

ISR Number: 4650501 Case Number: 5800687 I/F Code: I Report Date: 20050419

Drug Name: **ALBUTEROL SULFATE HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1005934984
Mfg. Date: 20050419
Mfg. Number: 2005-04-1443
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date: 20040603

FDA Date: 20050429

Follow Number:

Image ID: 4650501-6

Age: Gender: M Weight:

Occupation: OT

Country:

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

CHRONIC OBSTRUCTIVE PULMONARY DISEASE
EMPHYSEMA

ISR Number: 4672362 Case Number: 5807845 I/F Code: I Report Date: 20050511

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1006031815

Mfg. Date: 20050511

Mfg. Number: 2005-05-0678

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: ASTHMA EXACERBATION PROPHYLAXIS

Route: RESPIRATORY (INHALATION)

Dose: ORAL AER INH

Event Date: 20050419

FDA Date: 20050520

Follow Number:

Image ID: 4672362-1

Age: Gender: Weight:

Occupation: OT

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:

- CONDITION AGGRAVATED
- CONVULSION
- EPILEPSY
- GENERAL PHYSICAL HEALTH DETERIORATION

ISR Number: 4697198 Case Number: 5825729 I/F Code: I Report Date: 20050620
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1006135660
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 19540401
FDA Date: 20050621
Follow Number:
Image ID: 4697198-7
Age: Gender: M Weight: 150 LBS
Occupation: CN
Country:
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
INSOMNIA
TACHYCARDIA

ISR Number: 4743566 Case Number: 5866459 I/F Code: I Report Date: 20050808
Drug Name: **ALBUTEROL SULFATE HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1006312300
Mfg. Date: 20050802
Mfg. Number: 2005-08-0292
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DYSPNOEA
Route: RESPIRATORY (INHALATION)
Dose: 100MCG/DOSE ORAL AER INH
Event Date: 20050609
FDA Date: 20050809
Follow Number:
Image ID: 4743566-4
Age: Gender: F Weight:
Occupation: OT
Country: UNITED KINGDOM
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20050615
Therapy End: 20050608
Duration:
Adverse Reactions:
DISTURBANCE IN ATTENTION

ISR Number: 4825488 Case Number: 5926339 I/F Code: I Report Date: 20051026

Drug Name: **ALBUTEROL SULFATE HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1006613890

Mfg. Date: 20051026

Mfg. Number: 2005-10-1920

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 100 MCG ORAL AER INH

Event Date:

FDA Date: 20051109

Follow Number:

Image ID: 4825488-3

Age: Gender: M Weight:

Occupation:

Country: UNITED KINGDOM

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

Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date: 20040810

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- CHRONIC OBSTRUCTIVE PULMONARY DISEASE
- LOWER RESPIRATORY TRACT INFECTION
- PULMONARY TUBERCULOSIS

ISR Number: 4829990 Case Number: 5928345 I/F Code: I Report Date: 20051103
Drug Name: **ALBUTEROL SULFATE HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1006632348
Mfg. Date: 20051103
Mfg. Number: 2005-11-0231
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: 100 MCG INHALATION
Event Date: 20040603
FDA Date: 20051114
Follow Number:
Image ID: 4829990-X
Age: 74 YR Gender: M Weight:
Occupation:
Country: UNITED KINGDOM
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:
CHRONIC OBSTRUCTIVE PULMONARY DISEASE
LOWER RESPIRATORY TRACT INFECTION

ISR Number: 4830667 Case Number: 5928826 I/F Code: I Report Date: 20051103
Drug Name: **ALBUTEROL SULFATE HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1006634933
Mfg. Date: 20051103
Mfg. Number: 2005-11-0223
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS QID PRN INHALATION
Event Date: 20041101
FDA Date: 20051114
Follow Number:
Image ID: 4830667-5
Age: Gender: F Weight:
Occupation: OT
Country: UNITED KINGDOM
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20041101
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE

ISR Number: 4831053 Case Number: 5931923 I/F Code: I Report Date: 20051103
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1006636624
Mfg. Date: 20051103
Mfg. Number: 2005-11-0281
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date: 20040101
FDA Date: 20051114
Follow Number:
Image ID: 4831053-4
Age: Gender: Weight:
Occupation:
Country: UNITED KINGDOM
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20040304
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
CHRONIC OBSTRUCTIVE PULMONARY DISEASE

ISR Number: 4831119 Case Number: 5929222 I/F Code: I Report Date: 20051109
Drug Name: **ALBUTEROL SULFATE HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1006636791
Mfg. Date: 20051103
Mfg. Number: 2005-11-0238
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date: 20040101
FDA Date: 20051114
Follow Number:
Image ID: 4831119-9
Age: 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:
CARDIAC FAILURE
INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE

ISR Number: 4832090 Case Number: 5929105 I/F Code: I Report Date: 20051107
Drug Name: **ALBUTEROL SULFATE HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1006640027
Mfg. Date: 20051107
Mfg. Number: 2005-11-0394
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: 100 MCG/PUFF ORAL AER IN
Event Date:
FDA Date: 20051116
Follow Number:
Image ID: 4832090-6
Age: 89 YR Gender: F Weight:
Occupation: MD
Country: UNITED KINGDOM
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20050831
Therapy Start:
Therapy End:
Duration: 1 DAY
Adverse Reactions:
EMPHYSEMA

ISR Number: 4860924 Case Number: 5952201 I/F Code: I Report Date: 20051209
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1006741043
Mfg. Date: 20051207
Mfg. Number: 2005-12-0441
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: 100 MCG ORAL AER INH
Event Date: 20040603
FDA Date: 20051216
Follow Number:
Image ID: 4860924-8
Age: 74 YR Gender: M Weight:
Occupation: OT
Country: UNITED KINGDOM
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20040603
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 CHRONIC OBSTRUCTIVE PULMONARY DISEASE
 LOWER RESPIRATORY TRACT INFECTION

ISR Number: 4986169 Case Number: 6040658 I/F Code: I Report Date: 20060410

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1007223429

Mfg. Date: 20060410

Mfg. Number: 2006-03-1743

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: GFK009A

Expiration Date: 20061101

Indication: ASTHMA

Route:

Dose: ORAL AER INH

Event Date: 19970101

FDA Date: 20060424

Follow Number:

Image ID: 4986169-9

Age: 85 YR Gender: F Weight: 110 LBS

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 OPERATION
- DRUG INEFFECTIVE
- PHARMACEUTICAL PRODUCT COMPLAINT
- SPINAL FRACTURE

ISR Number: 5015007 Case Number: 6060609 I/F Code: I Report Date: 20060519
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1007337950
Mfg. Date: 20060519
Mfg. Number: 2006-05-1780
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: ORAL
Dose: ORAL AER INH
Event Date: 20060426
FDA Date: 20060530
Follow Number:
Image ID: 5015007-3
Age: 78 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: 20060426
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DEATH

ISR Number: 5026323 Case Number: 6072536 I/F Code: I Report Date: 20060605
Drug Name: **ALBUTEROL SULFATE HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1007381238
Mfg. Date: 20060530
Mfg. Number: 2006-06-0096
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: 100MCG ORAL AER INH
Event Date: 20060124
FDA Date: 20060608
Follow Number:
Image ID: 5026323-3
Age: 48 YR Gender: M Weight:
Occupation: OT
Country: UNITED KINGDOM
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20060321
Therapy End: 20060110
Duration:
Adverse Reactions:
EYE SWELLING
SWELLING FACE
URTICARIA

ISR Number: 5044824 Case Number: 6082867 I/F Code: I Report Date: 20060623
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1007446467
Mfg. Date: 20060623
Mfg. Number: 2006-06-2128
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: ORAL AER INH
Event Date:
FDA Date: 20060705
Follow Number:
Image ID: 5044824-9
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:
PNEUMONIA

ISR Number: 5075366 Case Number: 6108870 I/F Code: I Report Date: 20060804
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1007559544
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GHC052A
Expiration Date: 20080331
Indication: DYSPNOEA
Route: ORAL
Dose: 2 PUFFS EVERY 4 TO 6 HOURS PO
Event Date: 20060802
FDA Date: 20060807
Follow Number:
Image ID: 5075366-2
Age: 37 YR Gender: M Weight: 175 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20060802
Therapy End: 20060801
Duration:
Adverse Reactions:
EYELID OEDEMA
SWELLING FACE

ISR Number: 5155368 Case Number: 6178346 I/F Code: I Report Date: 20061113

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1007871527

Mfg. Date: 20061103

Mfg. Number: 2006SP005676

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: OEDEMA PERIPHERAL

Route: ORAL

Dose: 0 DF; PO

Event Date:

FDA Date: 20061114

Follow Number:

Image ID: 5155368-8

Age: 68 YR 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:

- DYSпноEA
- EXTRASYSTOLES
- HYPERHIDROSIS
- OEDEMA PERIPHERAL
- OVERDOSE
- PALLOR
- RESPIRATORY DISTRESS
- RESPIRATORY RATE INCREASED
- TACHYCARDIA
- VENTRICULAR TACHYCARDIA
- WHEEZING

ISR Number: 5171943 Case Number: 6202458 I/F Code: I Report Date: 20061201
Drug Name: **PROVENTIL**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1007935263
Mfg. Date: 20061128
Mfg. Number: 2006SP007310
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route:
Dose:
Event Date:
FDA Date: 20061205
Follow Number:
Image ID: 5171943-9
Age: 53 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: 20061001
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DEATH

ISR Number: 5201215 Case Number: 6217328 I/F Code: I Report Date: 20070103
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1008019902
Mfg. Date: 20061213
Mfg. Number: 2006SP008466
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: 105 MCG; PO
Event Date: 20060731
FDA Date: 20070104
Follow Number:
Image ID: 5201215-5
Age: 60 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: 20060731
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DEATH

ISR Number: 5213845 Case Number: 6224755 I/F Code: I Report Date: 20070112

Drug Name: **ALBUTEROL SULFATE**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1008062138

Mfg. Date: 20070109

Mfg. Number: 2007SP000471

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: PO

Event Date: 20061209

FDA Date: 20070117

Follow Number:

Image ID: 5213845-5

Age: 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:

DRUG INEFFECTIVE

MYOCARDIAL INFARCTION

ISR Number: 5256962 Case Number: 6262900 I/F Code: I Report Date: 20070303
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008219543
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20070227
FDA Date: 20070305
Follow Number:
Image ID: 5256962-6
Age: 55 YR Gender: F Weight: 270 LBS
Occupation:
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
 DYSPNOEA
 THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5258925 Case Number: 6263009 I/F Code: I Report Date: 20070302
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1008227142
Mfg. Date: 20070226
Mfg. Number: 2007SP003646
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070305
Follow Number:
Image ID: 5258925-3
Age: 47 YR Gender: F Weight:
Occupation:
Country:
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: N Rechallenge Code: D Death Date: 20070224
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
PNEUMONIA

ISR Number: 5259517 Case Number: 6265231 I/F Code: I Report Date: 20070305
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1008229835
Mfg. Date: 20070223
Mfg. Number: 2007SP003671
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070306
Follow Number:
Image ID: 5259517-2
Age: 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: 20070101
Therapy End: 20060101
Duration:
Adverse Reactions:
ASTHMA
CHOKING
CONDITION AGGRAVATED
DRUG INEFFECTIVE
NERVOUSNESS

ISR Number: 5268092 Case Number: 6273350 I/F Code: I Report Date: 20070313
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008262192
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: AS NEEDED INHAL
Event Date:
FDA Date: 20070314
Follow Number:
Image ID: 5268092-8
Age: Gender: M Weight: 200 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: N Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DRUG INEFFECTIVE
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5269419 Case Number: 6274376 I/F Code: I Report Date: 20070315

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008266962

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: GHG081A

Expiration Date: 20080701

Indication: BRONCHOSPASM

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY 6 HOURS INHAL

Event Date: 20070310

FDA Date: 20070316

Follow Number:

Image ID: 5269419-3

Age: 44 YR Gender: F Weight: 200 LBS

Occupation: OT

Country: UNITED STATES

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

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

Therapy Start: 20070310

Therapy End: 20070309

Duration: 1 DAY

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5283483 Case Number: 6286154 I/F Code: I Report Date: 20070315

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008320732

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS Q4 PRN INHALED OVER PAST 3 WEEKS

Event Date:

FDA Date: 20070328

Follow Number:

Image ID: 5283483-7

Age: Gender: Weight:

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- BRONCHOSPASM
- CHEST DISCOMFORT
- COUGH
- PALPITATIONS
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5288232 Case Number: 6287898 I/F Code: I Report Date: 20070326
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008335555
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GHG068A
Expiration Date: 20080701
Indication: ASTHMA
Route: ORAL
Dose: TWO PO QID PRN
Event Date: 20070225
FDA Date: 20070402
Follow Number:
Image ID: 5288232-4
Age: 26 YR Gender: F Weight:
Occupation: PH
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20070225
Therapy Start:
Therapy End: 20070212
Duration:
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE
LOSS OF CONSCIOUSNESS
RESUSCITATION

ISR Number: 5315337 Case Number: 6310487 I/F Code: I Report Date: 20070425

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1008439263

Mfg. Date: 20070419

Mfg. Number: 2007SP007403

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: 2 DF;QID;PO

Event Date:

FDA Date: 20070427

Follow Number:

Image ID: 5315337-1

Age: Gender: M Weight:

Occupation: OT

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20070412

Duration:

Adverse Reactions:

HAEMOPTYSIS

ISR Number: 5321342 Case Number: 6315405 I/F Code: I Report Date: 20070502
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1008464756
Mfg. Date: 20070426
Mfg. Number: 2007SP008022
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number: P2113
Expiration Date: 20080501
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: 2 DF; TID; PO
Event Date:
FDA Date: 20070504
Follow Number:
Image ID: 5321342-1
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
CONDITION AGGRAVATED
DRUG EFFECT DECREASED
THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5328255 Case Number: 6316569 I/F Code: I Report Date: 20070515
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008492092
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20070510
FDA Date: 20070516
Follow Number:
Image ID: 5328255-X
Age: Gender: F Weight: 130 LBS
Occupation:
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:
ASTHMA
CONDITION AGGRAVATED
COUGH
DYSPNOEA

ISR Number: 5339655 Case Number: 6330363 I/F Code: I Report Date: 20070523
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1008533221
Mfg. Date: 20070518
Mfg. Number: 2007SP009774
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070525
Follow Number:
Image ID: 5339655-6
Age: 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:
ASTHMA
CONDITION AGGRAVATED
REACTION TO DRUG EXCIPIENTS

ISR Number: 5343862 Case Number: 6331668 I/F Code: I Report Date: 20070529

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1008545018

Mfg. Date: 20070521

Mfg. Number: 2007SP009952

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: ORAL

Dose: PO

Event Date: 20070301

FDA Date: 20070531

Follow Number:

Image ID: 5343862-6

Age: 70 YR 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
- HYPERSENSITIVITY
- JOINT SWELLING
- WHEEZING

ISR Number: 5343878 Case Number: 6331553 I/F Code: I Report Date: 20070529

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1008545042

Mfg. Date: 20070517

Mfg. Number: 2007SP008063

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: ORAL

Dose: 2 DF; QID; PO

Event Date:

FDA Date: 20070531

Follow Number:

Image ID: 5343878-X

Age: 41 YR Gender: F Weight: 130 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ANAPHYLACTIC REACTION
- ASTHMA
- CARDIAC MURMUR
- CARDIOGENIC SHOCK
- FUNGAL INFECTION
- PHARYNGOLARYNGEAL PAIN

ISR Number: 5350364 Case Number: 6331831 I/F Code: I Report Date: 20070604
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008563516
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20070801
Indication: ASTHMA
Route: ORAL
Dose: 2 INHALATIONS Q4HRS PO AS NEEDED
Event Date: 20070604
FDA Date: 20070605
Follow Number:
Image ID: 5350364-X
Age: 11 YR Gender: M Weight: 90 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: Rechallenge Code: D Death Date:
Therapy Start: 20070604
Therapy End: 20060401
Duration:
Adverse Reactions:
COUGH
DEVICE MALFUNCTION
DRUG INEFFECTIVE
MEDICATION ERROR

ISR Number: 5353549 Case Number: 6335360 I/F Code: I Report Date: 20070607
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008575059
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS 4 TIMES DAILY ORAL
Event Date: 20070426
FDA Date: 20070608
Follow Number:
Image ID: 5353549-1
Age: Gender: F Weight: 130 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: LT Dechallenge Code: Y Rechallenge Code: Y Death Date:
Therapy Start:
Therapy End: 20070426
Duration:
Adverse Reactions:
 APNOEA
 BRONCHOSPASM

ISR Number: 5358343 Case Number: 6337606 I/F Code: I Report Date: 20070613
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008590847
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: 1-2 INHALATIONS AS NECESSARY INHAL
Event Date:
FDA Date: 20070614
Follow Number:
Image ID: 5358343-3
Age: Gender: F Weight: 250 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: D Rechallenge Code: Y Death Date:
Therapy Start:
Therapy End:
Duration: 1 MON
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 5361654 Case Number: 6342320 I/F Code: I Report Date: 20070614

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008601980

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 2-4 PUFFS 4X/DAY AS NEEDED INHAL

Event Date: 20070501

FDA Date: 20070615

Follow Number:

Image ID: 5361654-9

Age: 67 YR Gender: M Weight: 250 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20070614

Therapy End: 20070501

Duration:

Adverse Reactions:

- COUGH
- DIZZINESS
- DRUG INEFFECTIVE
- DYSPNOEA
- INCORRECT DOSE ADMINISTERED
- PHARMACEUTICAL PRODUCT COMPLAINT
- SNEEZING
- WHEEZING

ISR Number: 5367015 Case Number: 6344686 I/F Code: I Report Date: 20070607
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008619644
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: BRONCHITIS
Route: ORAL
Dose: 2 PUFFS 4 TIMES DAILY ORAL
Event Date: 20070426
FDA Date: 20070619
Follow Number:
Image ID: 5367015-0
Age: Gender: F Weight: 130 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: LT Dechallenge Code: Y Rechallenge Code: Y Death Date:
Therapy Start:
Therapy End: 20070426
Duration:
Adverse Reactions:
BRONCHOSPASM
RESPIRATORY ARREST

ISR Number: 5377942 Case Number: 6353407 I/F Code: I Report Date: 20070627

Drug Name: **PROVENTIL-HFA**
 NDA Number: 20503
 Role Code: PS VAL/VBM: 1
 Seq Number: 1008660597
 Mfg. Date: 20070622
 Mfg. Number: 2007SP012563
 Mfg. Sender: SCHERING-PLOUGH CORPORATION
 Lot Number:

Expiration Date:
 Indication: MULTIPLE ALLERGIES
 Route: ORAL
 Dose: ; PO

Event Date:
 FDA Date: 20070629

Follow Number:
 Image ID: 5377942-6

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:
- ANGER
 - FEELING ABNORMAL
 - NERVOUS SYSTEM DISORDER
 - OFF LABEL USE
 - OVERDOSE
 - PSYCHOTIC DISORDER
 - SELF-MEDICATION
 - SOMNOLENCE
 - THERAPEUTIC RESPONSE DECREASED
 - THROAT IRRITATION

ISR Number: 5381677 Case Number: 6355536 I/F Code: I Report Date: 20070704
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008675838
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASBESTOSIS
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4 HRS INHAL
Event Date:
FDA Date: 20070705
Follow Number:
Image ID: 5381677-3
Age: Gender: M Weight: 165 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: Y Death Date:
Therapy Start: 20040101
Therapy End: 19900101
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 DYSPNOEA
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5416593 Case Number: 6448551 I/F Code: I Report Date: 20070813

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008815067

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose: 1 PUFF FREQUENTLY

Event Date: 20070813

FDA Date: 20070814

Follow Number:

Image ID: 5416593-1

Age: 39 YR Gender: M Weight: 225 LBS

Occupation: CN

Country: UNITED STATES

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

Outcome Code: LT Dechallenge Code: N Rechallenge Code: Y Death Date:

Therapy Start: 20070808

Therapy End: 20070301

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

DYSPNOEA

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5428952 Case Number: 6405836 I/F Code: I Report Date: 20070824
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1008856954
Mfg. Date: 20070822
Mfg. Number: 2007SP016943
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070827
Follow Number:
Image ID: 5428952-1
Age: 55 YR Gender: M Weight:
Occupation: MD
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DEATH

ISR Number: 5433313 Case Number: 6411610 I/F Code: I Report Date: 20070827
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008869449
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GHH083A
Expiration Date: 20080831
Indication: ASTHMA
Route: OTHER
Dose: 90 MCG PRN OTHER
Event Date: 20070820
FDA Date: 20070828
Follow Number:
Image ID: 5433313-5
Age: 46 YR Gender: F Weight: 150 LBS
Occupation: CN
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: 20070820
Therapy End: 20070507
Duration:
Adverse Reactions:
 DEVICE MALFUNCTION
 DRUG INEFFECTIVE

ISR Number: 5455623 Case Number: 6428769 I/F Code: I Report Date: 20070912
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1008935851
Mfg. Date: 20070910
Mfg. Number: 2007SP018045
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20070914
Follow Number:
Image ID: 5455623-8
Age: Gender: M 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:
 ATRIAL FIBRILLATION

ISR Number: 5460873 Case Number: 6263344 I/F Code: I Report Date: 20070813

Drug Name: **PROVENTIL-HFA**

NDA Number: 17559

Role Code: PS VAL/VBM: 1

Seq Number: 1008951219

Mfg. Date: 20070202

Mfg. Number: 2007SP002325

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: FHD 017A

Expiration Date: 20080401

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: ORAL

Dose: 90 MCG;QID;PO

Event Date:

FDA Date: 20070824

Follow Number:

Image ID: 5460873-0

Age: 71 YR Gender: M Weight: 197 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20070319

Duration:

Adverse Reactions:

ASTHENIA

CARDIAC FAILURE

DYSPNOEA

THERAPEUTIC PRODUCT INEFFECTIVE

ISR Number: 5465284 Case Number: 6427509 I/F Code: I Report Date: 20070718
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008964396
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FHH027A
Expiration Date: 20080831
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: RESPIRATORY (INHALATION)
Dose: INHALE 2 PUFFS FOUR TIMES DAILY AS NEEDED
Event Date: 20070331
FDA Date: 20070920
Follow Number:
Image ID: 5465284-X
Age: 81 YR Gender: F Weight:
Occupation: PH
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:
Therapy End: 20070301
Duration:
Adverse Reactions:
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5465480 Case Number: 6431052 I/F Code: I Report Date: 20070813
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008965097
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GHJ049A
Expiration Date: 20080703
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: INHALE 2 PUFFS EVERY 6 HOURS AS NEEDED
Event Date: 20070806
FDA Date: 20070920
Follow Number:
Image ID: 5465480-1
Age: 78 YR Gender: F Weight: 180 LBS
Occupation: PH
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:
Therapy End:
Duration: 6 MON
Adverse Reactions:
 DEVICE FAILURE
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5489686 Case Number: 6472992 I/F Code: I Report Date: 20071001
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009054716
Mfg. Date: 20070712
Mfg. Number: 2007SP014047
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071010
Follow Number:
Image ID: 5489686-0
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:
ANAPHYLACTIC REACTION
PHARYNGEAL OEDEMA
PRURITUS

ISR Number: 5489687 Case Number: 6472998 I/F Code: I Report Date: 20071001

Drug Name: **PROVENTIL-HFA**
 NDA Number: 20503
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009054722
 Mfg. Date: 20070514
 Mfg. Number: 2007SP009253
 Mfg. Sender: SCHERING-PLOUGH CORPORATION
 Lot Number:

Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: ORAL
 Dose: PO
 Event Date: 20070508
 FDA Date: 20071010

Follow Number:
 Image ID: 5489687-2
 Age: 20 YR Gender: F Weight:
 Occupation: PH
 Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: Confidential:
 Outcome Code: OT Dechallenge Code: Y Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:

Duration:
 Adverse Reactions:
 ABDOMINAL PAIN
 ANXIETY
 HYPERSENSITIVITY
 NAUSEA

ISR Number: 5489688 Case Number: 6473000 I/F Code: I Report Date: 20071001
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009054723
Mfg. Date: 20070412
Mfg. Number: 2007SP006922
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number: GHB063A
Expiration Date: 20080201
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071010
Follow Number:
Image ID: 5489688-4
Age: Gender: F Weight:
Occupation: MD
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:
BRONCHOSPASM
HEART RATE INCREASED
THERAPEUTIC PRODUCT INEFFECTIVE

ISR Number: 5489689 Case Number: 6473001 I/F Code: I Report Date: 20071001
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009054724
Mfg. Date: 20070404
Mfg. Number: 2007SP006211
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071010
Follow Number:
Image ID: 5489689-6
Age: 42 YR Gender: F Weight: 149 LBS
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:
THERAPEUTIC PRODUCT INEFFECTIVE

ISR Number: 5489693 Case Number: 6473002 I/F Code: I Report Date: 20071001
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009054732
Mfg. Date: 20070328
Mfg. Number: 2007SP005838
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071010
Follow Number:
Image ID: 5489693-8
Age: 34 YR 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:
THERAPEUTIC PRODUCT INEFFECTIVE

ISR Number: 5489695 Case Number: 6473005 I/F Code: I Report Date: 20071001
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009054735
Mfg. Date: 20070327
Mfg. Number: 2007SP005625
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071010
Follow Number:
Image ID: 5489695-1
Age: 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:
VOMITING

ISR Number: 5489696 Case Number: 6473006 I/F Code: I Report Date: 20071001
 Drug Name: **PROVENTIL-HFA**
 NDA Number: 20503
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009054739
 Mfg. Date: 20070322
 Mfg. Number: 2007SP005328
 Mfg. Sender: SCHERING-PLOUGH CORPORATION
 Lot Number:
 Expiration Date:
 Indication: ASTHMA
 Route: ORAL
 Dose: PO
 Event Date: 20050101
 FDA Date: 20071010
 Follow Number:
 Image ID: 5489696-3
 Age: 8 YR Gender: M Weight:
 Occupation: CN
 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: 20050101
 Duration:
 Adverse Reactions:
 ANAPHYLACTIC REACTION

ISR Number: 5489697 Case Number: 6473014 I/F Code: I Report Date: 20071001
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009054742
Mfg. Date: 20070316
Mfg. Number: 2007SP005241
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071010
Follow Number:
Image ID: 5489697-5
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:
BRONCHOSPASM
NO THERAPEUTIC RESPONSE

ISR Number: 5489699 Case Number: 6474284 I/F Code: I Report Date: 20071001
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009054744
Mfg. Date: 20070314
Mfg. Number: 2007SP004838
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number: GHG081A
Expiration Date: 20080701
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date: 20070301
FDA Date: 20071010
Follow Number:
Image ID: 5489699-9
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:
DRUG EFFECT DECREASED

ISR Number: 5489701 Case Number: 6474287 I/F Code: I Report Date: 20071001

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1009054747

Mfg. Date: 20070312

Mfg. Number: 2007SP004727

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: GHC0528

Expiration Date: 20080301

Indication: ASTHMA

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20071010

Follow Number:

Image ID: 5489701-4

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- BLOOD PRESSURE INCREASED
- DISTURBANCE IN ATTENTION
- DYSPNOEA
- HEART RATE INCREASED
- HYPERHIDROSIS
- THERAPEUTIC PRODUCT INEFFECTIVE
- TREMOR
- VERTIGO

ISR Number: 5489704 Case Number: 6474289 I/F Code: I Report Date: 20071001
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009054750
Mfg. Date: 20070305
Mfg. Number: 2007SP004301
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number: GBB 015A
Expiration Date: 20070401
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071010
Follow Number:
Image ID: 5489704-X
Age: 44 YR 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:
NO THERAPEUTIC RESPONSE

ISR Number: 5489706 Case Number: 6487786 I/F Code: I Report Date: 20071001
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009054753
Mfg. Date: 20070207
Mfg. Number: 2007SP002431
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: SARCOIDOSIS
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071010
Follow Number:
Image ID: 5489706-3
Age: 39 YR Gender: F Weight: 260 LBS
Occupation: CN
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
HYPERSENSITIVITY

ISR Number: 5489707 Case Number: 6487788 I/F Code: I Report Date: 20071001
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009054757
Mfg. Date: 20070103
Mfg. Number: 2007SP000113
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose: INH
Event Date:
FDA Date: 20071010
Follow Number:
Image ID: 5489707-5
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: 3 DAY
Adverse Reactions:
NO THERAPEUTIC RESPONSE

ISR Number: 5504818 Case Number: 6462276 I/F Code: I Report Date: 20071030
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009112609
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FHL016A
Expiration Date: 20081231
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4 - 6 HOURS INHAL
Event Date: 20071029
FDA Date: 20071031
Follow Number:
Image ID: 5504818-3
Age: 39 YR Gender: F Weight: 210 LBS
Occupation: CN
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: 20071030
Therapy End: 20071010
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 LOSS OF CONSCIOUSNESS

ISR Number: 5506382 Case Number: 6463612 I/F Code: I Report Date: 20071031
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009118562
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GH1031A
Expiration Date: 20080930
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: INHAL
Event Date: 20070614
FDA Date: 20071101
Follow Number:
Image ID: 5506382-1
Age: 25 YR Gender: F Weight:
Occupation: PH
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20070630
Therapy End: 20070301
Duration:
Adverse Reactions:
DRUG EFFECT DECREASED

ISR Number: 5507213 Case Number: 6464927 I/F Code: I Report Date: 20071031

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1009121508

Mfg. Date: 20071022

Mfg. Number: 2007SP021821

Mfg. Sender: SCHEING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: EMPHYSEMA

Route: ORAL

Dose: ; PO

Event Date:

FDA Date: 20071102

Follow Number:

Image ID: 5507213-6

Age: Gender: M 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:

- CONDITION AGGRAVATED
- DYSPNOEA
- HEADACHE
- NAUSEA
- PALPITATIONS
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5512651 Case Number: 6471757 I/F Code: I Report Date: 20071106
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009141932
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: NOT ON FILE
Expiration Date: 20101101
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 100MCG 15+ DAILY INHAL 6 MONTHS C NO RESULTS
Event Date: 20071101
FDA Date: 20071108
Follow Number:
Image ID: 5512651-1
Age: 39 YR Gender: M Weight: 325 LBS
Occupation: OT
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20071105
Therapy End: 20070401
Duration: 6 MON
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 5518997 Case Number: 6475059 I/F Code: I Report Date: 20071113
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009165406
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FHI025A
Expiration Date: 20080901
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS UP TO 4 TIMES PER INHAL
Event Date: 20071113
FDA Date: 20071114
Follow Number:
Image ID: 5518997-5
Age: 30 YR Gender: F Weight: 175 LBS
Occupation: CN
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: 20071113
Therapy End: 20070701
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 DYSPNOEA
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5520378 Case Number: 6476092 I/F Code: I Report Date: 20071022

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009171103

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: FHL012A

Expiration Date: 20091201

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: ORAL

Dose: 2 PUFFS 3-4 HRS AS NEEDED ORAL INHALATION

Event Date: 20071015

FDA Date: 20071116

Follow Number:

Image ID: 5520378-5

Age: 58 YR Gender: F Weight: 168 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20071021

Therapy End: 20071015

Duration:

Adverse Reactions:

- ASTHENIA
- CHEST DISCOMFORT
- DIZZINESS
- DRUG EFFECT DECREASED
- PALPITATIONS
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5525165 Case Number: 6477620 I/F Code: I Report Date: 20071115

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1009191387

Mfg. Date: 20071112

Mfg. Number: 2007SP022754

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20071119

Follow Number:

Image ID: 5525165-X

Age: 31 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:

- DYSPNOEA
- HYPERVENTILATION
- LIP SWELLING

ISR Number: 5528581 Case Number: 6480106 I/F Code: I Report Date: 20071121

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1009204222

Mfg. Date: 20071116

Mfg. Number: 2007SP023177

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: ; PO

Event Date:

FDA Date: 20071126

Follow Number:

Image ID: 5528581-5

Age: Gender: M Weight:

Occupation: MD

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:

- FOREIGN BODY TRAUMA
- OESOPHAGEAL OBSTRUCTION
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5528745 Case Number: 6483524 I/F Code: I Report Date: 20071121
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009204681
Mfg. Date: 20071119
Mfg. Number: 2007SP023253
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071126
Follow Number:
Image ID: 5528745-0
Age: 53 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DEATH

ISR Number: 5531535 Case Number: 6483100 I/F Code: I Report Date: 20071121

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009215543

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 70239

Expiration Date: 20090331

Indication: DYSPNOEA

Route: ORAL

Dose: 2 PUFFS 2 HOURS PO

Event Date: 20071120

FDA Date: 20071128

Follow Number:

Image ID: 5531535-6

Age: 30 YR Gender: F Weight: 230 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: 20071120

Therapy End: 20071120

Duration:

Adverse Reactions:

- DRUG HYPERSENSITIVITY
- PRURITUS GENERALISED
- RASH
- URTICARIA

ISR Number: 5532145 Case Number: 6486448 I/F Code: I Report Date: 20071128
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009217540
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FHH023A
Expiration Date: 20080430
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4 X DAY INHAL
Event Date: 20070430
FDA Date: 20071129
Follow Number:
Image ID: 5532145-7
Age: Gender: F Weight: 137 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20071201
Therapy End: 20071025
Duration:
Adverse Reactions:
COUGH
DRUG INEFFECTIVE
DYSPNOEA
WHEEZING

ISR Number: 5534004 Case Number: 6491706 I/F Code: I Report Date: 20071128
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009224106
Mfg. Date: 20071120
Mfg. Number: 2007SP023410
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071130
Follow Number:
Image ID: 5534004-2
Age: 48 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:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DEATH

ISR Number: 5534005 Case Number: 6491735 I/F Code: I Report Date: 20071128
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009224107
Mfg. Date: 20071126
Mfg. Number: 2007SP023796
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071130
Follow Number:
Image ID: 5534005-4
Age: Gender: F Weight:
Occupation: MD
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DEATH

ISR Number: 5562917 Case Number: 6513483 I/F Code: I Report Date: 20071210
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1009296805
Mfg. Date: 20071206
Mfg. Number: 2007SP024423
Mfg. Sender: SCHERING -PLOUGH CORPORTATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20071212
Follow Number:
Image ID: 5562917-4
Age: 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:
FEAR
ILL-DEFINED DISORDER
PRURITUS

ISR Number: 5580935 Case Number: 6523920 I/F Code: I Report Date: 20071226

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1009359982

Mfg. Date: 20071217

Mfg. Number: 2007SP025012

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: FJC 031A

Expiration Date: 20080301

Indication: ASTHMA

Route: ORAL

Dose: PRN; PO

Event Date: 20071209

FDA Date: 20071227

Follow Number:

Image ID: 5580935-7

Age: Gender: F Weight: 163 LBS

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20060101

Duration:

Adverse Reactions:

INFLUENZA

NASOPHARYNGITIS

ISR Number: 5585274 Case Number: 6525499 I/F Code: I Report Date: 20080103
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009375167
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GID 004A
Expiration Date: 20090401
Indication: ASTHMA
Route:
Dose: 200 METERED DOSES 25+/DAY
Event Date:
FDA Date: 20080104
Follow Number:
Image ID: 5585274-6
Age: 45 YR Gender: F Weight: 125 LBS
Occupation: CN
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: 20071231
Therapy End: 20071001
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
PHARMACEUTICAL PRODUCT COMPLAINT
SINUS POLYP
THERAPEUTIC RESPONSE DECREASED

ISR Number: 5587883 Case Number: 6527774 I/F Code: I Report Date: 20080109
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009383782
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS AS NEEDED INHALED
Event Date: 20070101
FDA Date: 20080109
Follow Number:
Image ID: 5587883-7
Age: Gender: M Weight: 140 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: Dechallenge Code: N Rechallenge Code: Y Death Date:
Therapy Start:
Therapy End:
Duration: 6 MON
Adverse Reactions:
DRUG INEFFECTIVE
DYSPNOEA
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5592477 Case Number: 6530654 I/F Code: I Report Date: 20080110

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1009400280

Mfg. Date: 20080108

Mfg. Number: 2007SP022462

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: COUGH

Route: ORAL

Dose: PRN;PO

Event Date: 20071115

FDA Date: 20080111

Follow Number:

Image ID: 5592477-3

Age: 51 YR Gender: F Weight: 135 LBS

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start: 20071129

Therapy End: 20071115

Duration:

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5605199 Case Number: 6544506 I/F Code: I Report Date: 20080123

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1009447364

Mfg. Date: 20080117

Mfg. Number: 2008SP001481

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: PO

Event Date: 20080117

FDA Date: 20080124

Follow Number:

Image ID: 5605199-7

Age: 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: 20080117

Duration:

Adverse Reactions:

- ASTHENIA
- CHEST DISCOMFORT
- EYE PAIN
- HEADACHE
- HYPOAESTHESIA
- MUSCLE TIGHTNESS
- PARAESTHESIA

ISR Number: 5608876 Case Number: 6547495 I/F Code: I Report Date: 20080126

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009459779

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY SIX HOURS INHAL

Event Date: 20080102

FDA Date: 20080128

Follow Number:

Image ID: 5608876-7

Age: Gender: F Weight: 165 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20080126

Therapy End: 19920302

Duration:

Adverse Reactions:

- CONDITION AGGRAVATED
- DRUG EFFECT DECREASED
- NO THERAPEUTIC RESPONSE
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5612037 Case Number: 6550481 I/F Code: I Report Date: 20080127

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009470533

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date:

FDA Date: 20080129

Follow Number:

Image ID: 5612037-5

Age: 51 YR Gender: F Weight: 160 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG EFFECT DECREASED

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5612319 Case Number: 6551236 I/F Code: I Report Date: 20080130
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009471470
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS AS NEEDED AS REQUIRED INHAL
Event Date: 20080130
FDA Date: 20080131
Follow Number:
Image ID: 5612319-7
Age: 37 YR Gender: M Weight: 195 LBS
Occupation:
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:
Duration:
Adverse Reactions:
CHEST PAIN
DRUG INEFFECTIVE
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5615518 Case Number: 6552609 I/F Code: I Report Date: 20080201
 Drug Name: **PROVENTIL-HFA**
 NDA Number:
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009482390
 Mfg. Date:
 Mfg. Number:
 Mfg. Sender:
 Lot Number: FIC 056A
 Expiration Date: 20090331
 Indication: ASTHMA
 Route: RESPIRATORY (INHALATION)
 Dose: 200 METERED DOSES INHAL
 Event Date: 20071215
 FDA Date: 20080204
 Follow Number:
 Image ID: 5615518-3
 Age: 40 YR Gender: F Weight: 150 LBS
 Occupation:
 Country: UNITED STATES
 Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
 Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:
 Therapy Start:
 Therapy End: 20071201
 Duration:
 Adverse Reactions:
 DEVICE MALFUNCTION
 DRUG INEFFECTIVE

ISR Number: 5624307 Case Number: 6673399 I/F Code: I Report Date: 20080205

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009510618

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: FHF022A

Expiration Date: 20080630

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1 PUFF PRN INHAL

Event Date: 20070223

FDA Date: 20080206

Follow Number:

Image ID: 5624307-5

Age: 46 YR Gender: F Weight: 150 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20080205

Therapy End: 20070223

Duration:

Adverse Reactions:

- APPARENT LIFE THREATENING EVENT
- ASTHMA
- BLOOD PRESSURE INCREASED
- CHEST DISCOMFORT
- CONDITION AGGRAVATED
- DISORIENTATION
- DRUG INEFFECTIVE
- FEELING ABNORMAL
- FLUSHING
- HEADACHE
- HEART RATE INCREASED
- LUNG DISORDER
- NAUSEA
- PHARMACEUTICAL PRODUCT COMPLAINT
- TREMOR
- VERTIGO

ISR Number: 5625932 Case Number: 6559739 I/F Code: I Report Date: 20080206
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009516348
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: LOWER RESPIRATORY TRACT INFECTION
Route: OTHER
Dose: I BELEIVE 17G 1 PUFF OTHER
Event Date: 20080206
FDA Date: 20080212
Follow Number:
Image ID: 5625932-8
Age: Gender: M Weight: 250 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: RI Dechallenge Code: N Rechallenge Code: D Death Date:
Therapy Start: 20080206
Therapy End: 20080206
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5627849 Case Number: 6566864 I/F Code: I Report Date: 20080212

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009523222

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: FID018A

Expiration Date: 20090430

Indication: ASTHMA

Route:

Dose: AS NEEDED

Event Date:

FDA Date: 20080213

Follow Number:

Image ID: 5627849-1

Age: 54 YR Gender: F Weight: 140 LBS

Occupation:

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: 20080212

Therapy End: 20070801

Duration:

Adverse Reactions:

- ACTIVITIES OF DAILY LIVING IMPAIRED
- ASTHMA
- DRUG INEFFECTIVE
- DYSPNOEA
- GENERAL PHYSICAL HEALTH DETERIORATION
- QUALITY OF LIFE DECREASED

ISR Number: 5646430 Case Number: 6577646 I/F Code: I Report Date: 20080227

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009587933

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: GHL008A

Expiration Date: 20081231

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: ORAL

Dose: 2 PUFFS EVERY 4 HOURS PO

Event Date: 20080119

FDA Date: 20080228

Follow Number:

Image ID: 5646430-1

Age: 54 YR Gender: F Weight: 175 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20080119

Therapy End: 20080117

Duration:

Adverse Reactions:

- BLOOD GLUCOSE ABNORMAL
- DIZZINESS
- DYSPNOEA
- FEELING ABNORMAL
- HEADACHE
- HEART RATE INCREASED
- LUNG DISORDER
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5646814 Case Number: 6578296 I/F Code: I Report Date: 20080228
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009589285
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FIE027A
Expiration Date: 20090531
Indication: ASTHMA
Route: ORAL
Dose: 2 INHALATIONS 6 TIMES PER DAY PO
Event Date: 20080228
FDA Date: 20080229
Follow Number:
Image ID: 5646814-1
Age: 51 YR Gender: F Weight: 140 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20080228
Therapy End: 20080201
Duration:
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5650459 Case Number: 6581597 I/F Code: I Report Date: 20080303
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009600024
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 70238
Expiration Date: 20090331
Indication: DYSPNOEA
Route: ORAL
Dose: 2 PUFFS 4-6 HOURS PO
Event Date: 20071210
FDA Date: 20080304
Follow Number:
Image ID: 5650459-7
Age: 48 YR Gender: F Weight: 210 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20071210
Therapy End: 20071210
Duration:
Adverse Reactions:
URTICARIA

ISR Number: 5668745 Case Number: 6590707 I/F Code: I Report Date: 20080311
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009661539
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FIG019A
Expiration Date: 20090731
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS 4 TIMES A DAY PO
Event Date: 20080301
FDA Date: 20080312
Follow Number:
Image ID: 5668745-3
Age: 36 YR Gender: M Weight: 195 LBS
Occupation: CN
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: 20080207
Duration:
Adverse Reactions:
CHEST DISCOMFORT
DRUG EFFECT DECREASED
DYSPNOEA
THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5678109 Case Number: 6603746 I/F Code: I Report Date: 20080321

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009694876

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: OTHER

Dose: 2 PUFFS EVERY 4 HRS IF NEE OTHER

Event Date: 20070101

FDA Date: 20080324

Follow Number:

Image ID: 5678109-4

Age: 41 YR Gender: F Weight: 179 LBS

Occupation: OT

Country: UNITED STATES

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

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

Therapy Start: 20080321

Therapy End: 20070101

Duration:

Adverse Reactions:

- DEVICE FAILURE
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5690530 Case Number: 6609773 I/F Code: I Report Date: 20080330
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009732546
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GIA090A
Expiration Date: 20080731
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 90 MCG 2 INHAL
Event Date: 20080330
FDA Date: 20080331
Follow Number:
Image ID: 5690530-7
Age: 40 YR Gender: M Weight: 198 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20080330
Therapy End: 20080330
Duration:
Adverse Reactions:
NO THERAPEUTIC RESPONSE
PHARMACEUTICAL PRODUCT COMPLAINT