
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

ISR Number: 5691168 Case Number: 6610202 I/F Code: I Report Date: 20080331
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009735333
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4 HRS AS NEEDED INHAL
Event Date: 20080330
FDA Date: 20080401
Follow Number:
Image ID: 5691168-8
Age: 34 YR Gender: F Weight: 150 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: 1 YR
Adverse Reactions:
 DEVICE FAILURE
 DRUG INEFFECTIVE

ISR Number: 5699229 Case Number: 6614862 I/F Code: I Report Date: 20080405
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009763169
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GHH0168
Expiration Date: 20080801
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS AS NEEDED INHAL
Event Date: 20080405
FDA Date: 20080407
Follow Number:
Image ID: 5699229-4
Age: 30 YR Gender: F Weight: 299 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: 20080405
Therapy End: 20070601
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 FEELING ABNORMAL
 PHARMACEUTICAL PRODUCT COMPLAINT
 TREMOR

ISR Number: 5700791 Case Number: 6620413 I/F Code: I Report Date: 20080408

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009768983

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date:

FDA Date: 20080409

Follow Number:

Image ID: 5700791-3

Age: 28 YR Gender: M Weight: 185 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DEVICE MALFUNCTION

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5712792 Case Number: 6627057 I/F Code: I Report Date: 20080418

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009815937

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFSS EVERY 4 HR INHAL

Event Date: 20071001

FDA Date: 20080421

Follow Number:

Image ID: 5712792-X

Age: 31 YR Gender: F Weight: 235 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:

Duration: 8 MON

Adverse Reactions:

INCORRECT DOSE ADMINISTERED

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5712814 Case Number: 6627111 I/F Code: I Report Date: 20080418
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009816021
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FIC060A
Expiration Date: 20090331
Indication: ASTHMA
Route:
Dose: 2 PUFFS TWICE/DAY/NEEDED
Event Date: 20080418
FDA Date: 20080421
Follow Number:
Image ID: 5712814-6
Age: 45 YR Gender: F Weight: 140 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: 20080418
Therapy End: 20080418
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 DYSPNOEA
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5713904 Case Number: 6629042 I/F Code: I Report Date: 20080421

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009820528

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date: 20080401

FDA Date: 20080422

Follow Number:

Image ID: 5713904-4

Age: 30 YR Gender: F Weight: 150 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: 20080421

Therapy End: 20080419

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

DYSPNOEA

FEAR

ILL-DEFINED DISORDER

MIGRAINE

OVERDOSE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5719921 Case Number: 6637745 I/F Code: I Report Date: 20080423

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1009842744

Mfg. Date: 20080422

Mfg. Number: 2008SP005783

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: GIG069A

Expiration Date: 20090701

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20080424

Follow Number:

Image ID: 5719921-2

Age: Gender: M 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

FEELING ABNORMAL

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5723022 Case Number: 6636402 I/F Code: I Report Date: 20080409
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009854051
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GIG069A
Expiration Date: 20090731
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: USE 1 TO 2 INHALATIONS THREE TIMES DAILY AS NEEDED
Event Date: 20080118
FDA Date: 20080428
Follow Number:
Image ID: 5723022-7
Age: 59 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: N Death Date:
Therapy Start:
Therapy End: 20080301
Duration:
Adverse Reactions:
ASTHMA
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5723357 Case Number: 6636890 I/F Code: I Report Date: 20080428
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009855041
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: G1N094A
Expiration Date: 20090801
Indication: ASTHMA
Route:
Dose: ONE PUFF PRN ON GOING FOR YEARS
Event Date: 20080411
FDA Date: 20080429
Follow Number:
Image ID: 5723357-8
Age: Gender: M Weight: 200 LBS
Occupation: OT
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:
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5735925 Case Number: 6648627 I/F Code: I Report Date: 20080508
Drug Name: **PROVENTIL HFA (ALBUTEROL SULFATE (INHALATION))**
NDA Number: 20503
Role Code: PS VAL/VBM: 2
Seq Number: 1009900652
Mfg. Date: 20080505
Mfg. Number: 2008SP008310
Mfg. Sender: SCHERING -PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20080509
Follow Number:
Image ID: 5735925-8
Age: 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:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA
TREATMENT NONCOMPLIANCE

ISR Number: 5741329 Case Number: 6652679 I/F Code: I Report Date: 20080514
Drug Name: **PROVENTIL HFA (ALBUTEROL SULFATE (INHALATION))**
NDA Number: 20503
Role Code: PS VAL/VBM: 2
Seq Number: 1009921373
Mfg. Date: 20080509
Mfg. Number: 2008SP008853
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20080515
Follow Number:
Image ID: 5741329-4
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:
 ATRIAL FIBRILLATION
 CEREBROVASCULAR ACCIDENT
 HEART RATE INCREASED

ISR Number: 5758170 Case Number: 6669352 I/F Code: I Report Date: 20080530
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009987985
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20080530
FDA Date: 20080602
Follow Number:
Image ID: 5758170-9
Age: Gender: M Weight: 29 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: HO Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 5765251 Case Number: 6674573 I/F Code: I Report Date: 20080606

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010014803

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY 4 HOURS INHAL

Event Date: 20070101

FDA Date: 20080609

Follow Number:

Image ID: 5765251-2

Age: 64 YR Gender: F Weight: 90 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: 20071201

Therapy End: 20070601

Duration:

Adverse Reactions:

- DRUG INEFFECTIVE
- DYSPNOEA
- PHARMACEUTICAL PRODUCT COMPLAINT
- WHEEZING

ISR Number: 5777461 Case Number: 6685917 I/F Code: I Report Date: 20080613

Drug Name: **PROVENTIL**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1010055720

Mfg. Date: 20080607

Mfg. Number: 2008SP011211

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: FIG019A

Expiration Date: 20090701

Indication: ASTHMA

Route: ORAL

Dose: PO

Event Date: 20080603

FDA Date: 20080616

Follow Number:

Image ID: 5777461-9

Age: 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:

Duration:

Adverse Reactions:

- DEVICE FAILURE
- PHARMACEUTICAL PRODUCT COMPLAINT
- PULSE ABSENT
- RESPIRATORY ARREST

ISR Number: 5777936 Case Number: 6688084 I/F Code: I Report Date: 20080617

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010058155

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date: 20080617

FDA Date: 20080618

Follow Number:

Image ID: 5777936-2

Age: Gender: M Weight: 160 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5782693 Case Number: 6688815 I/F Code: I Report Date: 20080618

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1010077175

Mfg. Date: 20080617

Mfg. Number: 2008SP011827

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: GHI-009A

Expiration Date: 20080801

Indication: ASTHMA

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20080619

Follow Number:

Image ID: 5782693-X

Age: 78 YR 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:

- DRUG INEFFECTIVE
- FALL
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5783095 Case Number: 6690157 I/F Code: I Report Date: 20080618

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010078518

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 90 MCG 2 PUFFS 4 TIMES DAILY INHAL

Event Date: 20080209

FDA Date: 20080619

Follow Number:

Image ID: 5783095-2

Age: 38 YR Gender: F Weight: 180 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: 20080618

Therapy End: 20071015

Duration:

Adverse Reactions:

- ASTHMA
- DEVICE OCCLUSION
- DRUG EFFECT DECREASED
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5787057 Case Number: 6691833 I/F Code: I Report Date: 20080622
Drug Name: **PROVENTAL HFA 90MCG PER ACTUATION SCHERING-PLOUGH**
NDA Number:
Role Code: PS VAL/VBM: 2
Seq Number: 1010086747
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FII028A
Expiration Date: 20090901
Indication: ASTHMA
Route:
Dose: 2 PUFFS EVERY 4 HOURS
Event Date: 20080622
FDA Date: 20080623
Follow Number:
Image ID: 5787057-0
Age: 31 YR Gender: M Weight: 178 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: 20080622
Therapy End: 20061201
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 5794889 Case Number: 6694433 I/F Code: I Report Date: 20080626
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010110406
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GHL001A
Expiration Date: 20081231
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 2XDAILY INHAL
Event Date: 20080609
FDA Date: 20080627
Follow Number:
Image ID: 5794889-1
Age: 42 YR Gender: F Weight: 145 LBS
Occupation:
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: 20080609
Therapy End: 20080301
Duration:
Adverse Reactions:
ANAPHYLACTIC REACTION

ISR Number: 5800279 Case Number: 6698610 I/F Code: I Report Date: 20080701
 Drug Name: **PROVENTIL-HFA**
 NDA Number:
 Role Code: PS VAL/VBM: 1
 Seq Number: 1010130535
 Mfg. Date:
 Mfg. Number:
 Mfg. Sender:
 Lot Number:
 Expiration Date:
 Indication: ASTHMA
 Route:
 Dose: 90MCG PER INHALATION 2X EVERY 4HRS PRN
 Event Date: 20080626
 FDA Date: 20080702
 Follow Number:
 Image ID: 5800279-5
 Age: Gender: M Weight: 210 LBS
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
 Outcome Code: OT Dechallenge Code: D Rechallenge Code: Y Death Date:
 Therapy Start:
 Therapy End:
 Duration: 1 YR
 Adverse Reactions:
 DRUG INEFFECTIVE

ISR Number: 5804147 Case Number: 6700875 I/F Code: I Report Date: 20080706
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010146988
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FIK045A
Expiration Date: 20091130
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS 4 TIMES DAILY PO
Event Date: 20080703
FDA Date: 20080707
Follow Number:
Image ID: 5804147-4
Age: 50 YR Gender: F Weight: 105 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y
Outcome Code: OT Dechallenge Code: N Rechallenge Code: D Death Date:
Therapy Start: 20080704
Therapy End: 20080703
Duration:
Adverse Reactions:
BRONCHOSPASM
CHEST DISCOMFORT
DRUG INEFFECTIVE
DYSPNOEA
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5806742 Case Number: 6704460 I/F Code: I Report Date: 20080707
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010157886
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GIHO49A
Expiration Date: 20090801
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 X DLY OR AS NEED INHAL
Event Date: 20080707
FDA Date: 20080709
Follow Number:
Image ID: 5806742-5
Age: 24 YR Gender: F Weight: 134 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:
Therapy End:
Duration: 10 MON
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 5809695 Case Number: 6708072 I/F Code: I Report Date: 20080710
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010170223
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: MULTIPLE ALLERGIES
Route:
Dose: 2 PUFFS AS NEEDED
Event Date: 20080523
FDA Date: 20080711
Follow Number:
Image ID: 5809695-9
Age: Gender: M Weight: 235 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: 20080523
Therapy End: 20080508
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5810867 Case Number: 6705095 I/F Code: I Report Date: 20080709

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1010174523

Mfg. Date: 20080701

Mfg. Number: 2008SP013112

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: GHL008A

Expiration Date: 20081231

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: PO

Event Date: 20080119

FDA Date: 20080710

Follow Number:

Image ID: 5810867-8

Age: Gender: NS 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:

- BLOOD GLUCOSE ABNORMAL
- DIZZINESS
- DYSPNOEA
- HEADACHE
- HEART RATE INCREASED
- OXYGEN SATURATION DECREASED
- SENSORY DISTURBANCE

ISR Number: 5812308 Case Number: 6706881 I/F Code: I Report Date: 20080711
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1010179934
Mfg. Date: 20080707
Mfg. Number: 2008SP013705
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20080714
Follow Number:
Image ID: 5812308-3
Age: 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:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DEATH

ISR Number: 5812668 Case Number: 6711263 I/F Code: I Report Date: 20080713
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010181244
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FID 020A
Expiration Date: 20090430
Indication: DYSPNOEA
Route:
Dose: 2 PUFFS 4X DAILY, AS NEEDED
Event Date: 20070511
FDA Date: 20080714
Follow Number:
Image ID: 5812668-3
Age: Gender: M Weight: 170 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 OXYGEN SATURATION DECREASED

ISR Number: 5821210 Case Number: 6717232 I/F Code: I Report Date: 20080722

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010212929

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose:

Event Date: 20080722

FDA Date: 20080723

Follow Number:

Image ID: 5821210-2

Age: Gender: F Weight: 108 LBS

Occupation:

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: 20060101

Duration:

Adverse Reactions:

- ASTHMA
- BACK PAIN
- CONDITION AGGRAVATED
- DRUG INEFFECTIVE
- DYSPNOEA
- ECONOMIC PROBLEM
- GENERAL PHYSICAL HEALTH DETERIORATION
- HEADACHE
- INCREASED UPPER AIRWAY SECRETION
- THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5829579 Case Number: 6721340 I/F Code: I Report Date: 20080728
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1010245712
Mfg. Date: 20080718
Mfg. Number: 2008SP014696
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number: GIH091A
Expiration Date: 20090901
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: ORAL
Dose: PO
Event Date:
FDA Date: 20080729
Follow Number:
Image ID: 5829579-X
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:
HOSPITALISATION
PHARMACEUTICAL PRODUCT COMPLAINT
UNDERDOSE

ISR Number: 5833097 Case Number: 6723171 I/F Code: I Report Date: 20080724

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010259396

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS 6-8 TIMES/24HR INHALED

Event Date: 20080710

FDA Date: 20080804

Follow Number:

Image ID: 5833097-2

Age: Gender: F Weight: 140 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20080724

Therapy End: 20080607

Duration:

Adverse Reactions:

- ASTHMA
- BLOOD GLUCOSE INCREASED
- CHEST PAIN
- CONDITION AGGRAVATED
- DRUG EFFECT DECREASED
- PAIN IN EXTREMITY
- PHARMACEUTICAL PRODUCT COMPLAINT
- WEIGHT INCREASED

ISR Number: 5833589 Case Number: 6723784 I/F Code: I Report Date: 20080801

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010260660

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: GH0068A

Expiration Date: 20080731

Indication: ASTHMA

Route:

Dose: 1 -2 PUFFS PRN

Event Date: 20070225

FDA Date: 20080804

Follow Number:

Image ID: 5833589-6

Age: 26 YR Gender: F Weight: 150 LBS

Occupation: CN

Country: UNITED STATES

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

Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20070306

Therapy Start: 20070225

Therapy End: 20070211

Duration:

Adverse Reactions:

ASTHMA

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5834011 Case Number: 6723272 I/F Code: I Report Date: 20080802
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010262010
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GIH047A
Expiration Date: 20090831
Indication: ASTHMA
Route: RETROBULBAR
Dose: 2 PUFFS AS NEEDED RETROBULBAR
Event Date: 20080728
FDA Date: 20080804
Follow Number:
Image ID: 5834011-6
Age: 53 YR Gender: M Weight: 225 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: Dechallenge Code: N Rechallenge Code: Y Death Date:
Therapy Start: 20080731
Therapy End: 20080701
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5857955 Case Number: 6741990 I/F Code: I Report Date: 20080824
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010352872
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: RESPIRATORY (INHALATION)
Dose: 2 INHALATIONS 4 TIMES A DAY
Event Date: 20080815
FDA Date: 20080825
Follow Number:
Image ID: 5857955-8
Age: 54 YR Gender: F Weight: 118 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: N Rechallenge Code: Y Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 5871240 Case Number: 6752587 I/F Code: I Report Date: 20080902
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010404908
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20080902
FDA Date: 20080903
Follow Number:
Image ID: 5871240-X
Age: 21 YR Gender: M Weight: 180 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG EFFECT DECREASED

ISR Number: 5892913 Case Number: 6773335 I/F Code: I Report Date: 20080919
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010485839
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GHH011A
Expiration Date: 20080831
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS EVERY 4-6 HRS, PRN INHAL
Event Date: 20080919
FDA Date: 20080922
Follow Number:
Image ID: 5892913-9
Age: 23 YR Gender: M Weight: 210 LBS
Occupation: OT
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: 18 YR
Adverse Reactions:
 DIZZINESS
 DRUG INEFFECTIVE
 FALL
 FEELING ABNORMAL
 STARING

ISR Number: 5893363 Case Number: 6773873 I/F Code: I Report Date: 20080921
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010487404
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FIE027A
Expiration Date: 20090501
Indication: ASTHMA
Route:
Dose: 90MCG 8 /DAY
Event Date: 20080801
FDA Date: 20080922
Follow Number:
Image ID: 5893363-1
Age: Gender: M Weight: 163 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:
Duration: 10 DAY
Adverse Reactions:
DRUG EFFECT DECREASED

ISR Number: 5897275 Case Number: 6791183 I/F Code: I Report Date: 20080919
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010499356
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route:
Dose: 2 PUFFS AS NEEDED
Event Date: 20080101
FDA Date: 20080924
Follow Number:
Image ID: 5897275-9
Age: Gender: M Weight: 150 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: RI Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5902788 Case Number: 6779137 I/F Code: I Report Date: 20080927
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010518423
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 70807
Expiration Date: 20091231
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS 4 TIMES DAILY PO
Event Date:
FDA Date: 20080929
Follow Number:
Image ID: 5902788-7
Age: 32 YR Gender: F Weight: 335 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y
Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20080930
Therapy End: 20080501
Duration: 4 MON
Adverse Reactions:
ACTIVITIES OF DAILY LIVING IMPAIRED
ASTHMA
CONDITION AGGRAVATED
DRUG INEFFECTIVE

ISR Number: 5903186 Case Number: 6787528 I/F Code: I Report Date: 20080928

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010519690

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose: 2 PUFFS AS NEEDED

Event Date: 20080902

FDA Date: 20080929

Follow Number:

Image ID: 5903186-2

Age: Gender: F Weight: 108 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

ASTHMA

DRUG EFFECT DECREASED

PHARMACEUTICAL PRODUCT COMPLAINT