
ISR Number: 5907574 Case Number: 6784086 I/F Code: I Report Date: 20081001
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010535498
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GJA013A
Expiration Date: 20100131
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS 4 TIMES DAILY PO
Event Date: 20080926
FDA Date: 20081002
Follow Number:
Image ID: 5907574-X
Age: 37 YR Gender: F Weight: 360 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: 20081001
Therapy End: 20080115
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 5918522 Case Number: 6792132 I/F Code: I Report Date: 20081013
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010578191
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose: FREQUENTLY
Event Date: 20081001
FDA Date: 20081014
Follow Number:
Image ID: 5918522-0
Age: 30 YR Gender: M Weight: 245 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:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED

ISR Number: 5920942 Case Number: 6794143 I/F Code: I Report Date: 20081014
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010586305
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1-2 PUFFS AS NEEDED INHAL
Event Date: 20081014
FDA Date: 20081015
Follow Number:
Image ID: 5920942-5
Age: 31 YR Gender: F Weight: 126 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start: 20081011
Therapy End: 20081010
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 PRODUCT QUALITY ISSUE

ISR Number: 5920948 Case Number: 6794146 I/F Code: I Report Date: 20081014
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010586320
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FI1035A
Expiration Date: 20091231
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS AS NEEDED INHAL, USED IT SINCE IT CAME OUT
Event Date:
FDA Date: 20081015
Follow Number:
Image ID: 5920948-6
Age: 49 YR Gender: F Weight: 160 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 DYSPNOEA
 MALAISE
 PRODUCT QUALITY ISSUE

ISR Number: 5924727 Case Number: 6798052 I/F Code: I Report Date: 20081015

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1010600240

Mfg. Date: 20081008

Mfg. Number: 2008SP020517

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: FIL035A

Expiration Date: 20091201

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20081016

Follow Number:

Image ID: 5924727-5

Age: 51 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

PNEUMONIA

PRODUCT QUALITY ISSUE

ISR Number: 5928183 Case Number: 6799577 I/F Code: I Report Date: 20081021

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010612449

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY 4 HOURS PRN INHAL

Event Date: 20080205

FDA Date: 20081022

Follow Number:

Image ID: 5928183-2

Age: 14 YR Gender: F Weight: 100 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: 20081020

Therapy End: 20080205

Duration:

Adverse Reactions:

- CHEST DISCOMFORT
- DRUG INEFFECTIVE
- DYSPNOEA
- FEELING JITTERY
- HEART RATE INCREASED
- THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5932323 Case Number: 6801156 I/F Code: I Report Date: 20081026
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010628374
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose:
Event Date: 20081026
FDA Date: 20081027
Follow Number:
Image ID: 5932323-9
Age: Gender: Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 5932439 Case Number: 6801496 I/F Code: I Report Date: 20081025

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010628696

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: GHG068A

Expiration Date: 20080731

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 INHALATIONS UP TO EVERY 4 HOUR INHAL

Event Date: 20080430

FDA Date: 20081027

Follow Number:

Image ID: 5932439-7

Age: 48 YR Gender: F Weight: 344 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: 20080516

Therapy End: 20080430

Duration: 2 WK

Adverse Reactions:

- DRUG INEFFECTIVE
- PRODUCT QUALITY ISSUE

ISR Number: 5942785 Case Number: 6812781 I/F Code: I Report Date: 20081031

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1010666770

Mfg. Date: 20081027

Mfg. Number: 2008SP019115

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: ;PO

Event Date:

FDA Date: 20081103

Follow Number:

Image ID: 5942785-9

Age: 87 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

MEDICAL DEVICE COMPLICATION

PRODUCT QUALITY ISSUE

ISR Number: 5951278 Case Number: 6815414 I/F Code: I Report Date: 20081111

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010695898

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: DYSпноEA

Route: ORAL

Dose: 1-2 PUFFS 4-6 HOURS PO

Event Date: 20080827

FDA Date: 20081112

Follow Number:

Image ID: 5951278-4

Age: 51 YR Gender: M Weight: 220 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20081111

Therapy End: 19850107

Duration:

Adverse Reactions:

- DRUG INEFFECTIVE
- FEAR
- PRODUCT QUALITY ISSUE

ISR Number: 5954277 Case Number: 6816985 I/F Code: I Report Date: 20081112

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010708623

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose:

Event Date: 20030820

FDA Date: 20081113

Follow Number:

Image ID: 5954277-1

Age: 52 YR Gender: F Weight: 190 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:

- BRONCHOSPASM
- CONDITION AGGRAVATED
- COUGH
- DYSPNOEA
- LUNG DISORDER

ISR Number: 5956420 Case Number: 6827078 I/F Code: I Report Date: 20081113
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010715953
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 80119
Expiration Date: 20100228
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS AS NEEDED INHAL
Event Date: 20081111
FDA Date: 20081114
Follow Number:
Image ID: 5956420-7
Age: Gender: F Weight:
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:
Therapy End:
Duration:
Adverse Reactions:
CONDITION AGGRAVATED
DRUG INEFFECTIVE
EMPHYSEMA
PRODUCT QUALITY ISSUE

ISR Number: 5956433 Case Number: 6817988 I/F Code: I Report Date: 20081113
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010716002
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 0JA071A
Expiration Date: 20100101
Indication: ASTHMA
Route: ORAL
Dose: 1 PUFF 4 TIMES AS NEEDED PO
Event Date: 20081031
FDA Date: 20081114
Follow Number:
Image ID: 5956433-5
Age: 42 YR Gender: M Weight: 183 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: 20081112
Therapy End: 20081031
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 5956441 Case Number: 6817865 I/F Code: I Report Date: 20081113
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010716018
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20090825
Indication: ASTHMA
Route:
Dose: 4 TIMES A DAY
Event Date: 20060825
FDA Date: 20081114
Follow Number:
Image ID: 5956441-4
Age: 25 YR Gender: M Weight: 150 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: LT Dechallenge Code: N Rechallenge Code: Y Death Date:
Therapy Start: 20060826
Therapy End: 20050825
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PARADOXICAL DRUG REACTION
 PRODUCT QUALITY ISSUE

ISR Number: 5956467 Case Number: 6817885 I/F Code: I Report Date: 20081113
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010716119
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 19980101
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS EVERY 4 4-7 PUFFS EV FEW HR INHAL
Event Date: 20071027
FDA Date: 20081114
Follow Number:
Image ID: 5956467-0
Age: 33 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: 20070901
Therapy End: 20070610
Duration:
Adverse Reactions:
 DRUG EXPOSURE DURING PREGNANCY
 DRUG INEFFECTIVE
 RESPIRATORY DISORDER

ISR Number: 5956555 Case Number: 6830403 I/F Code: I Report Date: 20081113
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010716498
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20080901
FDA Date: 20081114
Follow Number:
Image ID: 5956555-9
Age: 32 YR Gender: F Weight: 330 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 5960099 Case Number: 6819736 I/F Code: I Report Date: 20081114
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010729045
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20060115
FDA Date: 20081118
Follow Number:
Image ID: 5960099-8
Age: 58 YR Gender: F Weight: 115 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:
DOCUMENTED HYPERSENSITIVITY TO ADMINISTERED DRUG
DRUG EFFECT DECREASED
PARADOXICAL DRUG REACTION
PRODUCT QUALITY ISSUE

ISR Number: 5965270 Case Number: 6825942 I/F Code: I Report Date: 20081120
Drug Name: **PROVENTIL-HFA**
NDA Number: 20503
Role Code: PS VAL/VBM: 1
Seq Number: 1010748975
Mfg. Date: 20081117
Mfg. Number: 2008SP023323
Mfg. Sender: SCHERING-PLOUGH CORPORATION
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose: INH
Event Date:
FDA Date: 20081121
Follow Number:
Image ID: 5965270-7
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:
DEATH

ISR Number: 5968469 Case Number: 6830482 I/F Code: I Report Date: 20081120
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010758982
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: GIH014A
Expiration Date: 20090228
Indication: ASTHMA
Route: ORAL
Dose: TWO PUFFS 2 TIMES A WEEK PO
Event Date: 20081118
FDA Date: 20081121
Follow Number:
Image ID: 5968469-9
Age: 34 YR Gender: F Weight: 150 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20081118
Therapy End: 20081118
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
PANIC REACTION
THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5971684 Case Number: 6838582 I/F Code: I Report Date: 20081125
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010773252
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 80016
Expiration Date: 20100331
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 2-3X PER DAY INHAL
Event Date: 20080601
FDA Date: 20081126
Follow Number:
Image ID: 5971684-1
Age: 34 Gender: M Weight: 150 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: Y Death Date:
Therapy Start:
Therapy End:
Duration: 6 MON
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE

ISR Number: 5972611 Case Number: 6836255 I/F Code: I Report Date: 20081125
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010775292
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose: 2 PUFFS 4XDAY
Event Date: 20081125
FDA Date: 20081126
Follow Number:
Image ID: 5972611-3
Age: 61 YR Gender: F Weight: 125 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DEVICE INEFFECTIVE
 DEVICE OCCLUSION
 DRUG INEFFECTIVE
 MEDICAL DEVICE COMPLICATION

ISR Number: 5977807 Case Number: 6840266 I/F Code: I Report Date: 20081129
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010791896
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ALL OF THEM
Expiration Date: 20100331
Indication: ASTHMA
Route: ORAL
Dose: 90MCG PER DOSE OR PUFF 6-8 TIMES DAILY PO
Event Date:
FDA Date: 20081201
Follow Number:
Image ID: 5977807-2
Age: 23 YR Gender: M Weight: 160 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: RI Dechallenge Code: D Rechallenge Code: Y Death Date:
Therapy Start: 20081129
Therapy End: 19850916
Duration: 23 YR
Adverse Reactions:
 DRUG INEFFECTIVE
 THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5977808 Case Number: 6840268 I/F Code: I Report Date: 20081129

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010791897

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date: 20090731

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 67GM /90MCG /200 METERED 2PUFFS AS NEEDED INHAL

Event Date: 20081129

FDA Date: 20081201

Follow Number:

Image ID: 5977808-4

Age: 55 YR Gender: F Weight: 173 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: 20081129

Therapy End: 20071027

Duration:

Adverse Reactions:

- BURNING SENSATION
- DIZZINESS
- DRUG INEFFECTIVE
- FEAR
- LUNG DISORDER
- NAUSEA
- PAIN
- RESPIRATORY TRACT IRRITATION
- THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5982955 Case Number: 6848640 I/F Code: I Report Date: 20081203

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010808588

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: ORAL

Dose: 2 PUFFS 2X PO

Event Date: 20080601

FDA Date: 20081205

Follow Number:

Image ID: 5982955-7

Age: Gender: Weight:

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration: 1 WK

Adverse Reactions:

- CONDITION AGGRAVATED
- DEVICE MALFUNCTION
- DRUG INEFFECTIVE
- PRODUCT QUALITY ISSUE

ISR Number: 5982957 Case Number: 6848641 I/F Code: I Report Date: 20081203
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010808597
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20090819
Indication: INCREASED UPPER AIRWAY SECRETION
Route: ENDOTRACHEAL
Dose: 2 PUFFS IN A.M., TWO IN P.M. ENDOTRACHEA
Event Date: 20081202
FDA Date: 20081205
Follow Number:
Image ID: 5982957-0
Age: 89 Gender: M Weight: 145 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: RI Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20081202
Therapy End: 20080919
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 PRODUCT QUALITY ISSUE
 STRESS

ISR Number: 5984400 Case Number: 6848632 I/F Code: I Report Date: 20081202
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010812318
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2-4 PUFFS WHEN NEEDED INHAL
Event Date: 20081202
FDA Date: 20081203
Follow Number:
Image ID: 5984400-4
Age: 34 YR Gender: M Weight: 220 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start: 20081202
Therapy End: 20080601
Duration:
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE

ISR Number: 5984432 Case Number: 6848635 I/F Code: I Report Date: 20081202
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010812402
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20080501
FDA Date: 20081203
Follow Number:
Image ID: 5984432-6
Age: 30 YR Gender: F Weight: 155 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 5988520 Case Number: 6858635 I/F Code: I Report Date: 20081207
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010823299
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: D70827
Expiration Date: 20091101
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 6 TO 8 HOURS
Event Date: 20081205
FDA Date: 20081208
Follow Number:
Image ID: 5988520-X
Age: 49 YR Gender: F Weight: 187 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: N Rechallenge Code: Y Death Date:
Therapy Start: 20081205
Therapy End: 20081205
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DRUG EFFECT DECREASED
PRODUCT QUALITY ISSUE

ISR Number: 5988618 Case Number: 6855263 I/F Code: I Report Date: 20081205
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010823507
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date:
FDA Date: 20081208
Follow Number:
Image ID: 5988618-6
Age: 23 YR Gender: F Weight: 300 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
PRODUCT QUALITY ISSUE

ISR Number: 5988627 Case Number: 6855751 I/F Code: I Report Date: 20081205
Drug Name: **PROVENTIL HFA ASTHMA INHALER**
NDA Number:
Role Code: PS VAL/VBM: 2
Seq Number: 1010823530
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20091201
Indication:
Route: RESPIRATORY (INHALATION)
Dose: 1 TO 2 PUFFS AS NEEDED 3 TIMES/WEEK INHAL
Event Date: 20071010
FDA Date: 20081208
Follow Number:
Image ID: 5988627-7
Age: 67 YR Gender: M Weight: 165 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: 20081001
Therapy End: 20080825
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DIZZINESS
DRUG INEFFECTIVE
FEAR
MOOD ALTERED
PRODUCT QUALITY ISSUE

ISR Number: 5988880 Case Number: 6855159 I/F Code: I Report Date: 20081205
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010824378
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS AS NEEDED INHAL
Event Date:
FDA Date: 20081208
Follow Number:
Image ID: 5988880-X
Age: 25 YR Gender: M Weight: 240 LBS
Occupation: OT
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: Y Death Date:
Therapy Start: 20050620
Therapy End: 20050612
Duration:
Adverse Reactions:
CHEST PAIN
PNEUMONIA

ISR Number: 6004004 Case Number: 6867143 I/F Code: I Report Date: 20081214

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010866530

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose: 2 PUFFS WHEN NEEDED INHAL

Event Date: 20081210

FDA Date: 20081216

Follow Number:

Image ID: 6004004-7

Age: 29 YR Gender: F Weight: 125 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:

Therapy End:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PRODUCT QUALITY ISSUE

ISR Number: 6004008 Case Number: 6867151 I/F Code: I Report Date: 20081214
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010866536
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20081214
FDA Date: 20081215
Follow Number:
Image ID: 6004008-4
Age: 20 YR Gender: F Weight: 160 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 CONDITION AGGRAVATED
 DRUG INEFFECTIVE
 DYSPNOEA
 PRODUCT QUALITY ISSUE
 WHEEZING

ISR Number: 6004465 Case Number: 6867175 I/F Code: I Report Date: 20081213
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010867995
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: RESPIRATORY DISORDER
Route: ORAL
Dose: 2 PUFFS BY MOUTH EVERY 6 HOURS PO
Event Date: 20081007
FDA Date: 20081215
Follow Number:
Image ID: 6004465-3
Age: 50 YR Gender: F Weight: 193 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: 20081029
Therapy End: 20080401
Duration:
Adverse Reactions:
PRODUCT QUALITY ISSUE

ISR Number: 6005907 Case Number: 6867412 I/F Code: I Report Date: 20081215
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010872430
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4 TIMES DAILY INHAL
Event Date:
FDA Date: 20081216
Follow Number:
Image ID: 6005907-X
Age: Gender: F Weight: 128 LBS
Occupation: OT
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: N Rechallenge Code: D Death Date:
Therapy Start: 20070101
Therapy End: 20060604
Duration: 6 MON
Adverse Reactions:
ANXIETY
ASTHENIA
DISCOMFORT
DRUG INEFFECTIVE
OXYGEN SATURATION DECREASED
PRODUCT QUALITY ISSUE
QUALITY OF LIFE DECREASED

ISR Number: 6005937 Case Number: 6867417 I/F Code: I Report Date: 20081215
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010872487
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 80159
Expiration Date: 20100301
Indication: ASTHMA
Route:
Dose: 2 INHALATIONS AS NEEDED
Event Date: 20081215
FDA Date: 20081216
Follow Number:
Image ID: 6005937-8
Age: 43 YR Gender: F Weight: 98 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: N Rechallenge Code: Y Death Date:
Therapy Start: 20081215
Therapy End: 20081208
Duration:
Adverse Reactions:
CONDITION AGGRAVATED
DRUG INEFFECTIVE
DYSPNOEA
PRODUCT QUALITY ISSUE

ISR Number: 6013333 Case Number: 6870916 I/F Code: I Report Date: 20080920
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010894910
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FIL025A
Expiration Date: 20091201
Indication:
Route:
Dose:
Event Date:
FDA Date: 20081218
Follow Number:
Image ID: 6013333-2
Age: 32 YR Gender: M 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:
Duration:
Adverse Reactions:
 DEVICE FAILURE

ISR Number: 6022407 Case Number: 6872696 I/F Code: I Report Date: 20081008
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010933341
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FIL027A
Expiration Date: 20091220
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS FOUR TIMES A DAY
Event Date:
FDA Date: 20081223
Follow Number:
Image ID: 6022407-1
Age: 51 YR Gender: M 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: 20080222
Therapy End: 20071201
Duration:
Adverse Reactions:
 DEVICE MALFUNCTION
 PRODUCT QUALITY ISSUE

ISR Number: 6023644 Case Number: 6873077 I/F Code: I Report Date: 20081226

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010936844

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose: 108MCG EVERY 4HRS INHAL

Event Date: 20081212

FDA Date: 20081229

Follow Number:

Image ID: 6023644-2

Age: 64 YR Gender: M Weight: 180 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20081214

Therapy End: 20081212

Duration:

Adverse Reactions:

- ABDOMINAL DISTENSION
- DRUG INEFFECTIVE
- DYSPNOEA
- NAUSEA
- PRODUCT QUALITY ISSUE

ISR Number: 6023647 Case Number: 6873091 I/F Code: I Report Date: 20081226

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010936851

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose:

Event Date:

FDA Date: 20081229

Follow Number:

Image ID: 6023647-8

Age: 48 YR Gender: F Weight: 160 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20080601

Therapy End: 20080201

Duration:

Adverse Reactions:

- ANXIETY
- DRUG INEFFECTIVE
- HEADACHE
- HEART RATE INCREASED
- PRODUCT QUALITY ISSUE

ISR Number: 6023667 Case Number: 6874518 I/F Code: I Report Date: 20081228
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010936883
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FJC0-14A
Expiration Date: 20100301
Indication: LUNG NEOPLASM MALIGNANT
Route: ORAL
Dose: 2 PUFFS 3 TIMES A DAY PO
Event Date:
FDA Date: 20081229
Follow Number:
Image ID: 6023667-3
Age: 69 YR Gender: M Weight: 140 LBS
Occupation: OT
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: 20081228
Therapy End: 20080703
Duration:
Adverse Reactions:
DRUG EFFECT DECREASED
DYSPNOEA
ECONOMIC PROBLEM
FRUSTRATION
PRODUCT QUALITY ISSUE
QUALITY OF LIFE DECREASED

ISR Number: 6024719 Case Number: 6875909 I/F Code: I Report Date: 20081229
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010940592
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: WHEEZING
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS AS NEEDED INHAL
Event Date: 20081229
FDA Date: 20081230
Follow Number:
Image ID: 6024719-4
Age: Gender: Weight:
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: 20081229
Therapy End: 20081201
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6028159 Case Number: 6877954 I/F Code: I Report Date: 20081230
Drug Name: **PROVENTIL-HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010952841
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4-6 HOURS INHAL
Event Date: 20081221
FDA Date: 20081231
Follow Number:
Image ID: 6028159-3
Age: 32 Gender: F Weight: 245 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: 20081221
Therapy End: 20081201
Duration:
Adverse Reactions:
DRUG INEFFECTIVE