | | Jaundice Vomiting | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| 1 DF, QHS | | Weight Decreased | Tofranil | SS | | ORAL |

Date:04/20/05ISR Number: 4642475-9Report Type:Direct Company Report #CTU 246683
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|----------|------|--------------|-------|
| Dose Disability 1 TIME PER DAY ORAL | | PT Abnormal Behaviour Attention Deficit/Hyperactivity Disorder Condition Aggravated Drug Effect Decreased | Concerta | PS | Sa Alza | ORAL |

Date:04/21/05ISR Number: 4641260-1Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050403373
Age: Gender:Female I/FU:I

| Outcome | Duration | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|----------|------|--------------|-------|
| Dose Other | | PT Speech Disorder | Concerta | PS | | |

Date:04/22/05ISR Number: 4642678-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050403369
Age:34 YR Gender:Male I/FU:I

| Outcome | Duration | Report Source | Product | Role | Manufacturer | Route |
|-------------------------------------|----------|------------------|----------|------|--------------|-------|
| Dose Disability OROPHARINGEAL | | PT Aggression | Concerta | PS | | |
| OROPHARINGEAL | | Flight Of Ideas | Concerta | SS | | |

| | | | |
|---------------|-------------------|------------------|---|
| OROPHARINGEAL | Thinking Abnormal | Sodium Valproate | C |
| OROPHARINGEAL | 400/600mg | Carbamazepine | C |
| OROPHARINGEAL | | Zuclopendixol | C |
| OROPHARINGEAL | | Propranolol | C |
| OROPHARINGEAL | | Propranolol | C |
| OROPHARINGEAL | | Zopiclone | C |
| UNKNOWN | | Lorazepam | C |
| UNKNOWN | | | |

Date:04/22/05ISR Number: 4642679-5Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20041103335
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Other | | Aggression | | Concerta | PS | | |
| OROPHARINGEAL | | 1 DAY Suicide Attempt | | | | | |

Date:04/26/05ISR Number: 4644709-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050403330
Age:46 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|---------------|----------|------|--------------|-------|
| Other | | Rectal Cancer | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/05ISR Number: 4644710-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20050404236
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|--------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | Homicidal Ideation | Concerta | PS | | |
| OROPHARINGEAL | | | Suicidal Ideation | | | | |

Date:04/26/05ISR Number: 4644711-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050404537
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----|-----------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | | Cognitive Disorder | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| Initial or Prolonged | | | Delusion | Concerta | SS | | |
| OROPHARINGEAL | | | Eye Pain | | | | |
| | | | Eye Pruritus | | | | |
| | | | Hallucination | | | | |
| | | | Loss Of Consciousness | | | | |
| | | | Vision Blurred | | | | |

Date:04/26/05ISR Number: 4644712-3Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20050404561
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|----|--------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | | Agitation | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| Initial or Prolonged | | | Amnesia | | | | |
| | | | Confusional State | | | | |
| | | | Delirium | | | | |
| | | | Drug Ineffective | | | | |
| | | | Grandiosity | | | | |
| | | | Hallucination | | | | |
| | | | Insomnia | | | | |
| | | | Psychotic Disorder | | | | |
| | | | Sedation | | | | |

Date:04/26/05ISR Number: 4644713-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050404626
Age:48 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|--------------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | | | | | |
| OROPHARINGEAL | | | Blood Pressure Increased | Concerta | PS | | |
| | | | Cold Sweat | | | | |
| | | | Depressed Level Of | | | | |
| | | | Consciousness | | | | |
| | | | Vertigo | | | | |

Date:04/26/05ISR Number: 4644714-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050204933
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | | | | | |
| OROPHARINGEAL | | | Aggression | Concerta | PS | | |
| | | | Agitation | Concerta | SS | | |
| OROPHARINGEAL | | | Hallucination | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/26/05ISR Number: 4644715-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050405165
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Grand Mal Convulsion | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Therapeutic Response | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Decreased | | Trileptal | C | | |
| Daily | | | | Loratadine | C | | |

Date:04/27/05ISR Number: 4645883-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050404234
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Homicidal Ideation | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Suicidal Ideation | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:04/27/05ISR Number: 4649625-9Report Type:Expedited (15-DaCompany Report #CEL-2005-00503-ROC
Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------------|----------|---------------------------|---------------|----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | Foreign | Metadate Cd Capsules | | | |
| Required | | Depressed Mood | Study | 20 Mg | | | |
| Intervention to | | Depression | Health | (Methylphenidate | | | |
| Prevent Permanent | | Headache | Professional | Hydrochloride) | PS | | ORAL |
| 20MG INCREASE | | | | | | | |
| Impairment/Damage | | Inappropriate Schedule Of | | | | | |
| TO 40MG EVERY | | | | | | | |
| MORNING PER | | Drug Administration | | | | | |
| ORAL THEN | | Intentional Self-Injury | | | | | |
| 20MG TWICE | | Self-Injurious Ideation | | | | | |
| | | Skin Laceration | | Methylphenidate | | | |
| | | | | (Methylphenidate) | C | | |

Date:04/28/05ISR Number: 4647362-8Report Type:Expedited (15-DaCompany Report #PHNU2005DE01743
Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------|---------------|------------|------|------------------|-------|
| Dose | | | | Ritaline | PS | Novartis Sector: | ORAL |
| Other | | Astrocytoma | | Ritalin-Sr | SS | Pharma | ORAL |

Date:04/28/05ISR Number: 4647414-2Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20050405756
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|------------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | |
| Other | | Anaphylactic Reaction | | Concerta | SS | | |
| OROPHARINGEAL | | Disturbance In Attention | | | | | |
| OROPHARINGEAL | (one 27 mg | Drug Ineffective | | | | | |
| tablet plus | | Nervousness | | | | | |
| one 18 mg | | | | Nasocort | C | | |
| tablet) | | | | Epi Pen | C | | |
| As needed | | | | | | | |

Date:04/28/05ISR Number: 4650265-6Report Type:Expedited (15-DaCompany Report #KII-2005-0016079
Age:22 YR Gender:Male I/FU:I

Outcome
Hospitalization -
Initial or Prolonged

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Freedom Of Information (FOI) Report

Other

| Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|------------|--|--|--|------|--------------|-------|
| | | Acidosis Activated Partial Thromboplastin Time Prolonged | Study Health Professional Other | Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet | | | |
| RESPIRATORY (INHALATION) | INHALATION | Anion Gap Increased | | | PS | | |
| RESPIRATORY (INHALATION) | INHALATION | Blood Calcium Decreased Blood Glucose Fluctuation | | Methylphenidate (Methylphenidate) | SS | | |
| RESPIRATORY (INHALATION) | INHALATION | Body Temperature Increased | | Cocaine (Cocaine) | SS | | |
| ORAL (INHALATION) | INHALATION | Coma Fall Hepatic Failure Hypotension Hypoxia | | Benzodazepine Derivatives (Benzodazepien Derivatives) | C | | ORAL |
| | | Intentional Misuse International Normalised Ratio Increased Multi-Organ Failure Pneumonia Aspiration Polysubstance Abuse Prothrombin Time Prolonged Pupillary Reflex Impaired Renal Failure Respiratory Arrest Rhabdomyolysis Sinus Tachycardia Troponin Increased Vomiting White Blood Cell Count Decreased | | | | | |

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---|---------------|----------|------|--------------|-------|
| Disability | | Condition Aggravated Depressed Mood Hallucination, Auditory | | Concerta | PS | | |

Date:04/29/05ISR Number: 4648803-2Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050403373

Age:41 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Other | | Road Traffic Accident | | Concerta | PS | | |
| OROPHARINGEAL | | Speech Disorder | | Concerta | SS | | |
| OROPHARINGEAL | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | Efexor | C | | |
| OROPHARINGEAL | | | | Stilnoct | C | | |
| OROPHARINGEAL | | | | Waran | C | | |
| OROPHARINGEAL | | | | Xanor | C | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/29/05ISR Number: 4650649-6Report Type:Direct
Age:59 YR Gender:Female I/FU:I

Company Report #CTU 247398

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------------|---------------|------------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depressed Level Of Consciousness | | Methylin 10mg Tab. Mallinckrodt | PS | Mallinckrodt | |
| 2 TABS | TID | Pharmaceutical Product Complaint | | | | | |

Date:05/02/05ISR Number: 4649637-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903580
Age:46 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-----------------------|---------------|-----------------|------|--------------|-------|
| Death | | Blood Disorder | | Cyclobenzaprine | PS | | |
| OROPHARINGEAL | | | | | | | |
| Hospitalization - | | Completed Suicide | | Ibuprofen | SS | | |
| OROPHARINGEAL | | | | | | | |
| Initial or Prolonged | | Electrocardiogram Qrs | | Chlorzoxazone | SS | | |
| OROPHARINGEAL | | | | | | | |
| Other | | Complex Shortened | | Methylphenidate | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Heart Rate Increased | | Haloperidol | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Intentional Misuse | | Diphenhydramine | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Respiratory Arrest | | Cephalexin | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Stupor | | Naproxen | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | | | Ethanol | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:05/02/05ISR Number: 4650024-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050406494
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Rash | | Concerta | PS | | |
| OROPHARINGEAL | | Social Avoidant Behaviour | | | | | |

Weight Decreased

Date:05/02/05ISR Number: 4650026-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050406497
Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|------------|------|--------------|-------|
| Dose | | | | Concerta | PS | | |
| Other | | Tic | | | | | |
| OROPHARINGEAL | | Weight Decreased | | Ritalin Ir | C | | |
| OROPHARINGEAL | | | | | | | |

Date:05/02/05ISR Number: 4651957-5Report Type:Direct Company Report #CTU 247487
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------------------------|---------------|---------------------------------------|------|--------------|-------|
| Dose | | | | Methylphenidate 20mg 3 Tablets Bid | PS | | ORAL |
| 20MG THREE | | Disturbance In Attention Headache | | | | | |
| BID PO | | Panic Reaction | | | | | |
| | | Pharmaceutical Product Complaint | | | | | |

Date:05/02/05ISR Number: 4652046-6Report Type:Direct Company Report #CTU 247555E
Age: Gender:Male I/FU:I

| Outcome | PT |
|---|---|
| Hospitalization - Initial or Prolonged Disability | Cerebrovascular Accident Dysarthria Ear Pain Headache Hemiparesis |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Vasospasm

| Dose | Duration | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|----------------|------|--------------|-------|
| 1 DAILY | | | Strattera 40mg | PS | | ORAL |
| ORAL | | | | | | |
| 1 DAILY | | | Concerta 18mg | SS | | ORAL |
| ORAL | | | | | | |

Date:05/03/05ISR Number: 4653240-0Report Type:Direct Company Report #CTU 247641
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|----------------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Drug Effect Decreased Pharmaceutical Product | | Concerta 36 Mg - Mcneil Pharm | PS | Mcneil Pharm | |
| 1 DAILY | | Complaint | | | | | |

Date:05/04/05ISR Number: 4652573-1Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20050406718
 Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression Suicidal Ideation | | Concerta | PS | | |

Date:05/05/05ISR Number: 4655633-4Report Type:Expedited (15-DaCompany Report #KII-2005-0016286
 Age:45 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|--|---|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Drug Abuser Drug Screen Positive Loss Of Consciousness Miosis | Study Health Professional Other | Morphine Sulfate (Similar To Nda 19-516)(Morphine Sulfate) Other | PS | | ORAL |
| ORAL | | | | | | | |

| | | | | |
|------|-------------------------------|--|----|------|
| ORAL | Respiratory Rate Increased | Benzodiazepine Derivatives() | SS | ORAL |
| ORAL | Sinus Tachycardia Tremor | Carisoprodol (Carisoprodol) | SS | ORAL |
| ORAL | | Tramadol (Tramadol) | SS | ORAL |
| ORAL | | Acetaminophen W/Hydrocodone Bitartrate (Paracetamol, Hydrocodone | SS | ORAL |
| ORAL | | Methylphenidate (Methylphenidate) | SS | ORAL |
| | | Cocaine (Cocaine) | SS | |

Date:05/05/05ISR Number: 4655649-8Report Type:Expedited (15-DaCompany Report #KII-2005-0016217
Age:58 YR Gender:Female I/FU:I

| | |
|----------------------|----------------------|
| Outcome | PT |
| Hospitalization - | Agitation |
| Initial or Prolonged | Coma |
| Other | Drug Screen Positive |
| | Hypertension |
| | Hyperventilation |
| | Hypotension |
| | Pneumonia Viral |
| | Pyrexia |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Outcome | Report Source | Product | Role | Manufacturer | Route |
|------|----------|--|--|--|------|--------------|-------|
| | | Sepsis Tachycardia White Blood Cell Count Increased | Study Health Professional Other | Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet | PS | | ORAL |
| | | | | Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) | SS | | ORAL |
| | | | | Methylphenidate (Methyphenidate) | SS | | ORAL |

Date:05/05/05ISR Number: 4656448-3Report Type:Expedited (15-DaCompany Report #MK200504-0264-1
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------------------------------|---------------|-------------------------------|------|--------------|-------|
| Hospitalization - Initial or Prolonged 10 MG | | Blood Pressure Fluctuation | Foreign | Tofranil 10 Mg Tablets 100 | PS | | |
| 10 MG | | Hepatitis B | | Ritalina 10mg | SS | | |

Date:05/06/05ISR Number: 4654521-7Report Type:Expedited (15-DaCompany Report #PHFR2005GB00962
Age:14 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|-------------|------|----------------------------|-------|
| Other | | Localised Infection White Blood Cell Count | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 40 mg, QD | 82080MIN | Decreased | | Antibiotics | SS | | |

Date:05/06/05ISR Number: 4655124-0Report Type:Expedited (15-DaCompany Report #FR-JNJFOC-20050406589
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Fatigue | | Concerta | PS | | |
| OROPHARINGEAL | | Weight Decreased | | | | | |

Date:05/06/05ISR Number: 4655255-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050406692
 Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucinations, Mixed | | Concerta | PS | | |
| OROPHARINGEAL | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:05/06/05ISR Number: 4655256-7Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20050405756
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|------------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anaphylactic Reaction | | Concerta | PS | | |
| OROPHARINGEAL | | | | Concerta | SS | | |
| OROPHARINGEAL | (one 27 mg | Disturbance In Attention | | | | | |
| tablet plus | | Drug Ineffective | | | | | |
| one 18 mg | | Nervousness | | | | | |
| tablet) | | | | Nasocort | C | | |
| | | | | Epi Pen | C | | |
| As needed | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/06/05ISR Number: 4655258-0Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20050406718
 Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---------------------------------|---------------|----------|------|--------------|-------|
| Hospitalization - Initial or Prolonged Other | | Depression Suicidal Ideation | | Concerta | PS | | |

Date:05/09/05ISR Number: 4656515-4Report Type:Expedited (15-DaCompany Report #PHBS2005NZ06293
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-----------------|---------------|---------|------|----------------------------|-------|
| Death UNKNOWN | | Drug Dependence | | Ritalin | PS | Novartis Sector: Pharma | |

Date:05/10/05ISR Number: 4657495-8Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20050500020
 Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|---------------------------------|---------------|----------|------|--------------|-------|
| Other OROPHARINGEAL | | Depression Suicidal Ideation | | Concerta | PS | | |

Date:05/10/05ISR Number: 4657496-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20050204516
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Other OROPHARINGEAL | | Cerebrovascular Accident | | Concerta | PS | | |
| Other OROPHARINGEAL | | Dehydration | | Concerta | SS | | |
| Other OROPHARINGEAL | | Gastroenteritis Viral | | | | | |

Date:05/10/05ISR Number: 4657621-0Report Type:Expedited (15-DaCompany Report #PHBS2005CL06320
Age:14 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|---------------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Hypertensive Crisis | | Ritalin | PS | Novartis Sector: Pharma | |
| 10 mg, UNK | | | | | | | |

Date:05/10/05ISR Number: 4657627-1Report Type:Expedited (15-DaCompany Report #PHBS2005NL06366
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-------------------|---------------|-----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Urinary Retention | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 15 mg/day | | | | | | | |
| | | | | Risperdal | C | | |

Date:05/10/05ISR Number: 4658516-9Report Type:Direct Company Report #CTU 248143
Age:13 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---------------------------------|---------------|-----------------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression Negative Thoughts | | Concerta 27 Mcneil | PS | Mcneil | ORAL |
| 27MG QAM | | | | | | | |
| ORAL | | | | | | | |
| | | Self-Injurious Ideation | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/11/05ISR Number: 4658692-8Report Type:Expedited (15-DaCompany Report #PHBS2005SE06316
 Age:40 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|---------------------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Bedridden Eating Disorder | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 20 mg, BID | | | | | | | |
| | | Movement Disorder Somnolence | | Ritalin-Sr | SS | Novartis Sector: Pharma | |
| 40 mg, BID | | | | | | | |
| | | Tremor | | Ritalin-Sr | SS | Novartis Sector: Pharma | ORAL |
| 120-140 mg/d | | | | | | | |

Date:05/11/05ISR Number: 4658693-XReport Type:Expedited (15-DaCompany Report #PHHO2005BR06966
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia Anxiety | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| 244 DAY | | | | | | | |
| | | Depression | | Ritalin La | SS | | ORAL |
| | | Dizziness | | Ritalin La | SS | | ORAL |
| | | Growth Retardation | | Synthroid | C | | |
| | | Headache | | | | | |
| | | Hyperhidrosis | | | | | |
| | | Hypertension | | | | | |
| | | Irritability | | | | | |
| | | Oral Pruritus | | | | | |
| | | Retching | | | | | |
| | | Sleep Disorder | | | | | |
| | | Suicide Attempt | | | | | |
| | | Tachycardia | | | | | |
| | | Weight Decreased | | | | | |

Date:05/11/05ISR Number: 4659156-8Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050500024
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Other
UNKNOWN

Anxiety
Depression
Tachycardia

Concerta PS

Date:05/11/05ISR Number: 4659157-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20050501245
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Anorexia | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Nausea | | | | | |
| | | Weight Decreased | | | | | |

Date:05/12/05ISR Number: 4660051-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050501858
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Macular Hole | | Concerta | PS | | |
| OROPHARINGEAL | Three | 18 mg | | | | | |
| Initial or Prolonged tablets | | Off Label Use | | | | | |
| | | Optic Nerve Disorder | | Provigil | C | | |
| | | Retinal Detachment | | | | | |
| | | Vision Blurred | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/12/05ISR Number: 4660052-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050501919
 Age:53 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|---|---------------|----------------------|--------|--------------|-------|
| Dose Hospitalization - OROPHARINGEAL Three Initial or Prolonged tablets in the morning, and three 54 mg tablets in | Oedema Peripheral 54 mg Prescribed Overdose | | Concerta | PS | | |
| | | | Zoloft Furosemide | C C | | |

Date:05/12/05ISR Number: 4662567-8Report Type:Expedited (15-DaCompany Report #CEL-2005-00551-SLO
 Age:12 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|-------------|-----------------------------------|---|------|--------------|-------|
| Dose Other Required Intervention to 5MG, BD, PO Prevent Permanent Impairment/Damage | Neutropenia | Foreign Health Professional | Methylphenidate (Methylphenidate Hydrochloride) | PS | | ORAL |

Date:05/12/05ISR Number: 4662753-7Report Type:Expedited (15-DaCompany Report #GBS041015696
 Age:8 YR Gender:Female I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------------|---|-----------------------|---|--------------|--------------|-------|
| Dose Other 40 MG DAY | Emotional Disorder Hallucination, Visual | Foreign Health | Strattera(Atomoxetine Hydrochloride) | PS | | |
| | Nightmare Thinking Abnormal | Professional Other | Methylphenidate Cefadroxil Pseudoephedrine Hydrochloride | SS C C | | |

Date:05/13/05ISR Number: 4661301-5Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050501308
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Life-Threatening | | Chest Pain | | Concerta | PS | | |
| OROPHARINGEAL | | 6 DAY Palpitations | | | | | |

Date:05/16/05ISR Number: 4662088-2Report Type:Expedited (15-DaCompany Report #PHBS2005BR06647
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------------------|---------------|------------|------|----------------------------|-------|
| Other | | Dyspnoea Dysstasia | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, UNK | | Heart Rate Increased | | Ritalin La | SS | | ORAL |
| 20 mg, QD | | Somnolence | | Tofranil | C | | ORAL |
| 1 DF, QHS | | | | | | | |

Date:05/16/05ISR Number: 4662089-4Report Type:Expedited (15-DaCompany Report #PHBS2005JP06683
Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|---------------------------|------|----------------------------|-------|
| Other | | Blood Creatine Phosphokinase Increased | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/d | | | | Morphine Hydrochloride | C | | |
| UNKNOWN | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/16/05ISR Number: 4662096-1Report Type:Expedited (15-DaCompany Report #PHHO2005BR06966
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia | | Ritalina | PS | Novartis Sector: | |
| 244 DAY | | Anxiety | | | | Pharma | ORAL |
| | | Depression | | Ritalin La | SS | | ORAL |
| | | Dizziness | | Ritalin La | SS | | ORAL |
| | | Growth Retardation | | Synthroid | C | | |
| | | Headache | | | | | |
| | | Hyperhidrosis | | | | | |
| | | Hypertension | | | | | |
| | | Irritability | | | | | |
| | | Oral Pruritus | | | | | |
| | | Retching | | | | | |
| | | Sleep Disorder | | | | | |
| | | Suicide Attempt | | | | | |
| | | Tachycardia | | | | | |
| | | Weight Decreased | | | | | |

Date:05/16/05ISR Number: 4662358-8Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050500994
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Growth Retardation | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | | | Ritalin | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:05/16/05ISR Number: 4662359-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050500996
 Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|-------------|------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cyanosis | | Concerta | PS | | |
| OROPHARINGEAL | Patient had | Leukopenia | | | | | |

received

treatment

with this

dosage for 2

OROPHARINGEAL

Concerta SS

OROPHARINGEAL

Ritalin C

Date:05/16/05ISR Number: 4662360-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050502610

Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cardiac Disorder | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Crying | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Depression | | | | | |
| | | Hypoaesthesia | | | | | |
| | | Paraesthesia | | | | | |

Date:05/16/05ISR Number: 4664272-0Report Type:Direct Company Report #CTU 248630

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| | | Nausea | | Ritalin 20 Sr | | | |
| 20 MG ONE | QD 1 | | | Generic | PS | | |
| YR | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/17/05ISR Number: 4663371-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050503193
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|--|---------------|---------------------------------------|------------------|--------------|-------|
| Hospitalization - OROPHARINGEAL | | Anger | | Concerta | PS | | |
| Initial or Prolonged Other | | Intentional Self-Injury Suicidal Ideation | | Lamictal Paxil | C C | | |
| Every morning | | | | Abilify | C | | |
| Every pm | | | | Trazadone | C | | |
| 50 mg to 100 mg daily | | | | Singulair Advair Advair Apri | C C C C | | |

Date:05/17/05ISR Number: 4663372-9Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20050503271
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|---------------------------------|---------------|----------|------|--------------|-------|
| Other OROPHARINGEAL | | Aggression Suicidal Ideation | | Concerta | PS | | |

Date:05/17/05ISR Number: 4664843-1Report Type:Direct Company Report #CTU 248924
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--------|---------------|--------------------------|------|--------------|-------|
| Dose | | Nausea | | Ritalin 20 Sr Generic | PS | | |
| 20MG ONE QD | 1 YR | | | | | | |

Date:05/17/05ISR Number: 4665954-7Report Type:Direct Company Report #CTU 248934
 Age:48 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------------------|---------------|---------------------|------|--------------|-------|
| Hospitalization - 5MG AM AND Initial or Prolonged NOON ORAL | | Depression | | Methylphenidate | 5mg | PS | ORAL |
| 15MG BID ORAL | | Suicidal Ideation | | Buspirone | 15mg | SS | ORAL |
| | | | | Paxil | | C | |
| | | | | Conjugated Estrogen | | C | |
| | | | | Hctz | | C | |
| | | | | Enalapril | | C | |
| | | | | Trazodone | | C | |

Date:05/18/05ISR Number: 4664485-8Report Type:Expedited (15-DaCompany Report #PHEH2005US05372
Age: Gender:Male I/FU:I

| Outcome | PT |
|---------|--------------------------|
| Other | Amnesia |
| | Angiopathy |
| | Anxiety |
| | Arthralgia |
| | Bone Pain |
| | Brain Damage |
| | Cerebral Disorder |
| | Cerebrovascular Accident |
| | Confusional State |
| | Depression |
| | Disturbance In Attention |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/23/05ISR Number: 4669530-1Report Type:Expedited (15-DaCompany Report #PHBS2005BR06647
Age:10 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|------------|-----------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Dyspnoea Dysstasia | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| | 10 mg, TID | | | | | | |
| | 20 mg, QD | Heart Rate Increased | | Ritalin La | SS | | ORAL |
| | 1 DF, QHS | Somnolence | | Tofranil | C | | ORAL |

Date:05/23/05ISR Number: 4669542-8Report Type:Expedited (15-DaCompany Report #PHRM2005FR01561
Age:6 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|-----------|--|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Loss Of Consciousness Syncope Vasovagal | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | 5 mg, BID | | | | | | |

Date:05/23/05ISR Number: 4669545-3Report Type:Expedited (15-DaCompany Report #PHBS2005NO07060
Age:8 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Speech Disorder | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| | 10/10/15 | | | | | | |
| | mg/day | | | | | | |

Date:05/23/05ISR Number: 4669546-5Report Type:Expedited (15-DaCompany Report #PHFR2005GB01807
Age:34 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Erosive Oesophagitis Gastritis Atrophic | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| | 60mg/day | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/23/05ISR Number: 4673551-2Report Type:Expedited (15-DaCompany Report #2004071481
 Age:46 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|---------------------|------|--------------|-------|
| Death | | Blood Disorder | Literature | Diphenhydramine | | | |
| Hospitalization - Initial or Prolonged | | Completed Suicide | Health | (Diphenhydramine) | PS | | |
| | | Depressed Level Of Consciousness | Professional | Ibuprofen | | | |
| | | Electrocardiogram Qrs Complex Prolonged | | (Ibuprofen) | SS | | |
| | | Heart Rate Increased | | Haloperidol | | | |
| | | Intentional Misuse | | (Haloperidol) | SS | | |
| | | Multiple Drug Overdose | | Chlorzoxazone | | | |
| | | Respiratory Arrest | | (Chlorzoxazone) | SS | | |
| | | Stupor | | Cyclobenzaprine | | | |
| | | | | (Cyclobenzaprine) | SS | | |
| | | | | Methylphenidate | | | |
| | | | | (Methylphenidate) | SS | | |
| | | | | Cefalexin | | | |
| | | | | (Cefalexin) | SS | | |
| | | | | Naproxen (Naproxen) | SS | | |
| | | | | Ethanol (Ethanol) | SS | | |

Date:05/24/05ISR Number: 4673142-3Report Type:Direct Company Report #CTU 249312
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------|----------|---|---------------|----------|------|--------------|-------|
| Death DAILY | | Arrhythmia | | Ritalin | PS | | |
| | | Atrial Fibrillation Cardiac Disorder Ejection Fraction Decreased Hypoaesthesia Incorrect Route Of Drug Administration | | Adderall | SS | | |

Date:05/25/05ISR Number: 4673124-1Report Type:Expedited (15-DaCompany Report #AT-JNJFOC-20050502381
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

Other Urticaria Concerta PS
 UNKNOWN
 UNKNOWN Concerta SS
 UNKNOWN Risperdal C
 UNKNOWN

Date:05/25/05ISR Number: 4673125-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050503482

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haematoma | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:05/25/05ISR Number: 4673126-5Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20050503496

Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression Psychotic Disorder | | Concerta | PS | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/25/05ISR Number: 4673127-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050503501

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine | | Concerta | PS | | |
| OROPHARINGEAL | | Phosphokinase Increased | | | | | |

Date:05/25/05ISR Number: 4673128-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050503892

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Haematoma | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:05/25/05ISR Number: 4673304-5Report Type:Expedited (15-DaCompany Report #PHBS2005CA07255

Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------------------|---------------|-----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Weight Increased | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | | | | Strattera | C | | |
| UNKNOWN | | | | | | | |

Date:05/25/05ISR Number: 4673413-0Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0381652A

Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------|---------------|-----------|------|-----------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Paxil | PS | Glaxosmithkline | ORAL |
| 25 DAY | | Agitation | | Dexedrine | SS | Glaxosmithkline | ORAL |
| 10MG per day | | Anger | | Ritalin | SS | | ORAL |
| 5MG Variable | | Anorexia | | | | | |
| dose | 512 DAY | | | | | | |

Anxiety
Fatigue
Hallucination, Auditory
Head Banging
Insomnia
Mental Disorder
Psychotic Disorder

Date:05/27/05ISR Number: 4675925-2Report Type:Periodic
Age:17 YR Gender:Female I/FU:F

Company Report #US-GLAXOSMITHKLINE-A0549009A

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------|---------------|---------------|------|-----------------|-------|
| Dose | | Tremor | | Wellbutrin Xl | PS | Glaxosmithkline | ORAL |
| 150MG Per day | | | | Fentanyl | SS | | |
| | | | | Anesthesia | SS | | |
| | | | | Concerta | SS | | |
| | | | | Ortho Cyclen | C | | |
| | | | | Tapazole | C | | |

Date:05/27/05ISR Number: 4676473-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050504298
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | Delirium | | Concerta | PS | | |
| Other | | | | | | | |
| OROPHARINGEAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/27/05ISR Number: 4676474-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050504423
 Age:21 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Anorexia | | Concerta | PS | | |
| OROPHARINGEAL | | Weight Decreased | | | | | |

Date:05/27/05ISR Number: 4676475-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20050304505
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression | | Concerta | PS | | |
| OROPHARINGEAL | | | | Zyrtec | C | | |
| | | | | Albuterol | C | | |
| | | | | Flovent | C | | |

Date:05/27/05ISR Number: 4676476-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050406692
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucinations, Mixed | | Concerta | PS | | |
| OROPHARINGEAL | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:05/27/05ISR Number: 4677929-2Report Type:Direct Company Report #CTU 249873
 Age:54 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Diarrhoea | | Ritalin | PS | | |
| | | Post Procedural | | Effexor Xr | SS | | |
| | | Complication | | Alprazolam | SS | | |
| | | Sepsis | | Prozac | SS | | |

Stevens-Johnson Syndrome
Subarachnoid Haemorrhage
Toxic Epidermal
Necrolysis

Provigil SS
Strattera SS
Vancomycin C
Zosyn C
Dilantin C
Flagyl C
Caspofungin C
Cipofloxacin C
Ylucanaxol C
Dilaudid C
Phenobarbetol C
Morphene C

Date:05/31/05ISR Number: 4677501-4Report Type:Expedited (15-DaCompany Report #PHBS2005BR07634
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------|---------------|----------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Confusional State | | Ritalina | PS | Novartis Sector: | |
| | | Fight In School | | | | Pharma | ORAL |
| 3 tab/d | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/31/05ISR Number: 4677503-8Report Type:Expedited (15-DaCompany Report #PHNU2005DE02092
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Thrombocytopenia | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| up to 20 mg, | | | | | | | |
| QD | | | | Ritaline | SS | Novartis Sector: Pharma | ORAL |

Date:05/31/05ISR Number: 4677512-9Report Type:Expedited (15-DaCompany Report #PHEH2005US03698
 Age:57 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|--|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Drug Ineffective Drug Withdrawal Syndrome | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 30 mg, QD | 5760 MIN | | | Clarinex | C | | |
| | | Feeling Jittery Feeling Of Despair Hallucination, Auditory Impulsive Behaviour Suicidal Ideation | | | | | |

Date:05/31/05ISR Number: 4678842-7Report Type:Expedited (15-DaCompany Report #S05-USA-02675-01
 Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|---------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Condition Aggravated Death Of Friend | Consumer | Lexapro (Escitalopram) | PS | | ORAL |
| 10 MG QD PO | | | | Lexapro (Escitalopram) | SS | | ORAL |
| 20 MG QD PO | | Depression Drug Ineffective | | Lexapro (Escitalopram) | SS | | ORAL |
| 30 MG QD PO | | Hallucination Overdose | | Lexapro (Escitalopram) | SS | | ORAL |
| | | Post-Traumatic Stress | | Lexapro | | | |

| | | | | |
|-------------|-----------------------|---------------------|----|------|
| 40 MG QD PO | Disorder | (Escitalopram) | SS | ORAL |
| | Suicidal Ideation | Lexapro | | |
| | Suicide Attempt | (Escitalopram) | SS | ORAL |
| 50 MG QD PO | Therapeutic Product | Lexapro | | |
| | Ineffective For | (Escitalopram) | SS | ORAL |
| 30 MG QD PO | Unapproved Indication | Lexapro | | |
| | | (Escitalopram) | SS | ORAL |
| 50 MG QD PO | | Elavil | | |
| | | (Amitriptyline | | |
| | | Hydrochloride) | SS | |
| 50 MG QD | | Klonopin | | |
| | | (Clonazepam) | SS | |
| 1 MG QD | | Ritalin | | |
| | | (Methylphenidate | | |
| | | Hydrochloride) | SS | |
| 30 MG QD | | Ability | | |
| | | (Aripiprazole) | SS | |
| | | Geodon (Ziprasidone | | |
| | | Hydrochloride) | SS | ORAL |
| 40 MG QD PO | | | | |

Date:06/01/05ISR Number: 4678515-0Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050503484
Age:15 YR Gender:Male I/FU:I

Outcome PT
Other Apathy
Asthenia

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|----|---------------|----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | |
| Other | | | | | | | |
| OROPHARINGEAL | | | | | | | |

Date:06/02/05ISR Number: 4679655-2Report Type:Expedited (15-DaCompany Report #BR-JNJFOC-20050507170
 Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | Haldol | PS | | |
| Other | | | | | | | |
| OROPHARINGEAL | patient | | | | | | |
| | | Blood Sodium Decreased | | | | | |
| | | Suicide Attempt | | | | | |
| | | | | Methylphenidate | SS | | |
| | | | | Lamotrigine | SS | | |

Date:06/02/05ISR Number: 4679685-0Report Type:Expedited (15-DaCompany Report #PHFR2005GB01971
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|------------|------|----------------------------|-------|
| Dose | | | | Ritalin | PS | Novartis Sector: Pharma | |
| Other | | | | | | | |
| | | Muscle Spasticity | | | | | |
| | | Nausea | | | | | |
| | | | | Fluoxetine | C | | |
| | | Serotonin Syndrome | | | | | |
| | | Vomiting | | | | | |

Date:06/02/05ISR Number: 4682358-1Report Type:Direct Company Report #CTU 250165
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------|---------------|-----------------|------|--------------|-------|
| Dose | | | | Methylphenidate | PS | | |
| Other | | | | | | | |
| | | Therapeutic Product | | | | | |

Ineffective

Date:06/03/05ISR Number: 4681173-2Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12985131
Age:69 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----|--------------------|-------------|------|------------------------------|-------|
| Death | | | Cerebral Ischaemia | Megace | PS | Bristol-Myers Squibb Company | |
| Hospitalization - Initial or Prolonged INTRAVENOUS | | | | Bevacizumab | SS | | |
| | | | | Gemcitabine | SS | | |
| | | | | Ritalin | SS | | |
| | | | | Osi-774 | SS | | ORAL |

Date:06/06/05ISR Number: 4682314-3Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050500024
Age:26 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----|---------------|----------|------|--------------|-------|
| Other | | | Anxiety | Concerta | PS | | |
| OROPHARINGEAL | 9 | MON | | | | | |
| | | | Depression | Concerta | SS | | |
| OROPHARINGEAL | 9 | MON | | | | | |
| | | | Palpitations | Concerta | SS | | |
| OROPHARINGEAL | 9 | MON | | | | | |
| | | | Tachycardia | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/07/05ISR Number: 4683811-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050507155
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Disability | | Lymphadenopathy | | Concerta | PS | | |
| OROPHARINGEAL | | Viral Infection | | | | | |

Date:06/07/05ISR Number: 4683812-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050600887
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Dysphagia | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| Initial or Prolonged | | Muscle Twitching Speech Disorder | | | | | |

Date:06/08/05ISR Number: 4685312-9Report Type:Expedited (15-DaCompany Report #PHFR2005GB01199
 Age:13 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---|---------------|--|---------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Choking Dyspnoea | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 15mg.day | | Headache | | Adrenaline | SS | | |
| 1/80000 | | Hypersensitivity Malaise Retching | | Lidocaine Hydrochloride Prednisolone | SS C | | ORAL |
| 40mg/day | 362 DAY | Shock | | Sodium Cromoglicate | C | | ORAL |
| 100 mg, QID | | | | Ranitidine | C | | ORAL |
| 150 mg, BID | | | | Ketotifen | C | | ORAL |
| 46080MIN | | | | | | | |

Date:06/08/05ISR Number: 4685313-0Report Type:Expedited (15-DaCompany Report #PHBS2005BE08040
 Age:46 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|--|---------------|------------------------------------|-------------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Agitation Cough | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 5 tab/week | | | | | | | |
| | | Depression Diarrhoea | | Ritalin | SS | Novartis Sector: Pharma | ORAL |
| 3-4 tab/d | | | | | | | |
| 20 mg, BID | | Feeling Abnormal | | Fontex | C | | |
| | | Feeling Cold | | Trazolan | C | | |
| 100 mg, QHS | | | | | | | |
| | | Hyperhidrosis Hyperventilation Increased Appetite | | Rivotril Novothyral Effortil | C C C | | |
| 5 mg, TID | | | | | | | |
| | | Increased Upper Airway Secretion Oral Pain Oral Pruritus Paraesthesia Oral Pharyngolaryngeal Pain Pneumonia Rhinorrhoea Weight Increased | | | | | |

Date:06/09/05ISR Number: 4686506-9Report Type:Expedited (15-DaCompany Report #PHBS2005CA08118
 Age:93 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|----------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Glaucoma | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 7.5 mg/d | | | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

80 mg/d

| | |
|-------------|---|
| Asa | C |
| Inhibace | C |
| Nitro Patch | C |
| Synthroid | C |
| Pantoloc | C |
| Insulin | C |
| Repaglinide | C |

Date:06/09/05ISR Number: 4686507-0Report Type:Expedited (15-DaCompany Report #PHBS2005JP08133
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|---------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Euphoric Mood | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 100 mg, | | | | | | | |
| ONCE/SINGLE | 1440 MIN | | | | | | |

Date:06/10/05ISR Number: 4687447-3Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050202933
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Weight Decreased | | Concerta | PS | | |
| UNKNOWN | | | | | | | |

Date:06/10/05ISR Number: 4687628-9Report Type:Expedited (15-DaCompany Report #PHNU2005DE02207
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Thrombocytopenia | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, QD | | | | | | | |
| UNKNOWN | | | | Concerta | C | | |

Date:06/10/05ISR Number: 4687629-0Report Type:Expedited (15-DaCompany Report #PHEH2005US06346
Age:17 YR Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-----------------------|-------------------|----------|------|------------------|-------|
| Dose | Duration | | | | | |
| Life-Threatening | Depression | | Ritalin | PS | Novartis Sector: | |
| Hospitalization - | Drug Ineffective | | | | Pharma | ORAL |
| 30 mg, QD | | | | | | |
| Initial or Prolonged | Hallucination | | Lexapro | SS | | ORAL |
| 10 mg, QD | 10080MIN | | | | | |
| Other | Post-Traumatic Stress | | Lexapro | SS | | ORAL |
| 20 mg, QD | 10080MIN | | | | | |
| 30 mg, QD | 10080MIN | Disorder | Lexapro | SS | | ORAL |
| 40 mg, QD | 10080MIN | Suicidal Ideation | Lexapro | SS | | ORAL |
| 50 mg, QD | | Suicide Attempt | Lexapro | SS | | ORAL |
| | | | Lexapro | SS | | ORAL |
| 30 mg, QD | | | Lexapro | SS | | ORAL |
| 50 mg, QD | | | Elavil | SS | | ORAL |
| 50 mg, QD | | | Klonopin | SS | | ORAL |
| 1 mg, QD | | | Abilify | SS | | ORAL |
| UNK, UNK | 104 DAY | | Geodon | SS | | ORAL |
| 40 mg, QD | | | | | | |

Date:06/14/05ISR Number: 4689747-XReport Type:Expedited (15-DaCompany Report #PHBS2005ZA08323
Age:13 YR Gender:Female I/FU:I

| Outcome | PT |
|----------------------|---------------------------|
| Hospitalization - | Hepatic Function Abnormal |
| Initial or Prolonged | Pyrexia |
| | Spleen Disorder |
| | Splenic Infection |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| | | | | | | | |
|---------|----------|----------------------------------|---------------|---------|------|----------------------------|-------|
| | | Splenomegaly Thrombocytopenia | | | | | |
| Dose | Duration | | Report Source | Product | Role | Manufacturer | Route |
| | | | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | | | | | | | |

Date:06/14/05ISR Number: 4689857-7Report Type:Expedited (15-DaCompany Report #CA-JNJFOC-20050600213
Age:8 YR Gender:Male I/FU:F

| | | | | | | | |
|---------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Aggression | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Obsessive-Compulsive | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |
| | | Disorder | | | | | |

Date:06/15/05ISR Number: 4690428-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050601382
Age:17 YR Gender:I/FU:I

| | | | | | | | |
|---------------|----------|--------------|---------------|----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Death | | Sudden Death | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:06/15/05ISR Number: 4690429-9Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050602118
Age:11 YR Gender:Male I/FU:I

| | | | | | | | |
|---------------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
| Dose | | | | | | | |
| Other | | Abdominal Pain | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| | | Drug Withdrawal Syndrome | | | | | |
| | | Tremor | | | | | |

Date:06/15/05ISR Number: 4690887-XReport Type:Expedited (15-DaCompany Report #PHBS2005BR07634
Age:4 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Confusional State Fight In School | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| 3 tab/d | | | | | | | |

Date:06/15/05ISR Number: 4690891-1Report Type:Expedited (15-DaCompany Report #PHRM2005FR01561
Age:6 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Apathy Fall | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 5 mg, BID | 15840MIN | Hypotonia Loss Of Consciousness Syncope Vasovagal | | | | | |

Date:06/16/05ISR Number: 4691673-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050601562
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Arthralgia | | Concerta | PS | | |
| OROPHARINGEAL | | Blood Creatine Phosphokinase Increased Myalgia | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/17/05ISR Number: 4692548-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20050601892
 Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Dystonia | | Concerta | PS | | |
| OROPHARINGEAL | | Growth Retardation Speech Disorder | | Risperdal | SS | | |

Date:06/17/05ISR Number: 4692549-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050601900
 Age:8 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Grand Mal Convulsion | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

Date:06/20/05ISR Number: 4694360-4Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12998167
 Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|---|--------------------------------|---|----------------------------------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Depression Drug Ineffective Hallucination Intentional Misuse Post-Traumatic Stress Disorder Suicidal Ideation Suicide Attempt | | Abilify Lexapro Elavil Klonopin Ritalin Geodon | PS SS SS SS SS | Otsuka Pharmaceutical Company, Ltd. | ORAL ORAL ORAL |

Date:06/20/05ISR Number: 4694379-3Report Type:Expedited (15-DaCompany Report #PHNR2005AU00976
 Age:11 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Amnesia Feeling Abnormal | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:06/20/05ISR Number: 4694381-1Report Type:Expedited (15-DaCompany Report #PHBS2005NL08451
Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------|---------------|---------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged UNK, UNK | | Status Epilepticus | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:06/20/05ISR Number: 4694480-4Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20050505167
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|--------------|---------------|----------|------|--------------|-------|
| Other OROPHARINGEAL | | Sleep Terror | | Concerta | PS | | |

Date:06/20/05ISR Number: 4695528-3Report Type:Direct Company Report #CTU 251527
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|---------------|--|----------|-----------------------|--------------|
| Required Intervention to 20MG TID Prevent Permanent ORAL Impairment/Damage 54MG BID | | Acarodermatitis Bacterial Infection Obsessive-Compulsive Disorder Rash Papular | | Methylphenidate 20mg Mallinkrodt Concerta 54mg Mcneil | PS SS | Mallinkrodt Mcneil | ORAL ORAL |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

ORAL

| | |
|---------------|---|
| Motrin | C |
| Nasalide | C |
| Vit B Complex | C |
| Paxil | C |
| Robitussin | C |
| Atacand | C |
| Glipizide | C |
| Ctm | C |
| Immodium | C |

Date:06/21/05ISR Number: 4695691-4Report Type:Expedited (15-DaCompany Report #PHBS2005SE08708
Age:19 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------|---------------|-----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | 40 mg/d | Mania | | Ritalina | PS | Novartis Sector: Pharma | ORAL |
| UNKNOWN | 10 mg/d | | | Iktorivil | C | | |
| UNKNOWN | 200 mg/d | | | Seroquel | C | | |
| UNKNOWN | | | | Propavan | C | | |
| UNKNOWN | | | | Risperdal | C | | |

Date:06/21/05ISR Number: 4695785-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050603549
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|----------|---------------|----------|------|--------------|-------|
| Other OROPHARINGEAL | | Dystonia | | Concerta | PS | | |

Date:06/21/05ISR Number: 4695786-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050604311
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
|---------|----------|----|---------------|---------|------|--------------|-------|

Life-Threatening Cerebrovascular Accident Concerta PS
OROPHARINGEAL
Other

Date:06/22/05ISR Number: 4696905-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050605089
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Depression | | Concerta | PS | | |
| OROPHARINGEAL | | Heart Rate Increased Hypoaesthesia Suicidal Ideation | | Crestor | C | | |

Date:06/22/05ISR Number: 4697194-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050500996
Age:12 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|-------------|------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cyanosis | | Concerta | PS | | |
| OROPHARINGEAL | Patient had | Leukopenia | | | | | |
| received | | | | | | | |
| treatment | | | | | | | |
| with this | | | | | | | |
| dosage for 2 | | | | | | | |
| OROPHARINGEAL | | | | Concerta | SS | | |
| OROPHARINGEAL | | | | Ritalin | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/23/05ISR Number: 4698019-9Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12979936
 Age:68 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----------------------|---------------|-------------|------|------------------------------|-------|
| Death | | Cerebral Ischaemia | | Megace | PS | Bristol-Myers Squibb Company | |
| Hospitalization - Initial or Prolonged | | Myocardial Ischaemia | | Bevacizumab | SS | | |
| INTRAVENOUS | | | | Gemcitabine | SS | | |
| INTRAVENOUS | | | | Ritalin | SS | | |
| | | | | Osi-774 | SS | | ORAL |

Date:06/23/05ISR Number: 4698089-8Report Type:Expedited (15-DaCompany Report #PHBS2005CA08926
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------|---------|------|----------------------------|-------|
| Other | | Cellulitis Infection | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 25 mg/d | | Rash Papular | | | | | |

Date:06/23/05ISR Number: 4698093-XReport Type:Expedited (15-DaCompany Report #PHNU2005DE02323
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-----------------------|---------------|------------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged | | Overdose Poisoning | | Ritalin-Sr | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/day | | | | Ritalin-Sr | SS | Novartis Sector: Pharma | ORAL |
| Other | | | | | | | |
| 400 mg, | | | | | | | |
| ONCE/SINGLE | | | | | | | |

Date:06/23/05ISR Number: 4698200-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050604639
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|----------|------|--------------|-------|
| Other | | Abnormal Behaviour | | Concerta | PS | | |
| OROPHARINGEAL | | Affect Lability Anorexia Pain In Extremity Weight Gain Poor | | | | | |

Date:06/24/05ISR Number: 4699166-8Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20050603414
 Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------|---------------|-----------|------|--------------|-------|
| Other | | Cardiac Flutter | | Concerta | PS | | |
| UNKNOWN | | Conduction Disorder | | Risperdal | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:06/24/05ISR Number: 4699167-XReport Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050603828
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------------------|---------------|----------|------|--------------|-------|
| Other | | Blood Glucose Increased | | Concerta | PS | | |
| OROPHARINGEAL | | Blood Insulin Decreased | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/24/05ISR Number: 4699168-1Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050604133
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------|---------------|----------|------|--------------|-------|
| Death | | Death | | Concerta | PS | | |
| UNKNOWN | | | | | | | |

Date:06/24/05ISR Number: 4699169-3Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050601562
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--|---------------|----------|------|--------------|-------|
| Other | | Arthralgia | | Concerta | PS | | |
| OROPHARINGEAL | | Blood Creatine Phosphokinase Increased Myalgia | | | | | |

Date:06/24/05ISR Number: 4701210-6Report Type:Expedited (15-DaCompany Report #2005089211
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--|------------------------|---|------|--------------|-------|
| Hospitalization - Initial or Prolonged 120 MG (1 D), Other ORAL | | Convulsion Drooling | Health Professional | Geodon (Ziprasidone) | PS | | ORAL |
| ORAL | | Dystonia | Company | | | | |
| ORAL | | Jaw Disorder Oral Intake Reduced Sydenham'S Chorea | Representative | Strattera (Atomoxetine Hydrochloride) | SS | | ORAL |
| ORAL | | | | Conerta (Methylphenidate Hydrochloride) | SS | | ORAL |
| ORAL | | | | Depakote (Valproate Semisodium) | C | | ORAL |

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------------------|---------------|----------|------|--------------|-------|
| | | Abnormal Behaviour | | Concerta | PS | | |
| OROPHARINGEAL | | Aggression | | Concerta | SS | | |
| OROPHARINGEAL | | Diarrhoea | | Concerta | SS | | |
| OROPHARINGEAL | | Drug Administration Error | | | | | |
| | | Hallucination, Auditory | | | | | |
| | | Headache | | | | | |
| | | Off Label Use | | | | | |
| | | Personality Change | | | | | |
| | | Stomach Discomfort | | | | | |

Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|--------------|---------------|----------|------|--------------|-------|
| | | Sleep Terror | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/27/05ISR Number: 4700271-8Report Type:Expedited (15-DaCompany Report #PHFR2005GB02196
Age:11 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|-----------------------|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Hallucinations, Mixed | | Methylphenidate | PS | Novartis Sector: Pharma | ORAL |
| 15mg/day | | | | Melatonin | C | | ORAL |
| 3mg/nocte | | | | | | | |

Date:06/27/05ISR Number: 4700272-XReport Type:Expedited (15-DaCompany Report #PHEH2005US06795
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------|---------------|-------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Syncope Vomiting | | Ritalin | PS | Novartis Sector: Pharma | |
| 10 mg, QD | | | | | | | |
| Other | | Weight Decreased | | Ritalin | SS | Novartis Sector: Pharma | |
| 20 mg, QD | | | | | | | |
| 40 mg, QD | | | | Ritalin La | SS | | |
| | | | | Abilify | C | | |
| | | | | Risperdal | C | | |
| | | | | Concerta | C | | |
| | | | | Adderall | C | | |
| | | | | Hydroxyzine | C | | |
| | | | | Depakene | C | | |

Date:06/27/05ISR Number: 4700273-1Report Type:Expedited (15-DaCompany Report #PHBS2005US08999
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---------------------------------------|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Aggression Extrapyramidal Disorder | | Methylphenidate | PS | Novartis Sector: Pharma | |
| UNKNOWN | 36 mg/d | | | | | | |
| | | Musculoskeletal Stiffness | | Methylphenidate | SS | Novartis Sector: Pharma | |
| | | Suicide Attempt | | | | | |
| UNKNOWN | 54 mg/d | | | | | | |

150 mg, BID Tic Fluvoxamine C
 1 mg, BID Guanfacine C
 0.5 mg, TID Risperidone C

Date:06/27/05ISR Number: 4700283-4Report Type:Expedited (15-DaCompany Report #PHBS2005JP06683
 Age:70 YR Gender: I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|---|---------------|---------------------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Creatine Phosphokinase Increased | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/d | 4320 MIN | | | | | | |
| UNKNOWN | 60 mg/d | Body Temperature Increased | | Morphine Hydrochloride | C | | |
| 120 mg/d | | C-Reactive Protein Increased | | Morphine Hydrochloride | C | | |
| | | Cardiomyopathy Hyperhidrosis Myoglobin Blood Increased Neuroleptic Malignant Syndrome | | | | | |

Date:06/28/05ISR Number: 4700962-9Report Type:Expedited (15-DaCompany Report #PHBS2005JP08859
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | Aggression | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | | | | | | | |

Date:06/30/05ISR Number: 4704838-2Report Type:Direct
Age:9 YR Gender:Male I/FU:I

Company Report #CTU 252325

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|------------------|---------------|----------------|------|--------------|-------|
| Dose Required 18 MG ONCE | | Trichotillomania | | Concerta 18 Mg | PS | | ORAL |
| Intervention to A DAY ORAL Prevent Permanent Impairment/Damage | | | | | | | |

Date:07/01/05ISR Number: 4705131-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050606762
Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|--|---------------|----------|------|--------------|-------|
| Dose Other OROPHARINGEAL | | Increased Tendency To Bruise Lower Limb Fracture | | Concerta | PS | | |

Date:07/01/05ISR Number: 4705300-3Report Type:Expedited (15-DaCompany Report #PHBS2005JP09292
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|-----------|---------------|---------|------|----------------------------|-------|
| Dose Other 244 DAY | | Leukaemia | | Ritalin | PS | Novartis Sector: Pharma | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/01/05ISR Number: 4705323-4Report Type:Expedited (15-DaCompany Report #PHBS2005ZA05762
 Age:11 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------|---------------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Hepatic Enzyme Increased | | Ritalin | PS | Novartis Sector: Pharma | |
| UNKNOWN | 10 mg/d | Hepatitis A | | | | | |
| | | Hepatomegaly | | Ritalin | SS | Novartis Sector: Pharma | |
| 25 mg/d | 63360MIN | Jaundice | | | | | |
| | | Liver Disorder | | Vitamin B | C | | |
| | | Nausea | | Vitamin C | C | | |
| | | Urticaria | | Omega 3 | C | | |
| | | | | Omega-6 Fatty Acids | C | | |

Date:07/01/05ISR Number: 4707275-XReport Type:Direct Company Report #CTU 252425
 Age:8 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|-------------------------|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Adderall Xr | PS | | ORAL |
| 30MG ONCE | | Anger | | | | | |
| PER DAY | | Physical Assault | | | | | |
| ORAL | | Self-Injurious Ideation | | Ritalin La | SS | | ORAL |
| ONCE PER DAY | | | | Ni | | | |
| ORAL | | | | | | | |

Date:07/05/05ISR Number: 4707840-XReport Type:Direct Company Report #CTU 252525
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hallucination | | Concerta | PS | | ORAL |
| ONCE DAILY | | Laboratory Test Abnormal | | 54+18mg | | | |
| ORAL | | Ocular Icterus | | | | | |

Date:07/05/05ISR Number: 4708213-6Report Type:Direct
Age: Gender: I/FU:I

Company Report #USP 57206

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | Medication Error | | Sonata | PS | Jones Pharma | |
| CAPSULE | | | | Concerta | SS | Alza | |
| TABLET, | | | | | | | |
| EXTENDED | | | | | | | |
| RELEASE | | | | | | | |

Date:07/06/05ISR Number: 4707101-9Report Type:Expedited (15-DaCompany Report #PHBS2005JP05433
Age:7 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|---|---------------|----------------------|----------|----------------------------|--------------|
| Hospitalization - Initial or Prolonged 20 mg/d | | Cataplexy Eye Rolling | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| | | Hyperventilation Loss Of Consciousness | | Ritaline Depromel | SS SS | | ORAL ORAL |
| 50 mg/d | | Tic Tonic Convulsion Tremor | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/06/05ISR Number: 4707113-5Report Type:Expedited (15-DaCompany Report #PHNR2005AU01033
Age:15 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------------|---------------|--------------------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Retinal Pigmentation | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| | | | | Dexamfetamine Sulfate | SS | | |

Date:07/06/05ISR Number: 4707116-0Report Type:Expedited (15-DaCompany Report #PHNR2005AU01047
Age:99 Gender:Unknown I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|--|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Cardiac Arrest Ventricular Fibrillation | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 60 mg , daily | 3325 DAY | | | | | | |

Date:07/06/05ISR Number: 4707117-2Report Type:Expedited (15-DaCompany Report #PHNR2005AU01059
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---|---------------|------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper Anorexia Choreoathetosis | | Ritalin La | PS | Novartis Sector: Pharma | ORAL |
| 20 mg/day | | | | Omeprazole | SS | | |

Date:07/06/05ISR Number: 4707568-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050606833
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Delusion | | Concerta | PS | | |
| OROPHARINGEAL | | Drug Ineffective | | Concerta | SS | | |
| OROPHARINGEAL | | Tic | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | | |

Date:07/06/05ISR Number: 4707569-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050607321
Age:9 YR Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------------------|---------------|----------|------|--------------|-------|
| Dose | Duration | | | | | |
| Hospitalization - | Aggression | | Concerta | PS | | |
| Initial or Prolonged | Anxiety | | Abilify | C | | |
| Other | Bipolar Disorder | | Tenex | C | | |
| | Electroencephalogram | | | | | |
| | Abnormal | | | | | |
| | Psychotic Disorder | | | | | |
| | Schizophrenia | | | | | |
| | Suicidal Ideation | | | | | |

Date:07/06/05ISR Number: 4707570-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050504298
Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|---------------|----------|------|--------------|-------|
| Dose | Duration | | | | | |
| Other | Delirium | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | |
| | | | Concerta | SS | | |
| OROPHARINGEAL | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/08/05ISR Number: 4709389-7Report Type:Expedited (15-DaCompany Report #PHNR2005AU01047
 Age: Gender:Unknown I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------------------|--|------------|------|----------------------------|-------|
| Dose Life-Threatening 60 mg , daily | Duration 3325 DAY | Cardiac Arrest Ventricular Fibrillation | Ritalin La | PS | Novartis Sector: Pharma | ORAL |

Date:07/08/05ISR Number: 4709390-3Report Type:Expedited (15-DaCompany Report #PHNU2005DE01277
 Age:14 YR Gender:Female I/FU:F

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------|----------|---|---------------------------|------|----------------------------|-------|
| Dose Other UNK, IRD | Duration | Drug Withdrawal Syndrome Hallucination, Auditory | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 20 mg, QD | | | Ritalin - Slow Release | C | | ORAL |
| 20 mg, QD | | | Ritalin - Slow Release | C | | ORAL |
| 37.5 mg, QD | | | L-Thyroxin | C | | ORAL |
| | | | Loratadine | C | | |

Date:07/08/05ISR Number: 4709391-5Report Type:Expedited (15-DaCompany Report #PHNR2005AU01067
 Age:7 YR Gender: I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------------------|---|--------------------------|------|----------------------------|-------|
| Dose Hospitalization - Initial or Prolonged 10 mg, QD | Duration 90720MIN | Anxiety Obsessive-Compulsive Disorder | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, QD | 89280MIN | | Dexamfetamine Sulfate | SS | | ORAL |

Date:07/08/05ISR Number: 4709399-XReport Type:Expedited (15-DaCompany Report #PHBS2005JP08133
 Age:19 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|---------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Anxiety Mania | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 100 mg, | | Tremor | | | | | |
| ONCE/SINGLE | 1440 MIN | | | | | | |

Date:07/08/05ISR Number: 4709408-8Report Type:Expedited (15-DaCompany Report #PHNU2005DE02207
Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|------------------|---------------|----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Thrombocytopenia | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 10 - 15 mg, | | | | | | | |
| QD | | | | | | | |
| 18 mg, QD | | | | Concerta | C | | ORAL |

Date:07/08/05ISR Number: 4709794-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050606853
Age: Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------------|----------|---|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - OROPHARINGEAL | | Encephalitis | | Concerta | PS | | |
| Initial or Prolonged | | Hypertension | | | | | |
| Other | | Urinary Tract Infection Enterococcal | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/08/05ISR Number: 4709795-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050607585
 Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|-----------------|---------------|----------|------|--------------|-------|
| Life-Threatening | | Suicide Attempt | | Concerta | PS | | |
| OROPHARINGEAL | | | | | | | |
| Other | | | | Seroquel | C | | |

Date:07/11/05ISR Number: 4712017-8Report Type:Direct Company Report #CTU 252968
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|-----------------------|---------------|----------------|------|--------------|-------|
| Other | | Abnormal Behaviour | | Concerta 18 Mg | PS | | ORAL |
| 1 ONCE A | | | | | | | |
| DAY ORAL | | Agitation | | | | | |
| | | Anger | | | | | |
| | | Hallucination | | | | | |
| | | Hallucination, Visual | | | | | |
| | | Impulsive Behaviour | | | | | |
| | | Screaming | | | | | |

Date:07/11/05ISR Number: 4712823-XReport Type:Direct Company Report #CTU 252983
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|---------------|------|--------------|-------|
| Other | | Drug Effect Decreased | | Ritalin 10 Mg | PS | | |
| 1 TID | | | | | | | |
| | | Therapeutic Response | | | | | |
| | | Unexpected With Drug | | | | | |
| | | Substitution | | | | | |

Date:07/12/05ISR Number: 4711595-2Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050602118
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| | | | |
|---------------|--------------------------|----------|----|
| Other | Abdominal Pain | Concerta | PS |
| OROPHARINGEAL | | | |
| | Drug Withdrawal Syndrome | Concerta | SS |
| OROPHARINGEAL | | | |
| | Tremor | Concerta | SS |
| OROPHARINGEAL | | | |

Date:07/12/05ISR Number: 4711596-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050701152
 Age:13 YR Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|------------|---------------|----------|------|--------------|-------|
| Death | | Arrhythmia | | Concerta | PS | | |
| OROPHARINGEAL | | | | Zyrtec | C | | |

Date:07/12/05ISR Number: 4711939-1Report Type:Expedited (15-DaCompany Report #PHEH2005US07492
 Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-------------|----------|----------------|---------------|--------------------|------|----------------------------|-------|
| Other | | Duodenal Ulcer | | Ritalin | PS | Novartis Sector: Pharma | |
| 10 mg, QD | | | | Adderall | SS | | |
| 18 mg, UNK | | | | Concerta | C | | |
| 7.5 mg, UNK | | | | Remeron | C | | |
| 30 mg, UNK | | | | Melatonin | C | | |
| | | | | Belladonna Extract | C | | |
| | | | | Prevacid | C | | |
| | | | | Zithromax Z-Pack | C | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/12/05ISR Number: 4711941-XReport Type:Expedited (15-DaCompany Report #PHNU2005DE02505
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|----|-------------------------|----------|------|----------------------------|-------|
| Hospitalization - Initial or Prolonged 30 mg/day | | | Splenic Vein Thrombosis | Ritaline | PS | Novartis Sector: Pharma | ORAL |

Date:07/12/05ISR Number: 4711942-1Report Type:Expedited (15-DaCompany Report #PHBS2005JP08133
Age:19 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|----------|----|-----------------------------------|---------|------|----------------------------|-------|
| Other 100 mg, ONCE/SINGLE | 1440 MIN | | Anxiety Irritability Tremor | Ritalin | PS | Novartis Sector: Pharma | ORAL |

Date:07/12/05ISR Number: 4712098-1Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050603867
Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------|----------|----|---|----------|------|--------------|-------|
| Other OROPHARINGEAL | | | Generalised Anxiety 1060 DAY Disorder | Concerta | PS | | |

Date:07/12/05ISR Number: 4712099-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050604311
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------------------------------|----------|----|--------------------------|-----------|------|--------------|-------|
| Life-Threatening OROPHARINGEAL | | | Cerebrovascular Accident | Concerta | PS | | |
| Other OROPHARINGEAL | | | | Strattera | C | | |
| OROPHARINGEAL | | | | Strattera | C | | |

OROPHARINGEAL

Date:07/12/05ISR Number: 4712100-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050700727

Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Pancreatitis | | Concerta | PS | | |

OROPHARINGEAL

Date:07/12/05ISR Number: 4712827-7Report Type:Direct Company Report #CTU 252988

Age:16 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|------------|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Agitation | | Concerta 18mg | PS | | ORAL |
| CONCERTA 18, | | Anxiety | | | | | |
| 36, 54 ORAL | | Depression | | . | C | | |

Date:07/13/05ISR Number: 4713117-9Report Type:Expedited (15-DaCompany Report #PHBS2005CA08926

Age:7 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|---------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Cellulitis | | Ritalin | PS | Novartis Sector: | ORAL |
| 25 mg/d | | Infection | | | | Pharma | |
| | | Rash Papular | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/14/05ISR Number: 4714428-3Report Type:Expedited (15-DaCompany Report #IE-JNJFOC-20050405477
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------|----------|-------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Leukopenia | | Concerta | PS | | |
| OROPHARINGEAL | | Neutropenia | | | | | |

Date:07/14/05ISR Number: 4715411-4Report Type:Direct Company Report #USP 57236
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|----------------|------|--------------|-------|
| Dose | | | | | | | |
| TABLET | | Drug Dispensing Error | | Oxycodone 5 Mg | PS | Mallinckrodt | |
| TABLET | | Medication Error | | Methylin 5 Mg | SS | Mallinckrodt | |

Date:07/14/05ISR Number: 4716878-8Report Type:Expedited (15-DaCompany Report #8010920
 Age:16 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------------|---------------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Rhabdomyolysis | Health Professional | Metadate Cd | PS | | |
| | | | | Wellbutrin Sr | C | | |
| | | | | Wellbutrin | C | | |

Date:07/15/05ISR Number: 4714843-8Report Type:Expedited (15-DaCompany Report #US-SOLVAY-00305002231
 Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------------------|----------|-------------------------|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - UNKNOWN | Daily | Drug Dose Omission | | Fluvoxamine | PS | | |
| Initial or Prolonged unknown | | Dystonia | | | | | |
| UNKNOWN | Daily | Extrapyramidal Disorder | | Fluvoxamine | SS | | |
| | | Neurotransmitter Level | | | | | |

milligram(s) Altered

UNKNOWN Daily dose: Methylphenidate SS
36

milligram(s)
UNKNOWN Daily dose: Risperidone SS
1.5

milligram(s)
UNKNOWN Daily dose: Methylphenidate SS
54

milligram(s)
UNKNOWN Daily dose: 2 Guanfacine C

Date:07/15/05ISR Number: 4715279-6Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050700865
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypotension Syncope | | Concerta | PS | | ORAL |

Date:07/18/05ISR Number: 4716071-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050700425
Age:35 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypertension | | Concerta | PS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/18/05ISR Number: 4716072-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050700662
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|---------------------|---------|--------------|-------|
| Dose | | | | | | | |
| Other | | Electrocardiogram Qt Prolonged Syncope | | Concerta Lexapro | PS C | | ORAL |

Date:07/18/05ISR Number: 4716073-2Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050603828
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Blood Glucose Increased Blood Insulin Decreased | | Concerta | PS | | ORAL |

Date:07/18/05ISR Number: 4716074-4Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050503484
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Apathy Asthenia Confusional State | | Concerta | PS | | ORAL |

Date:07/19/05ISR Number: 4718704-XReport Type:Expedited (15-DaCompany Report #S05-USA-02675-01
 Age:17 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|--|---------------|---------------------------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged 50 MG QD PO | | Abnormal Behaviour Condition Aggravated | Consumer | Lexapro (Escitalopram) | PS | | ORAL |
| 10 MG QD PO | | Depression Drug Ineffective | | Lexapro (Escitalopram) | SS | | ORAL |
| 20 MG QD PO | | Hallucination Intentional Misuse | | Lexapro (Escitalopram) | SS | | ORAL |
| | | Overdose | | Lexapro | | | |

| | | | | |
|-------------|-------------------------|---------------------|----|------|
| 30 MG QD PO | Post-Traumatic Stress | (Escitalopram) | SS | ORAL |
| | Disorder | Lexapro | | |
| 40 MG QD PO | Suicidal Ideation | (Escitalopram) | SS | ORAL |
| | Suicide Attempt | Lexapro | | |
| 50 MG QD PO | Treatment Noncompliance | (Escitalopram) | SS | ORAL |
| | | Lexapro | | |
| 30 MG QD PO | | (Escitalopram) | SS | ORAL |
| | | Elavil | | |
| 50 MG QD | | (Amitriptyline | | |
| | | Hydrochloride) | SS | |
| 1 MG QD | | Klonopin | | |
| | | (Clonazepam) | SS | |
| | | Ritalin | | |
| | | (Methylphenidate | | |
| 30 MG QD | | Hydrochloride) | SS | |
| | | Abilify | | |
| | | (Aripiprazole) | SS | |
| | | Geodon (Ziprasidone | | |
| 40 MG QD PO | | Hydrochloride) | SS | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/19/05ISR Number: 4724537-0Report Type:Direct
 Age: Gender:Female I/FU:I

Company Report #CTU 253601

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------------------------------|------|--------------|-------|
| Dose | | Anger Mood Swings | | Methylphenidate 20 Mg Tablets | PS | | |
| QAM | | | | | | | |
| | | Therapeutic Response Unexpected With Drug | | Methylphenidate 10 Mg Tablets | SS | | |
| QAM | | | | | | | |
| | | Substitution | | | | | |

Date:07/20/05ISR Number: 4718269-2Report Type:Expedited (15-DaCompany Report #PHFR2005GB02497
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|---------|------|----------------------------|-------|
| Dose | | Cardiac Disorder | | Ritalin | PS | Novartis Sector: Pharma | |
| Other | | | | | | | |

Date:07/20/05ISR Number: 4718270-9Report Type:Expedited (15-DaCompany Report #PHEH2005US07724
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|---------|------|----------------------------|-------|
| Dose | | Dementia Dementia Alzheimer'S Type Hypersomnia | | Ritalin | PS | Novartis Sector: Pharma | |
| Other | | | | | | | |

Date:07/20/05ISR Number: 4718271-0Report Type:Expedited (15-DaCompany Report #PHBS2005JP10244
 Age: Gender: I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|---------------|---------|------|----------------------------|-------|
| Dose | | Drug Toxicity | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| Other | | | | | | | |

100 mg/d

Date:07/20/05ISR Number: 4718278-3Report Type:Expedited (15-DaCompany Report #PHFR2005GB01807
Age:34 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------|----------|--|---------------|-----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | Erosive Oesophagitis Gastritis Atrophic | | Ritaline | PS | Novartis Sector: Pharma | ORAL |
| 60mg/day | | Ulcer | | Thyroxine | C | | |
| UNKNOWN | | | | | | | |

Date:07/21/05ISR Number: 4720689-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050701674
Age:17 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|--------------|---------------|--------------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Sudden Death | | Concerta | PS | | ORAL |
| Life-Threatening | | | | Erythromycin | C | | |

Date:07/21/05ISR Number: 4720690-3Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050702556
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Fall | | Concerta | PS | | |
| | | Feeling Abnormal | | Concerta | SS | | |
| | | Loss Of Consciousness | | Concerta | SS | | |
| | | Migraine | | | | | |
| | | Vomiting | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/21/05ISR Number: 4720691-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050702560
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cerebral Atrophy | | Concerta | PS | | ORAL |

Date:07/22/05ISR Number: 4722772-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050702243
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Epilepsy | | Concerta | PS | | ORAL |

Date:07/22/05ISR Number: 4722883-8Report Type:Expedited (15-DaCompany Report #PHBS2005JP08859
 Age:56 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|------------|---------------|-----------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged 20 mg/d | | Aggression | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 100 mg/d | | | | Symmetrel | C | | ORAL |

Date:07/22/05ISR Number: 4722884-XReport Type:Expedited (15-DaCompany Report #PHNU2005DE02505
 Age:17 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--|----------|-------------------------|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged 30 mg/day | | Splenic Vein Thrombosis | | Methylphenidate | PS | Novartis Sector: Pharma | ORAL |

Date:07/22/05ISR Number: 4722885-1Report Type:Expedited (15-DaCompany Report #PHFR2005GB02481
 Age:65 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|---------------|---------|------|--------------|-------|
| Dose | | | | | | | |

| Outcome | Dose | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|-------------|----------|-----------------------------------|---------------|-----------------|------|----------------------------|-------|
| Life-Threatening | 10 mg, BID | | Haematuria | | Methylphenidate | PS | Novartis Sector: Pharma | ORAL |
| | 200 mg, QID | | | | Gabapentin | SS | | ORAL |
| Date:07/25/05ISR Number: 4723390-9Report Type:Expedited (15-DaCompany Report #PHEH2005US06346 Age:17 YR Gender:Female I/FU:F | | | | | | | | |
| Life-Threatening | 30 mg, QD | | Depression | | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| Hospitalization - Initial or Prolonged | 10 mg, QD | 10080MIN | Drug Ineffective | | Lexapro | SS | | ORAL |
| Other | 20 mg, QD | 10080MIN | Hallucination | | Lexapro | SS | | ORAL |
| | 30 mg, QD | 10080MIN | Overdose | | Lexapro | SS | | ORAL |
| | 40 mg, QD | 10080MIN | Post-Traumatic Stress Disorder | | Lexapro | SS | | ORAL |
| | 50 mg, QD | | Suicidal Ideation | | Lexapro | SS | | ORAL |
| | 30 mg, QD | | Suicide Attempt | | Lexapro | SS | | ORAL |
| | 50 mg, QD | | | | Lexapro | SS | | ORAL |
| | 50 mg, QD | | | | Elavil | SS | | ORAL |
| | 1 mg, QD | 341 DAY | | | Klonopin | SS | | ORAL |
| | UNK, UNK | 135 DAY | | | Abilify | SS | | ORAL |
| | 40 mg, QD | 46080MIN | | | Geodon | SS | | ORAL |
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/25/05ISR Number: 4723880-9Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050702397
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Confusional State | | Concerta | PS | | ORAL |
| 3 MON | | Hallucination Sleep Disorder Tic | | | | | |

Date:07/25/05ISR Number: 4723881-0Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050702991
 Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Death | | Cerebral Haematoma | | Concerta | PS | | ORAL |
| Hospitalization - Initial or Prolonged | | | | | | | |

Date:07/25/05ISR Number: 4727437-5Report Type:Direct Company Report #CTU 254216
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------|----------|--|---------------|---------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Cardiac Disorder | | Concerta 27mg | PS | | |
| 1 TABLET DAI | | Chest Pain Suicidal Ideation Tachycardia | | | | | |

Date:07/26/05ISR Number: 4724912-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050703143
 Age:7 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|-----------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Delusion | | Concerta | PS | | ORAL |
| At bedtime | | Hallucination, Visual | | Strattera | SS | | ORAL |

Date:07/26/05ISR Number: 4724913-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050604311

Age: Gender:Male I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|-----------------------|---------------|-----------|------|--------------|-------|
| Dose | Duration | | | | | |
| Life-Threatening | Cerebrovascular Spasm | | Concerta | PS | | ORAL |
| Hospitalization - | | | Strattera | SS | | ORAL |
| Initial or Prolonged | | | Strattera | SS | | ORAL |
| Disability | | | Strattera | SS | | ORAL |
| Other | | | | | | |

Date:07/26/05ISR Number: 4724914-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050703719

Age: Gender:Female I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|-----------------|---------------|----------|------|--------------|-------|
| Dose | Duration | | | | | |
| Life-Threatening | Suicide Attempt | | Concerta | PS | | ORAL |
| Other | | | | | | |

Date:07/26/05ISR Number: 4724915-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20050703729

Age: Gender: I/FU:I

| Outcome | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | Duration | | | | | |
| Other | Idiopathic | | Concerta | PS | | ORAL |
| | Thrombocytopenic Purpura | | | | | |

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/26/05ISR Number: 4724958-6Report Type:Expedited (15-DaCompany Report #US-ROCHE-410971
 Age:17 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------------------------------|----------|-----------------------------------|---------------|----------|------|--------------|-------|
| Hospitalization - UNKNOWN | | Depression | | Klonopin | PS | Roche | |
| Initial or Prolonged UNKNOWN | | Drug Effect Decreased OVERDOSE | | Klonopin | SS | Roche | |
| THERAPY. | | Hallucination | | | | | |
| 7 DAY | | Post-Traumatic Stress Disorder | | Lexapro | SS | | ORAL |
| 7 DAY | | | | Lexapro | SS | | ORAL |
| 7 DAY | | Suicidal Ideation | | Lexapro | SS | | ORAL |
| 7 DAY | | Suicide Attempt | | Lexapro | SS | | ORAL |
| | | | | Lexapro | SS | | ORAL |
| | | | | Lexapro | SS | | ORAL |
| | | | | Lexapro | SS | | ORAL |
| UNKNOWN | | | | Elavil | SS | | |
| UNKNOWN | | | | Ritalin | SS | | |
| UNKNOWN | | | | Abilify | SS | | |
| UNKNOWN | 104 DAY | | | Geodon | SS | | ORAL |

Date:07/26/05ISR Number: 4725516-XReport Type:Direct Company Report #CTU 254250
 Age:63 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------------|----------|--|---------------|--------------------------|------|--------------|-------|
| Other 20MG 4X A DAY ORAL | | Dizziness Drug Withdrawal Syndrome | | Ritalin 20mg Novartis | PS | Novartis | ORAL |
| | | Fear | | | | | |
| | | Hyperhidrosis Irritability Pharmaceutical Product Complaint | | | | | |

Date:07/27/05ISR Number: 4726152-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050703136
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-----------------------|---------------|-----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Concerta | PS | | ORAL |
| | | Anger | | Concerta | SS | | ORAL |
| | | Homicidal Ideation | | Clonidine | C | | |
| | | Loss Of Consciousness | | Clonidine | C | | |

Date:07/29/05ISR Number: 4728461-9Report Type:Expedited (15-DaCompany Report #PHBS2005DE10779
Age:8 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|---------------|-----------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Convulsion | | Methylphenidate | PS | Novartis Sector: | |
| | | Hyponatraemia | | | | Pharma | |
| UNKNOWN | | Vomiting | | Desmopressin | SS | | |
| UNKNOWN | 20 ug/d | 20160MIN | | | | | |

Date:07/29/05ISR Number: 4728462-0Report Type:Expedited (15-DaCompany Report #PHBS2005JP10811
Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------|---------------|----------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Lip Exfoliation | | Ritalin | PS | Novartis Sector: | |
| | | Parkinson'S Disease | | | | Pharma | ORAL |
| | | Posture Abnormal | | Antipsychotics | C | | |
| UNKNOWN | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/29/05ISR Number: 4728538-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050704272
Age:14 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Chest Pain | | Concerta | PS | | ORAL |
| | | Hyperkalaemia | | Abilify | C | | |
| | | Palpitations | | | | | |

Date:07/29/05ISR Number: 4728539-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20050704465
Age:7 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|-------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | | Concerta | PS | | ORAL |
| | | Blood Amylase Increased | | | | | |
| | | Lipase Increased | | | | | |

Date:07/29/05ISR Number: 4728540-6Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050705166
Age:13 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|-------------------------|---------------|-------------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Extrapyramidal Disorder | | Concerta | PS | | ORAL |
| Hospitalization - | | Suicide Attempt | | Concerta | SS | | ORAL |
| Initial or Prolonged | | | | Risperidone | SS | | ORAL |
| Other | | | | Risperidone | SS | | ORAL |
| | | | | Guanfacine | C | | |
| | | | | Fluvoxamine | C | | |

Date:07/29/05ISR Number: 4729324-5Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20040902388
Age:10 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Weight Decreased | | Concerta | PS | | ORAL |

Date:07/29/05ISR Number: 4729325-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050704181
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Neutrophil Count | | Concerta | PS | | |
| UNKNOWN | | Decreased | | Concerta | SS | | |
| UNKNOWN | | | | | | | |

Date:07/29/05ISR Number: 4729326-9Report Type:Expedited (15-DaCompany Report #SE-JNJFOC-20050704904
Age:10 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Hypertension | | Concerta | PS | | ORAL |
| 239 DAY | | Tachycardia | | | | | |

Date:07/29/05ISR Number: 4729327-0Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050602118
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain | | Concerta | PS | | ORAL |
| | | Drug Withdrawal Syndrome | | Concerta | SS | | ORAL |
| | | Tremor | | Concerta | SS | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/29/05ISR Number: 4733750-8Report Type:Expedited (15-DaCompany Report #2005-BP-11853RO
Age:56 YR Gender:Female I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|--|---|---|------|--------------|-------|
| | | Aggression Anger Condition Aggravated Excitability Hypomania | Foreign Literature Health Professional | Citalopram (Citalopram Hydrobromide) Methylpenidate (Methylphenidate) | | | |
| 20 MG | | Initial Insomnia Irritability | | Venlafaxine (Venlafaxine) | PS | | |
| 300 MG | | Verbal Abuse | | Risperidone (Risperidone) | SS | | |
| 0.5 MG | | | | Ramipril (Ramipril) | C | | |

Date:08/02/05ISR Number: 4731822-5Report Type:Direct Company Report #CTU 255167
Age:32 YR Gender:Female I/FU:I

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|----------------------|------|--------------|-------|
| Hospitalization - 10 MG 1 Initial or Prolonged CAPSUEL Required ORAL | | Delirium Feeling Abnormal Hallucination, Visual | | Metadate Cd 10 Mg | PS | | ORAL |
| Intervention to Prevent Permanent Impairment/Damage | | Heart Rate Increased Irritability Pain Panic Disorder Vein Disorder | | Mirtazapine | C | | |

Date:08/02/05ISR Number: 4731943-7Report Type:Expedited (15-DaCompany Report #DE-JNJFOC-20050800028
Age: Gender:Male I/FU:F

| Outcome Dose Other | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|--------------------------|----------|-----------------|---------------|----------|------|--------------|-------|
| | | Eye Haemorrhage | | Concerta | PS | | ORAL |

Date:08/03/05ISR Number: 4733428-0Report Type:Periodic Company Report #US-JNJFOC-20050601892
Age:5 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----------|---------------|-----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | ORAL |
| Other | | Dystonia | | Risperdal | SS | | |

Date:08/03/05ISR Number: 4733429-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050705525
Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|---------------|----------|------|--------------|-------|
| Dose | | | | Concerta | PS | | ORAL |
| Other | | Hallucination | | | | | |

Date:08/05/05ISR Number: 4735707-XReport Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-12998167
Age:17 YR Gender:Female I/FU:F

| Outcome | PT |
|----------------------|-----------------------|
| Hospitalization - | Depression |
| Initial or Prolonged | Drug Ineffective |
| | Hallucination |
| | Intentional Misuse |
| | Post-Traumatic Stress |
| | Disorder |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

| Dose | Duration | Suicidal Ideation Suicide Attempt | Report Source | Product | Role | Manufacturer | Route |
|------|----------|--------------------------------------|---------------|----------|------|---|-------|
| | | | | Abilify | PS | Otsuka Pharmaceutical Company, Ltd. | |
| | | | | Lexapro | SS | | ORAL |
| | | | | Elavil | SS | | ORAL |
| | | | | Klonopin | SS | | |
| | | | | Ritalin | SS | | |
| | | | | Geodon | SS | | ORAL |

Date:08/05/05ISR Number: 4735874-8Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050800738
Age:9 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|----|------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | | Neutrophil Count | Concerta | PS | | |
| UNKNOWN | | | Decreased | Ritalin | SS | | |

Date:08/05/05ISR Number: 4735875-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20050800959
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|----|-------------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - Initial or Prolonged | | | Diabetes Mellitus | Concerta | PS | | ORAL |

Date:08/08/05ISR Number: 4736220-6Report Type:Expedited (15-DaCompany Report #PHFR2005GB02645
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------|----------|----|---------------|--------------|------|----------------------------|-------|
| Dose | | | | | | | |
| Other | | | Chest Pain | Ritalin | PS | Novartis Sector: Pharma | ORAL |
| 10 mg, TID | 4320 MIN | | | Flaxseed Oil | C | | |
| UNKNOWN | | | | | | | |

Date:08/09/05ISR Number: 4738030-2Report Type:Expedited (15-DaCompany Report #PHFR2005GB02631
Age:12 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|-----------|----------|---------------|---------------|-----------------|------|----------------------------|-------|
| Dose | | | | Methylphenidate | PS | Novartis Sector: Pharma | ORAL |
| Other | | Hallucination | | | | | |
| 10mg/day | | | | Methylphenidate | SS | Novartis Sector: Pharma | ORAL |
| 5 mg, TID | | | | Benylin | C | | |
| UNKNOWN | | | | | | | |

Date:08/09/05ISR Number: 4738119-8Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050601382
Age:17 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------|---------------|--------------|------|--------------|-------|
| Dose | | | | Concerta | PS | | ORAL |
| Death | | Fall | | Erythromycin | C | | |
| | | Sudden Death | | | | | |
| UNKNOWN | | | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/10/05ISR Number: 4740465-9Report Type:Expedited (15-DaCompany Report #PHNU2005DE02723
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------------|---------------|------------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Blood Pressure Increased | | Ritaline | PS | Novartis Sector: | |
| | | Hallucination | | Amfetamine | SS | Pharma | ORAL |
| UNKNOWN | | | | | | | |

Date:08/10/05ISR Number: 4740756-1Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050801422
 Age: Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|--------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Aggression | | Concerta | PS | | ORAL |
| 5 MON | | | | | | | |
| | | Cyanosis | | Concerta | SS | | ORAL |
| 5 MON | | | | | | | |
| | | Psychotic Disorder | | Concerta | SS | | ORAL |
| 5 MON | | | | | | | |
| | | Suicide Attempt | | | | | |

Date:08/11/05ISR Number: 4742580-2Report Type:Expedited (15-DaCompany Report #US-ROCHE-410971
 Age:17 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Depression | | Klonopin | PS | Roche | |
| UNKNOWN | | 341 DAY | | | | | |
| Initial or Prolonged | | Hallucination | | Klonopin | SS | Roche | |
| UNKNOWN | | OVERDOSE | | | | | |
| | | Overdose | | | | | |
| THERAPY. | | | | | | | |
| | | Post-Traumatic Stress | | Lexapro | SS | | ORAL |
| 7 DAY | | | | | | | |
| | | Disorder | | Lexapro | SS | | ORAL |
| 7 DAY | | | | | | | |
| | | Self Injurious Behaviour | | Lexapro | SS | | ORAL |
| 7 DAY | | | | | | | |
| | | Suicidal Ideation | | Lexapro | SS | | ORAL |
| 7 DAY | | | | | | | |
| | | Suicide Attempt | | Lexapro | SS | | ORAL |

| | | | | | |
|---------------|-------------|---------|---------|----|------|
| | | | Lexapro | SS | ORAL |
| | | | Lexapro | SS | ORAL |
| | | | Elavil | SS | |
| UNKNOWN | | | | | |
| | | | Ritalin | SS | |
| UNKNOWN | | | | | |
| | THE PATIENT | | Ritalin | SS | |
| UNKNOWN | | | | | |
| WAS WEANED | | | | | |
| OFF THE DRUG. | | | | | |
| | | | Abilify | SS | |
| UNKNOWN | | 135 DAY | | | |
| | | | Geodon | SS | ORAL |
| 32 DAY | | | | | |

Date:08/11/05ISR Number: 4742913-7Report Type:Expedited (15-DaCompany Report #PHFR2005GB02706
Age:24 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------|---------------|---------|------|------------------|-------|
| Dose | | | | | | | |
| Other | | Cryptorchism | | Ritalin | PS | Novartis Sector: | |
| | | Gynaecomastia | | | | Pharma | |
| UNKNOWN | | | | | | | |
| | | Hypotrichosis | | | | | |

Date:08/12/05ISR Number: 4744079-6Report Type:Expedited (15-DaCompany Report #ES-JNJFOC-20050800749
Age:9 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|------------------|----------|--------------------------|---------------|----------|------|--------------|-------|
| Dose | | | | | | | |
| Life-Threatening | | Thrombocytopenic Purpura | | Concerta | PS | | |
| UNKNOWN | | 256 DAY | | | | | |
| | | | | Concerta | SS | | |
| UNKNOWN | | 256 DAY | | | | | |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/16/05ISR Number: 4746052-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050703136
 Age: Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|------------------------|---------------|------------|------|--------------|-------|
| Dose | | | | | | | |
| Other | | Abdominal Pain Upper | | Concerta | PS | | ORAL |
| | | Aggression | | Concerta | SS | | ORAL |
| | | Anger | | Clonidine | I | | |
| | | Chest Pain | | Clonidine | I | | |
| | | Dizziness | | Imipramine | I | | |
| | | Drug Interaction | | | | | |
| | | Fatigue | | | | | |
| | | Headache | | | | | |
| | | Heart Rate Increased | | | | | |
| | | Homicidal Ideation | | | | | |
| | | Hot Flush | | | | | |
| | | Insomnia | | | | | |
| | | Loss Of Consciousness | | | | | |
| | | Muscle Spasms | | | | | |
| | | Nausea | | | | | |
| | | Pharyngolaryngeal Pain | | | | | |
| | | Vomiting | | | | | |

Date:08/17/05ISR Number: 4746616-4Report Type:Expedited (15-DaCompany Report #PHFR2005GB02645
 Age:12 YR Gender:Male I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|------------|---------------|-----------------|------|------------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Chest Pain | | Methylphenidate | PS | Novartis Sector: | |
| Initial or Prolonged | | Dyspnoea | | | | Pharma | ORAL |
| 10 mg, QD | 4320 MIN | | | | | | |
| Other | | | | Flaxseed Oil | C | | |
| UNKNOWN | | | | | | | |

Date:08/17/05ISR Number: 4746629-2Report Type:Expedited (15-DaCompany Report #PHBS2005NO11756
 Age:37 YR Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|----------------------|----------|---------------|---------------|---------|------|------------------|-------|
| Dose | | | | | | | |
| Hospitalization - | | Epistaxis | | Ritalin | PS | Novartis Sector: | |
| Initial or Prolonged | | Hypoaesthesia | | | | Pharma | ORAL |
| 20 mg, TID | 484 DAY | | | | | | |

| | | | | |
|-------------|-----------------|----------|----|------|
| 50 mg, BID | Hypotonia | Cataflam | SS | ORAL |
| | Nausea | Paracet | C | ORAL |
| 3000 mg, QD | Self-Medication | | | |

Date:08/17/05ISR Number: 4746632-2Report Type:Expedited (15-DaCompany Report #PHEH2005US08715
 Age:6 YR Gender:Male I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---------|----------|---------------------------------------|---------------|---------|------|----------------------------|-------|
| Other | | Formication Hallucination, Tactile | | Ritalin | PS | Novartis Sector: Pharma | |

Date:08/17/05ISR Number: 4746957-0Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20050802206
 Age: Gender:Female I/FU:I

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|-------------------|---------------|--|-------------------|--------------|-------|
| Hospitalization - Initial or Prolonged | | Ulcer Haemorrhage | | Concerta Zoloft Birth Control Vitamin C | PS C C C | | ORAL |

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/18/05ISR Number: 4747915-2Report Type:Expedited (15-DaCompany Report #PHFR2000GB01403
 Age:15 YR Gender:Female I/FU:F

| Outcome | Duration | PT | Report Source | Product | Role | Manufacturer | Route |
|---|----------|---|---------------|----------|------|----------------------------|-------|
| Life-Threatening Hospitalization - 10 or 20mg, Initial or Prolonged ONCE/SINGLE | 1440 MIN | Asthenia Blood Pressure Increased Body Temperature Increased Cyanosis Feeling Hot Hyperhidrosis Pulse Pressure Decreased Respiratory Arrest Visual Disturbance | | Ritaline | PS | Novartis Sector: Pharma | ORAL |

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Summary report for FOI selections:

Selection by inexact search of active ingredient:

METHYLPHENIDATE%

Selection by inexact search of Tradename/Verbatim:

RITALIN%

Total number of reports: 3,170

From: 01-NOV-1997 To: Present

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