
ISR Number: 4652400 Case Number: 5793796 I/F Code: I Report Date: 20050414
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1005943083
Mfg. Date: 20050414
Mfg. Number: 2005-04-1493
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: EMPHYSEMA
Route:
Dose: 7-8 DOSES QD
Event Date: 20040201
FDA Date: 20050502
Follow Number:
Image ID: 4652400-2
Age: 88 YR Gender: M Weight: 150 LBS
Occupation: CN
Country:
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: N Rechallenge Code: D Death Date:
Therapy Start: 20050101
Therapy End: 20030101
Duration:
Adverse Reactions:
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4652451 Case Number: 5792918 I/F Code: I Report Date: 20050420
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1005943263
Mfg. Date: 20050420
Mfg. Number: 2005-04-1889
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date: 20041101
FDA Date: 20050502
Follow Number:
Image ID: 4652451-8
Age: Gender: M Weight:
Occupation: MD
Country:
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DEATH

ISR Number: 4658754 Case Number: 5799558 I/F Code: I Report Date: 20050502
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1005968934
Mfg. Date: 20050429
Mfg. Number: 2005-04-2334
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: ORAL
Dose: ORAL AER INH
Event Date: 20020901
FDA Date: 20050509
Follow Number:
Image ID: 4658754-5
Age: Gender: M Weight:
Occupation: CN
Country:
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20020901
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DEATH

ISR Number: 4673647 Case Number: 5808975 I/F Code: I Report Date: 20050518

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1006039661

Mfg. Date: 20050514

Mfg. Number: 2005-05-0863

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: 4BBS822

Expiration Date: 20061001

Indication: INFECTION

Route: ORAL

Dose: ORAL AER INH

Event Date: 20050512

FDA Date: 20050523

Follow Number:

Image ID: 4673647-5

Age: 19 YR Gender: F Weight: 250 LBS

Occupation: OT

Country:

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

AMNESIA

CYANOSIS

DEPRESSED LEVEL OF CONSCIOUSNESS

DEVICE FAILURE

FOREIGN BODY TRAUMA

INFECTION

PAIN

SENSATION OF FOREIGN BODY

ISR Number: 4685742 Case Number: 5819347 I/F Code: I Report Date: 20050519
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1006090068
Mfg. Date: 20050519
Mfg. Number: 2005-05-1295
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number: 4BBS612
Expiration Date: 20061001
Indication:
Route: ORAL
Dose: 3 PUFFS ORAL AER INH
Event Date:
FDA Date: 20050608
Follow Number:
Image ID: 4685742-5
Age: 82 YR Gender: F Weight:
Occupation: PH
Country:
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DEMENTIA
 DIZZINESS
 DRUG INEFFECTIVE
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4708992 Case Number: 5836794 I/F Code: I Report Date: 20050622

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1006183447

Mfg. Date: 20050622

Mfg. Number: 2004-10-0939

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date:

FDA Date: 20050707

Follow Number:

Image ID: 4708992-8

Age: 92 YR Gender: F Weight: 102 LBS

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: Y Rechallenge Code: Y Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ATRIAL FIBRILLATION
- DYSPNOEA
- FEELING ABNORMAL
- HEART RATE INCREASED
- INSOMNIA
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4711297 Case Number: 5839172 I/F Code: I Report Date: 20050628
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1006192887
Mfg. Date: 20050628
Mfg. Number: 2005-06-2261
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number: 5BBS507
Expiration Date: 20070101
Indication:
Route: ORAL
Dose: ORAL AER INH
Event Date:
FDA Date: 20050711
Follow Number:
Image ID: 4711297-2
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: U Rechallenge Code: U Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
COUGH
DRUG INEFFECTIVE
DYSPNOEA
INSOMNIA
PHARMACEUTICAL PRODUCT COMPLAINT
TONGUE DRY

ISR Number: 4714128 Case Number: 5838656 I/F Code: I Report Date: 20041007
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1006204337
Mfg. Date: 20041007
Mfg. Number: 2004-10-0647
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date: 20040626
FDA Date: 20050630
Follow Number:
Image ID: 4714128-X
Age: 52 YR Gender: F Weight:
Occupation: MD
Country:
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA

ISR Number: 4714129 Case Number: 5838657 I/F Code: I Report Date: 20041116
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1006204338
Mfg. Date: 20041116
Mfg. Number: 2004-11-1117
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date:
FDA Date: 20050630
Follow Number:
Image ID: 4714129-1
Age: Gender: Weight:
Occupation: PH
Country:
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: U Rechallenge Code: U Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ANAPHYLACTIC REACTION

ISR Number: 4714131 Case Number: 5838660 I/F Code: I Report Date: 20050105
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1006204340
Mfg. Date: 20050105
Mfg. Number: 2005-01-2351
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date: 20040927
FDA Date: 20050630
Follow Number:
Image ID: 4714131-X
Age: 40 YR Gender: F Weight:
Occupation: OT
Country:
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ANXIETY
ASTHMA
BRONCHITIS
DRUG INEFFECTIVE

ISR Number: 4716698 Case Number: 5845819 I/F Code: I Report Date: 20050705

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1006218542

Mfg. Date: 20050705

Mfg. Number: 2005-07-0376

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: 4BBS638

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date: 20040101

FDA Date: 20050714

Follow Number:

Image ID: 4716698-4

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: U Rechallenge Code: U Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- GASTROINTESTINAL DISORDER
- HIP FRACTURE
- MEDICAL DEVICE COMPLICATION
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4780498 Case Number: 5890500 I/F Code: I Report Date: 20050919

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1006458137

Mfg. Date: 20050919

Mfg. Number: 2005-09-1105

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: 1BBS646

Expiration Date: 20031201

Indication:

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date:

FDA Date: 20050926

Follow Number:

Image ID: 4780498-X

Age: 20 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: U Rechallenge Code: U Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

CATARACT

EYE DISORDER

ISR Number: 4784447 Case Number: 5891409 I/F Code: I Report Date: 20050928
Drug Name: **PROVENTIL**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1006470831
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route: ORAL
Dose: 1 PO Q3-4 PRN PO
Event Date: 20050927
FDA Date: 20050929
Follow Number:
Image ID: 4784447-X
Age: 33 YR Gender: F Weight: 135 LBS
Occupation: MD
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start: 20050927
Therapy End: 20050801
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 4787443 Case Number: 5896483 I/F Code: I Report Date: 20050923
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1006480622
Mfg. Date: 20050923
Mfg. Number: 2005-09-1507
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: INHALATION
Event Date:
FDA Date: 20051003
Follow Number:
Image ID: 4787443-1
Age: Gender: F Weight:
Occupation: OT
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
LIVER FUNCTION TEST ABNORMAL

ISR Number: 4807356 Case Number: 5914477 I/F Code: I Report Date: 20051010
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1006545315
Mfg. Date: 20051012
Mfg. Number: 2005-10-0886
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date: 20050601
FDA Date: 20051020
Follow Number:
Image ID: 4807356-6
Age: 45 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20050601
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ACUTE RESPIRATORY DISTRESS SYNDROME
DRUG INEFFECTIVE
PNEUMONIA

ISR Number: 4817299 Case Number: 5920017 I/F Code: I Report Date: 20051019

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1006582755

Mfg. Date: 20051019

Mfg. Number: 2005-10-1304

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: SINUSITIS

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date: 20050915

FDA Date: 20051031

Follow Number:

Image ID: 4817299-X

Age: 46 YR Gender: M Weight: 60 KG

Occupation:

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:

Therapy Start: 20050921

Therapy End: 20050921

Duration:

Adverse Reactions:

CARDIAC ARREST

DYSPNOEA

FALL

HEART RATE IRREGULAR

REACTION TO DRUG EXCIPIENTS

SINUSITIS

ISR Number: 4817300 Case Number: 5920025 I/F Code: I Report Date: 20051025

Drug Name: **PROVENTIL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1006582756

Mfg. Date: 20051025

Mfg. Number: 2005-10-1606

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: PRN ORAL AER INH

Event Date: 20051001

FDA Date: 20051031

Follow Number:

Image ID: 4817300-3

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- CONVULSION
- DRUG EFFECT DECREASED
- DRUG INTOLERANCE
- HEADACHE
- MALAISE
- PHARMACEUTICAL PRODUCT COMPLAINT
- POOR QUALITY DRUG ADMINISTERED

ISR Number: 4826188 Case Number: 5925869 I/F Code: I Report Date: 20051107

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1006616337

Mfg. Date: 20051102

Mfg. Number: 2005-09-1147

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: 5BBS534

Expiration Date: 20070401

Indication:

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date:

FDA Date: 20051109

Follow Number:

Image ID: 4826188-6

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: U Rechallenge Code: U Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- MALaise
- PHARMACEUTICAL PRODUCT COMPLAINT
- PHARYNGOLARYNGEAL PAIN
- SURGERY

ISR Number: 4835203 Case Number: 5933153 I/F Code: I Report Date: 20051104
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1006651299
Mfg. Date: 20051104
Mfg. Number: 2005-11-0250
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number: 4BBS827
Expiration Date: 20061001
Indication:
Route:
Dose: INHALATION
Event Date:
FDA Date: 20051114
Follow Number:
Image ID: 4835203-5
Age: Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: U Rechallenge Code: U Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DEVICE MALFUNCTION
 DIZZINESS
 EXTRASYSTOLES
 MALAISE
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4859898 Case Number: 5952806 I/F Code: I Report Date: 20051206
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1006736722
Mfg. Date: 20051206
Mfg. Number: 2005-12-0387
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: EMPHYSEMA
Route: RESPIRATORY (INHALATION)
Dose: INHALATION
Event Date: 19980101
FDA Date: 20051215
Follow Number:
Image ID: 4859898-5
Age: 70 YR Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 19980101
Therapy Start:
Therapy End: 19900101
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 SUFFOCATION FEELING
 UNEVALUABLE EVENT

ISR Number: 4866279 Case Number: 5954554 I/F Code: I Report Date: 20051213
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1006763522
Mfg. Date: 20051213
Mfg. Number: 2005-11-1749
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: EMPHYSEMA
Route: RESPIRATORY (INHALATION)
Dose: 4 PUFFS BID ORAL AER INH
Event Date:
FDA Date: 20051221
Follow Number:
Image ID: 4866279-7
Age: 84 YR Gender: F Weight: 145 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End: 19900101
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 DYSPNOEA
 FEELING ABNORMAL

ISR Number: 4867228 Case Number: 5955060 I/F Code: I Report Date: 20051215

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1006767166

Mfg. Date: 20051212

Mfg. Number: 2005-12-0696

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date: 20020801

FDA Date: 20051222

Follow Number:

Image ID: 4867228-8

Age: Gender: M Weight:

Occupation: MD

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: U Rechallenge Code: U Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- CORONARY ARTERY INSUFFICIENCY
- COUGH
- DYSPNOEA
- NASOPHARYNGITIS

ISR Number: 4883835 Case Number: 5967699 I/F Code: I Report Date: 20060105

Drug Name: **PROVENTIL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1006833306

Mfg. Date: 20060105

Mfg. Number: 2006-01-0377

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: INHALATION/ 3 DOSE (S)

Event Date: 20000101

FDA Date: 20060113

Follow Number:

Image ID: 4883835-0

Age: 41 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: Y Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DRUG INEFFECTIVE
- REACTION TO PRESERVATIVES

ISR Number: 4896246 Case Number: 5980471 I/F Code: I Report Date: 20060113

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1006883378

Mfg. Date: 20060113

Mfg. Number: 2006-01-0961

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: INHALATION

Event Date:

FDA Date: 20060126

Follow Number:

Image ID: 4896246-9

Age: 24 YR Gender: F Weight:

Occupation: MD

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: U Rechallenge Code: U Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- CAESAREAN SECTION
- CARDIOMEGALY
- DRUG EXPOSURE DURING PREGNANCY
- ELECTROCARDIOGRAM ST SEGMENT ABNORMAL
- MITRAL VALVE INCOMPETENCE
- OEDEMA PERIPHERAL
- PERIPARTUM CARDIOMYOPATHY
- PLEURAL EFFUSION
- PULMONARY CONGESTION
- PULMONARY HYPERTENSION
- RESPIRATORY DISTRESS
- RESPIRATORY TRACT INFECTION
- SINUS TACHYCARDIA
- TRICUSPID VALVE INCOMPETENCE
- VENTRICULAR DYSFUNCTION

ISR Number: 4936666 Case Number: 6006285 I/F Code: I Report Date: 20060228

Drug Name: **ALBUTEROL**
 NDA Number: 17559
 Role Code: PS VAL/VBM: 1
 Seq Number: 1007026698
 Mfg. Date: 20060222
 Mfg. Number: 2006-02-0249
 Mfg. Sender: SCHERING-PLOUGH CORPORATION
 Lot Number: 5BBS852*
 Expiration Date: 20070901
 Indication: ASTHMA
 Route: ORAL
 Dose: TO 8 PUFFS QD ORAL AER I
 Event Date: 20060101
 FDA Date: 20060302

Follow Number:
 Image ID: 4936666-7
 Age: 46 YR Gender: F Weight:
 Occupation: PH
 Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:
 Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:

Therapy Start:
 Therapy End:
 Duration:

Adverse Reactions:
 ANXIETY
 BLOOD PRESSURE INADEQUATELY CONTROLLED
 CHEST PAIN
 DEATH OF RELATIVE
 DYSARTHRIA
 DYSPNOEA
 FEELING DRUNK
 HEADACHE
 NAUSEA
 ORAL DISCOMFORT
 SOMNOLENCE
 VOMITING

ISR Number: 4951306 Case Number: 6016526 I/F Code: I Report Date: 20060313
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1007081555
Mfg. Date: 20060313
Mfg. Number: 2006-03-0677
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: ORAL
Dose: ORAL AER INH
Event Date: 20060310
FDA Date: 20060317
Follow Number:
Image ID: 4951306-9
Age: 39 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date: 20060310
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
FALL
MALAISE
RESUSCITATION

ISR Number: 4970165 Case Number: 6030089 I/F Code: I Report Date: 20060324

Drug Name: **PROVENTIL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1007157327

Mfg. Date: 20060324

Mfg. Number: 2006-03-1795

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date:

FDA Date: 20060406

Follow Number:

Image ID: 4970165-1

Age: Gender: F Weight:

Occupation: MD

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: U Rechallenge Code: U Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

TOOTH DECALCIFICATION

TOOTH EROSION

ISR Number: 5009475 Case Number: 6057255 I/F Code: I Report Date: 20060516
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1007315933
Mfg. Date: 20060516
Mfg. Number: 2006-05-1262
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: ORAL
Dose: ORAL AER INH
Event Date: 20050603
FDA Date: 20060522
Follow Number:
Image ID: 5009475-0
Age: Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20060306
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
HOSPITALISATION

ISR Number: 5017080 Case Number: 6064986 I/F Code: I Report Date: 20060517
Drug Name: **PROVENTIL**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1007345242
Mfg. Date: 20060517
Mfg. Number: 2006-05-1705
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date:
FDA Date: 20060526
Follow Number:
Image ID: 5017080-5
Age: 84 YR Gender: F Weight:
Occupation: MD
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End: 20050729
Duration:
Adverse Reactions:
DEATH

ISR Number: 5019025 Case Number: 6064654 I/F Code: I Report Date: 20060522

Drug Name: **PROVENTIL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1007352687

Mfg. Date: 20060522

Mfg. Number: 2006-05-1795

Mfg. Sender: SCHERNG-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date: 20060507

FDA Date: 20060530

Follow Number:

Image ID: 5019025-0

Age: 74 YR Gender: M Weight:

Occupation: MD

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20060507

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

CORONARY ARTERY DISEASE

ISR Number: 5044822 Case Number: 6083965 I/F Code: I Report Date: 20060623

Drug Name: **PROVENTIL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1007446457

Mfg. Date: 20060623

Mfg. Number: 2006-06-1902

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS PRN ORAL AER INH

Event Date:

FDA Date: 20060705

Follow Number:

Image ID: 5044822-5

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: N Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- HYPERSENSITIVITY
- OESOPHAGEAL DISORDER
- VOMITING

ISR Number: 5054308 Case Number: 6090556 I/F Code: I Report Date: 20060707
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1007477698
Mfg. Date: 20060707
Mfg. Number: 2006-07-0330
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date:
FDA Date: 20060713
Follow Number:
Image ID: 5054308-X
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: U Rechallenge Code: U Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
MYOCARDIAL INFARCTION

ISR Number: 5055184 Case Number: 6094115 I/F Code: I Report Date: 20060711

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1007481668

Mfg. Date: 20060710

Mfg. Number: 2006-07-0380

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date:

FDA Date: 20060717

Follow Number:

Image ID: 5055184-1

Age: 58 YR Gender: F Weight:

Occupation: OT

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20060703

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

BRAIN HERNIATION

HAEMORRHAGE INTRACRANIAL

ISR Number: 5060775 Case Number: 6111314 I/F Code: I Report Date: 20050810

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1007504003

Mfg. Date: 20050805

Mfg. Number: 2005-08-0550

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date: 20050606

FDA Date: 20060630

Follow Number:

Image ID: 5060775-8

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- CHEST DISCOMFORT
- CONSTIPATION
- DYSKINESIA
- INSOMNIA
- TOOTH DISORDER
- TREMOR
- VISION BLURRED

ISR Number: 5060778 Case Number: 6111317 I/F Code: I Report Date: 20050927
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1007504012
Mfg. Date: 20050927
Mfg. Number: 2005-09-1878
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date: 20000101
FDA Date: 20060630
Follow Number:
Image ID: 5060778-3
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA

ISR Number: 5060783 Case Number: 6111457 I/F Code: I Report Date: 20060103
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1007504026
Mfg. Date: 20060103
Mfg. Number: 2006-01-0112
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: NASOPHARYNGITIS
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date:
FDA Date: 20060630
Follow Number:
Image ID: 5060783-7
Age: 92 YR Gender: M Weight:
Occupation: PH
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
BRONCHOSPASM PARADOXICAL

ISR Number: 5066735 Case Number: 6100945 I/F Code: I Report Date: 20060720

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1007527673

Mfg. Date: 20060717

Mfg. Number: 2006-07-1437

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: BRONCHOSPASM

Route: ORAL

Dose: 2 PUFFS Q 4HR ORAL AER I

Event Date: 20020306

FDA Date: 20060728

Follow Number:

Image ID: 5066735-5

Age: Gender: M Weight:

Occupation: LW

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20020306

Therapy Start: 20060306

Therapy End: 20060306

Duration:

Adverse Reactions:

DYSпноEA

FALL

ISR Number: 5122456 Case Number: 6147617 I/F Code: I Report Date: 20061002
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1007739090
Mfg. Date: 20060925
Mfg. Number: 2006-08-0204
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose: DF; INH
Event Date:
FDA Date: 20061004
Follow Number:
Image ID: 5122456-1
Age: Gender: F Weight:
Occupation: PH
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: N Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
PORPHYRIA NON-ACUTE

ISR Number: 5144687 Case Number: 6168490 I/F Code: I Report Date: 20061030
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1007826011
Mfg. Date: 20061011
Mfg. Number: 2006SP004757
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 DF; Q6H; INH
Event Date:
FDA Date: 20061031
Follow Number:
Image ID: 5144687-7
Age: 46 YR Gender: F Weight: 203 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5144792 Case Number: 6169421 I/F Code: I Report Date:

Drug Name: **PROVENTIL GENTLEHALER**

NDA Number: 72273

Role Code: PS VAL/VBM: 1

Seq Number: 1007826677

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose: 2 ACTUATIONS AS NEEDED

Event Date:

FDA Date: 20061103

Follow Number:

Image ID: 5144792-5

Age: 49 YR Gender: M Weight: 267 LBS

Occupation: MD

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y

Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG EFFECT DECREASED

THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5145415 Case Number: 6157422 I/F Code: I Report Date: 20061030
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1007829496
Mfg. Date: 20061016
Mfg. Number: 2006SP004403
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: 0 DF; PO
Event Date:
FDA Date: 20061031
Follow Number:
Image ID: 5145415-1
Age: Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: U Rechallenge Code: U Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5205837 Case Number: 6219157 I/F Code: I Report Date: 20070107
Drug Name: **PROVENTIL**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008031877
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20080430
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS AS NEEDED PO
Event Date: 20061210
FDA Date: 20070108
Follow Number:
Image ID: 5205837-7
Age: 55 YR Gender: F Weight: 130 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: LT Dechallenge Code: N Rechallenge Code: D Death Date:
Therapy Start: 20061210
Therapy End: 20061210
Duration:
Adverse Reactions:
 DEVICE FAILURE
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5206939 Case Number: 6220175 I/F Code: I Report Date: 20061226
Drug Name: **PROVENTIL**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008035294
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GHFO62A
Expiration Date: 20071220
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: INHALE 2 PUFFS FOUR TIMES DAILY AS NEEDED
Event Date: 20061207
FDA Date: 20070105
Follow Number:
Image ID: 5206939-1
Age: 45 YR Gender: M Weight:
Occupation: PH
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End: 20061122
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 DYSPNOEA
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5245005 Case Number: 6252922 I/F Code: I Report Date: 20070220
Drug Name: **PROVENTIL**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008175357
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: 2-4 PUFFS AS NEEDED PO
Event Date: 20070202
FDA Date: 20070221
Follow Number:
Image ID: 5245005-6
Age: 31 YR Gender: F Weight: 200 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration: 20 YR
Adverse Reactions:
DRUG INEFFECTIVE
FEELING ABNORMAL
HEADACHE
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5252143 Case Number: 6262087 I/F Code: I Report Date: 20070222

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1008199322

Mfg. Date: 20070215

Mfg. Number: 2007SP003035

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: 2 DF; PO

Event Date:

FDA Date: 20070226

Follow Number:

Image ID: 5252143-0

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: Y Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

DYSPNOEA

ISR Number: 5253381 Case Number: 6261986 I/F Code: I Report Date: 20070223
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1008203588
Mfg. Date: 20070214
Mfg. Number: 2007SP002987
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date: 20061001
Indication: ASTHMA
Route: ORAL
Dose: 2 DF;PRN;PO
Event Date: 20070201
FDA Date: 20070226
Follow Number:
Image ID: 5253381-3
Age: 17 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End: 20070214
Duration:
Adverse Reactions:
EXPIRED DRUG ADMINISTERED
PNEUMONIA

ISR Number: 5266883 Case Number: 6270318 I/F Code: I Report Date: 20070309

Drug Name: **ALBUTEROL**
 NDA Number: 17559
 Role Code: PS VAL/VBM: 1
 Seq Number: 1008256912
 Mfg. Date: 20070228
 Mfg. Number: 2007SP003911
 Mfg. Sender: SCHERING-PLOUGH CORPORATION
 Lot Number:

Expiration Date:
 Indication: ASTHMA
 Route: ORAL
 Dose: ;UNK;PO

Event Date:
 FDA Date: 20070313

Follow Number:
 Image ID: 5266883-0
 Age: 44 YR Gender: F Weight:

Occupation: CN
 Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:
 Outcome Code: OT Dechallenge Code: Rechallenge Code: D Death Date:

Therapy Start:
 Therapy End:
 Duration:

Adverse Reactions:
 BONE DISORDER
 FALL
 FRACTURE
 LUNG DISORDER

ISR Number: 5273216 Case Number: 6277177 I/F Code: I Report Date: 20070315
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1008281288
Mfg. Date: 20070307
Mfg. Number: 2007SP004417
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070319
Follow Number:
Image ID: 5273216-2
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
RESPIRATORY FAILURE

ISR Number: 5277665 Case Number: 6280923 I/F Code: I Report Date: 20070319

Drug Name: **PROVENTIL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1008299048

Mfg. Date: 20070308

Mfg. Number: 2007SP004634

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20070321

Follow Number:

Image ID: 5277665-8

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

DYSPNOEA

ISR Number: 5277769 Case Number: 6279701 I/F Code: I Report Date: 20070319
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1008299372
Mfg. Date: 20070308
Mfg. Number: 2007SP004637
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070321
Follow Number:
Image ID: 5277769-X
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
HOSPITALISATION

ISR Number: 5285490 Case Number: 6288325 I/F Code: I Report Date: 20070326
Drug Name: **PROVENTIL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1008327444
Mfg. Date: 20070319
Mfg. Number: 2007SP004029
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070328
Follow Number:
Image ID: 5285490-7
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: LT Dechallenge Code: Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DYSпноEA
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5308475 Case Number: 6305977 I/F Code: I Report Date: 20070420

Drug Name: **PROVENTIL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1008411949

Mfg. Date: 20070417

Mfg. Number: 2007SP007121

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20070423

Follow Number:

Image ID: 5308475-0

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- DIZZINESS
- NAUSEA
- PHARYNGEAL OEDEMA
- VOMITING

ISR Number: 5327711 Case Number: 6314869 I/F Code: I Report Date: 20070501
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1008489470
Mfg. Date: 20070425
Mfg. Number: 2007SP006030
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: UNK;PO
Event Date: 20070309
FDA Date: 20070503
Follow Number:
Image ID: 5327711-8
Age: 14 YR Gender: F Weight: 73.4 KG
Occupation: OT
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INTERACTION
 DYSPNOEA
 HEART RATE IRREGULAR
 MALAISE

ISR Number: 5331657 Case Number: 6323148 I/F Code: I Report Date: 20070514
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1008505664
Mfg. Date: 20070508
Mfg. Number: 2007SP008879
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070516
Follow Number:
Image ID: 5331657-9
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
INFECTION

ISR Number: 5331715 Case Number: 6322607 I/F Code: I Report Date: 20070514

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1008505842

Mfg. Date: 20070510

Mfg. Number: 2007SP008962

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20070516

Follow Number:

Image ID: 5331715-9

Age: Gender: F Weight:

Occupation: PH

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:
CONVULSION

ISR Number: 5331961 Case Number: 6324208 I/F Code: I Report Date: 20070516

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1008507093

Mfg. Date: 20070514

Mfg. Number: 2007SP009300

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20070521

Follow Number:

Image ID: 5331961-4

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

COUGH

GLAUCOMA

ISR Number: 5352976 Case Number: 6335426 I/F Code: I Report Date: 20070606
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1008573241
Mfg. Date: 20070228
Mfg. Number: 2007SP004028
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: ORAL
Dose: ; PO
Event Date: 20070101
FDA Date: 20070607
Follow Number:
Image ID: 5352976-6
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
PULMONARY THROMBOSIS

ISR Number: 5354872 Case Number: 6337413 I/F Code: I Report Date: 20070607
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1008579278
Mfg. Date: 20070605
Mfg. Number: 2007SP011051
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070611
Follow Number:
Image ID: 5354872-7
Age: Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
RESPITE CARE

ISR Number: 5371456 Case Number: 6347901 I/F Code: I Report Date: 20070620
 Drug Name: **ALBUTEROL**
 NDA Number: 17559
 Role Code: PS VAL/VBM: 1
 Seq Number: 1008635645
 Mfg. Date: 20070618
 Mfg. Number: 2007SP012131
 Mfg. Sender: SCHERING-PLOUGH CORPORATION
 Lot Number:
 Expiration Date:
 Indication: ASTHMA
 Route: ORAL
 Dose: PO
 Event Date: 20070101
 FDA Date: 20070622
 Follow Number:
 Image ID: 5371456-5
 Age: Gender: F Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: N Mfg. Notified: Confidential:
 Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 BRONCHITIS
 DYSPHONIA

ISR Number: 5376693 Case Number: 6352844 I/F Code: I Report Date: 20070627
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1008655407
Mfg. Date: 20070625
Mfg. Number: 2007SP012735
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070629
Follow Number:
Image ID: 5376693-1
Age: 80 YR Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
GLAUCOMA
RENAL FAILURE

ISR Number: 5378345 Case Number: 6355307 I/F Code: I Report Date: 20070701
Drug Name: **PROVENTIL**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008662748
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA EXERCISE INDUCED
Route: RESPIRATORY (INHALATION)
Dose: TOOK ONE PUFF 1X INHAL
Event Date: 20070623
FDA Date: 20070702
Follow Number:
Image ID: 5378345-0
Age: 54 YR Gender: F Weight: 180 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20070623
Therapy End: 20070623
Duration:
Adverse Reactions:
ASTHMA
CHOKING
CONDITION AGGRAVATED
FUNGAL INFECTION
GASTROINTESTINAL FUNGAL INFECTION
LUNG INFECTION
PHARYNGITIS
SYSTEMIC CANDIDA

ISR Number: 5387432 Case Number: 6360483 I/F Code: I Report Date: 20070710

Drug Name: **PROVENTIL**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008699776

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose: 1-2 PUFFS AS NEEDED

Event Date:

FDA Date: 20070711

Follow Number:

Image ID: 5387432-2

Age: Gender: Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N

Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5396894 Case Number: 6368192 I/F Code: I Report Date: 20070720

Drug Name: **ALBUTEROL**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1008736570

Mfg. Date: 20070717

Mfg. Number: 2007SP013467

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: 6-BBS-647

Expiration Date: 20081201

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: PO

Event Date: 20070101

FDA Date: 20070723

Follow Number:

Image ID: 5396894-6

Age: 66 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- BURNING SENSATION
- DRUG EFFECT DECREASED
- LUNG DISORDER
- PO2 DECREASED

ISR Number: 5480696 Case Number: 6442470 I/F Code: I Report Date: 20071001
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1009021388
Mfg. Date: 20070927
Mfg. Number: 2007SP017514
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071003
Follow Number:
Image ID: 5480696-6
Age: 86 YR Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE

ISR Number: 5480697 Case Number: 6442481 I/F Code: I Report Date: 20071001
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1009021390
Mfg. Date: 20070927
Mfg. Number: 2007SP019603
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date: 20010801
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date: 20070801
FDA Date: 20071003
Follow Number:
Image ID: 5480697-8
Age: Gender: Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20070801
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
EXPIRED DRUG ADMINISTERED
NEOPLASM MALIGNANT

ISR Number: 5485505 Case Number: 6445846 I/F Code: I Report Date: 20071009

Drug Name: **PROVENTIL**

NDA Number: 72273

Role Code: PS VAL/VBM: 1

Seq Number: 1009040295

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route:

Dose: 2 ACTUATIONS AS NEEDED;

Event Date: 20070301

FDA Date: 20071010

Follow Number:

Image ID: 5485505-7

Age: 46 YR Gender: F Weight: 181 LBS

Occupation:

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N

Outcome Code: RI Dechallenge Code: D Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- DRUG INEFFECTIVE
- DYSPNOEA
- LOSS OF CONSCIOUSNESS
- PHARMACEUTICAL PRODUCT COMPLAINT
- RESPIRATORY ARREST

ISR Number: 5534003 Case Number: 6491701 I/F Code: I Report Date: 20071128
Drug Name: **ALBUTEROL**
NDA Number: 17559
Role Code: PS VAL/VBM: 1
Seq Number: 1009224105
Mfg. Date: 20071120
Mfg. Number: 2007SP023414
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: PO
Event Date: 20071112
FDA Date: 20071130
Follow Number:
Image ID: 5534003-0
Age: Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
FOREIGN BODY TRAUMA
WRONG TECHNIQUE IN DRUG USAGE PROCESS

ISR Number: 5563510 Case Number: 6513699 I/F Code: I Report Date: 20071213
Drug Name: **PROVENTIL**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009298915
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose: 2 SPRAYS 3-4 TIMES DAILY
Event Date: 20071213
FDA Date: 20071214
Follow Number:
Image ID: 5563510-X
Age: 53 YR Gender: M Weight: 250 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
THERAPEUTIC PRODUCT INEFFECTIVE

ISR Number: 5564810 Case Number: 6513759 I/F Code: I Report Date: 20071213
Drug Name: **PROVENTIL**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009304054
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20071213
FDA Date: 20071214
Follow Number:
Image ID: 5564810-X
Age: Gender: F Weight: 170 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start: 20071213
Therapy End: 20071213
Duration:
Adverse Reactions:
 DEVICE FAILURE
 DRUG INEFFECTIVE

ISR Number: 5580447 Case Number: 6523233 I/F Code: I Report Date: 20071228
Drug Name: **PROVENTIL**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009358454
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FNL014A
Expiration Date: 20081231
Indication:
Route: ORAL
Dose: 2 PUFFS 4 TIMES A DAY OTHER
Event Date:
FDA Date: 20071231
Follow Number:
Image ID: 5580447-0
Age: 65 YR Gender: M Weight: 147 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20071228
Therapy End: 20050101
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5581543 Case Number: 6521983 I/F Code: I Report Date: 20080101
Drug Name: **PROVENTIL**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009361960
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20081031
Indication: EMPHYSEMA
Route: ORAL
Dose: ONE DOSE ONCE PO
Event Date: 20070715
FDA Date: 20080102
Follow Number:
Image ID: 5581543-4
Age: 80 YR Gender: F Weight: 100 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
MALAISE