

ISR Number: 6148925 Case Number: 6969063 I/F Code: I Report Date: 20090406

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1011400963

Mfg. Date: 20090330

Mfg. Number: 2009SP006826

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: 80288

Expiration Date: 20100501

Indication: ASTHMA

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20090407

Follow Number:

Image ID: 6148925-3

Age: 13 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:

FOREIGN BODY TRAUMA

HYPOPHAGIA

OROPHARYNGEAL PAIN

SCRATCH

VOMITING

ISR Number: 6150124 Case Number: 6969375 I/F Code: I Report Date: 20090227

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011404985

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: ORAL

Dose: 2 PUFFS Q4H PRN ORAL

Event Date: 20080901

FDA Date: 20090407

Follow Number:

Image ID: 6150124-6

Age: 39 YR Gender: F Weight:

Occupation: PH

Country: UNITED STATES

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

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

Therapy Start: 20081201

Therapy End: 20080901

Duration:

Adverse Reactions:

BLOOD IMMUNOGLOBULIN E INCREASED

FOOD ALLERGY

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ISR Number: 6155114 Case Number: 6973298 I/F Code: I Report Date: 20090410  
Drug Name: **PROVENTIL-HFA**  
NDA Number: 20503  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011427409  
Mfg. Date: 20090402  
Mfg. Number: 2009SP007211  
Mfg. Sender: SCHERING-PLOUGH CORPORATION  
Lot Number: 80168  
Expiration Date: 20100301  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: ORAL  
Dose: PO  
Event Date:  
FDA Date: 20090413  
Follow Number:  
Image ID: 6155114-5  
Age: 86 YR 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:  
HOT FLUSH  
HYPERHIDROSIS  
INFECTION PARASITIC  
PRODUCT QUALITY ISSUE

ISR Number: 6160279 Case Number: 6977601 I/F Code: I Report Date: 20090415

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011450144

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: GJE083A

Expiration Date: 20100510

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS TWICE DAILY INHAL

Event Date: 20090410

FDA Date: 20090416

Follow Number:

Image ID: 6160279-5

Age: 25 YR Gender: F Weight: 225 LBS

Occupation: CN

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: 20090415

Therapy End: 20081001

Duration:

Adverse Reactions:

DRUG EFFECT DECREASED

PRODUCT QUALITY ISSUE

PRODUCT SUBSTITUTION ISSUE

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ISR Number: 6161319 Case Number: 6977974 I/F Code: I Report Date: 20090416  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011454882  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: 80288  
Expiration Date: 20100531  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS EVERY 4 HOURS  
Event Date: 20090410  
FDA Date: 20090417  
Follow Number:  
Image ID: 6161319-X  
Age: 53 YR Gender: F Weight: 200 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: 20090416  
Therapy End: 20090101  
Duration:  
Adverse Reactions:  
ASTHMA  
DRUG EFFECT DECREASED  
PNEUMONIA  
PRODUCT QUALITY ISSUE

ISR Number: 6161558 Case Number: 6976805 I/F Code: I Report Date: 20090416

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011455950

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date: 20090416

FDA Date: 20090417

Follow Number:

Image ID: 6161558-8

Age: 40 Gender: M Weight: 140 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:

- DRUG INEFFECTIVE
- INCORRECT DRUG ADMINISTRATION DURATION
- OVERDOSE
- PRODUCT QUALITY ISSUE

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ISR Number: 6178671 Case Number: 6989605 I/F Code: I Report Date: 20090429  
Drug Name: **PROVENTIL-HFA**  
NDA Number: 20503  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011525197  
Mfg. Date: 20090427  
Mfg. Number: 2009SP008906  
Mfg. Sender: SCHERING-PLOUGH CORPORATION  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: ORAL  
Dose: PO  
Event Date:  
FDA Date: 20090430  
Follow Number:  
Image ID: 6178671-1  
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:  
PARTIAL SEIZURES

ISR Number: 6181149 Case Number: 6993266 I/F Code: I Report Date: 20090501  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011535230  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: GJE017A  
Expiration Date: 20100531  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route:  
Dose: 2 PUFFS 6 HOURS  
Event Date:  
FDA Date: 20090504  
Follow Number:  
Image ID: 6181149-2  
Age: Gender: F Weight: 145 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PRODUCT SUBSTITUTION ISSUE

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ISR Number: 6190234 Case Number: 6999565 I/F Code: I Report Date: 20090512  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011572796  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: FII030A  
Expiration Date: 20090930  
Indication: BRONCHOSPASM  
Route: ORAL  
Dose: 6.7 GRAMS 2 PUFFS 4 TIMES A PO  
Event Date: 20090428  
FDA Date: 20090513  
Follow Number:  
Image ID: 6190234-0  
Age: 29 Gender: F Weight: 144 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: 20090512  
Therapy End: 20090419  
Duration: 1 MON  
Adverse Reactions:  
ABDOMINAL DISCOMFORT  
ASTHMA  
HEADACHE  
NAUSEA  
NO THERAPEUTIC RESPONSE  
PRODUCT SUBSTITUTION ISSUE

ISR Number: 6198947 Case Number: 7005321 I/F Code: I Report Date: 20090518  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011610890  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20090101  
FDA Date: 20090519  
Follow Number:  
Image ID: 6198947-1  
Age: 31 YR Gender: F Weight: 130 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: Y Rechallenge Code: D Death Date:  
Therapy Start: 20090515  
Therapy End: 20090102  
Duration:  
Adverse Reactions:  
DRUG DELIVERY SYSTEM MALFUNCTION

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ISR Number: 6198972 Case Number: 7005328 I/F Code: I Report Date: 20090518  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011610999  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20100430  
Indication: ASTHMA  
Route:  
Dose: 1 INHALLATION 5-10 TIMES DAILY  
Event Date: 20090518  
FDA Date: 20090519  
Follow Number:  
Image ID: 6198972-0  
Age: 42 YR Gender: M Weight: 180 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: 20090518  
Therapy End: 20090426  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    DYSPTNOEA  
    PRODUCT QUALITY ISSUE

ISR Number: 6199039 Case Number: 7006103 I/F Code: I Report Date: 20090519

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011611198

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date: 20090509

FDA Date: 20090520

Follow Number:

Image ID: 6199039-8

Age: 8 YR Gender: F Weight: 55 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:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DRUG INEFFECTIVE
- PRODUCT QUALITY ISSUE

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ISR Number: 6204378 Case Number: 7009514 I/F Code: I Report Date: 20090521

Drug Name: **PROVENTIL-HFA**

NDA Number: 20503

Role Code: PS VAL/VBM: 1

Seq Number: 1011633685

Mfg. Date: 20090512

Mfg. Number: 2009SP009979

Mfg. Sender: SCHERING-PLOUGH CORPORATION

Lot Number: GJC008A

Expiration Date: 20100331

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: ORAL

Dose: PO

Event Date:

FDA Date: 20090522

Follow Number: 1

Image ID: 6204378-8

Age: Gender: 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:

- CHRONIC OBSTRUCTIVE PULMONARY DISEASE
- CONDITION AGGRAVATED
- DRUG INEFFECTIVE

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ISR Number: 6213001 Case Number: 7012964 I/F Code: I Report Date: 20090601  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011668260  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20090831  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 SPRAYS AS NEEDED INHAL  
Event Date: 20090529  
FDA Date: 20090602  
Follow Number:  
Image ID: 6213001-8  
Age: 74 YR Gender: F Weight: 180 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20090601  
Therapy End: 20090101  
Duration:  
Adverse Reactions:  
DRUG EFFECT DECREASED  
DYSPNOEA  
PRODUCT SUBSTITUTION ISSUE

ISR Number: 6213314 Case Number: 7014605 I/F Code: I Report Date: 20090529  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011669059  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date:  
FDA Date: 20090601  
Follow Number:  
Image ID: 6213314-X  
Age: Gender: F Weight: 165 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: OT Dechallenge Code: Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DEVICE INEFFECTIVE

ISR Number: 6216830 Case Number: 7016364 I/F Code: I Report Date: 20090603  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011682691  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: GJD029A  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date:  
FDA Date: 20090603  
Follow Number:  
Image ID: 6216830-X  
Age: Gender: F Weight: 156 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:  
    DEVICE MALFUNCTION  
    PRODUCT QUALITY ISSUE

ISR Number: 6219355 Case Number: 7019241 I/F Code: I Report Date: 20090604

Drug Name: **PROVENTIL-HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011692581

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: GIJ012A

Expiration Date: 20090430

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS AS NEEDED- INHAL SEVERAL MONTHS

Event Date:

FDA Date: 20090605

Follow Number:

Image ID: 6219355-0

Age: 22 YR Gender: F Weight: 127 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:

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DIZZINESS
- GAIT DISTURBANCE
- NAUSEA
- PALPITATIONS
- TREMOR

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ISR Number: 6221748 Case Number: 6961018 I/F Code: I Report Date: 20090605  
Drug Name: **ALBUTEROL SULFATE**  
NDA Number: 20503  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011702607  
Mfg. Date: 20090319  
Mfg. Number: 2009SP006142  
Mfg. Sender: SCHERING-PLOUGH CORPORATION  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route:  
Dose:  
Event Date:  
FDA Date: 20090608  
Follow Number:  
Image ID: 6221748-2  
Age: 86 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: 20090222  
Therapy Start: 20090210  
Therapy End:  
Duration:  
Adverse Reactions:  
CEREBROVASCULAR ACCIDENT

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ISR Number: 6237575 Case Number: 7035294 I/F Code: I Report Date: 20090616  
Drug Name: **PROVENTIL-HFA**  
NDA Number: 20503  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011761004  
Mfg. Date: 20090609  
Mfg. Number: 2009SP012596  
Mfg. Sender: SCHERING-PLOUGH CORPORATION  
Lot Number: 19246914B00116  
Expiration Date: 20080831  
Indication: ASTHMA  
Route: ORAL  
Dose: PO  
Event Date:  
FDA Date: 20090617  
Follow Number: 1  
Image ID: 6237575-6  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
EXPIRED DRUG ADMINISTERED

ISR Number: 6250123 Case Number: 7043382 I/F Code: I Report Date: 20090625  
Drug Name: **PROVENTIL-HFA**  
NDA Number: 20503  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011810099  
Mfg. Date: 20090619  
Mfg. Number: 2009SP013708  
Mfg. Sender: SCHERING-PLOUGH CORPORATION  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route:  
Dose: PO  
Event Date:  
FDA Date: 20090626  
Follow Number:  
Image ID: 6250123-X  
Age: 84 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:  
DEVICE MALFUNCTION