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ISR Number: 4674938 Case Number: 5809633 I/F Code: I Report Date: 20050512

Drug Name: **ALBUTEROL SULFATE HFA**

NDA Number: 21457

Role Code: PS VAL/VBM: 1

Seq Number: 1006044603

Mfg. Date: 20050512

Mfg. Number: 2005-05-0005

Mfg. Sender: IVAX RESEARCH, INC.

Lot Number: ACR94A

Expiration Date: 20060201

Indication: BRONCHITIS

Route: RESPIRATORY (INHALATION)

Dose: 1 PUFF INHALATION

Event Date: 20050420

FDA Date: 20050525

Follow Number:

Image ID: 4674938-4

Age: 48 YR Gender: M Weight:

Occupation: CN

Country:

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

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

Therapy Start: 20050420

Therapy End: 20050420

Duration:

Adverse Reactions:

- APNOEA
- DYSPNOEA
- FALL
- HEAD INJURY
- LOSS OF CONSCIOUSNESS
- MEMORY IMPAIRMENT
- PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5093499 Case Number: 6136700 I/F Code: I Report Date: 20060504

Drug Name: **ALBUTEROL SULATE**

NDA Number: 21457

Role Code: PS VAL/VBM: 1

Seq Number: 1007629372

Mfg. Date: 20060201

Mfg. Number: 2006-US-00627

Mfg. Sender: IVAX RESEARCH INC

Lot Number: ADA72A

Expiration Date: 20061219

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS QID, INHALATION

Event Date: 20060125

FDA Date: 20060731

Follow Number:

Image ID: 5093499-1

Age: 76 YR Gender: F Weight: 120 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20060125

Duration:

Adverse Reactions:

- DRUG INEFFECTIVE
- DYSPNOEA

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ISR Number: 5094650 Case Number: 6136706 I/F Code: I Report Date: 20060706  
Drug Name: **ALBUTEROL**  
NDA Number: 21457  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007633478  
Mfg. Date: 20060505  
Mfg. Number: 145670USA  
Mfg. Sender: TEVA USA  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date:  
FDA Date: 20060731  
Follow Number:  
Image ID: 5094650-X  
Age: Gender: Weight:  
Occupation: PH  
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:  
PHARYNGEAL OEDEMA

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ISR Number: 5119176 Case Number: 6143455 I/F Code: I Report Date: 20060928

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1007722946

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date: 20071230

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1 TO 2 PUFFS AS NEEDED INHAL

Event Date: 20060928

FDA Date: 20060929

Follow Number:

Image ID: 5119176-6

Age: Gender: F Weight: 175 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20060929

Therapy End: 20060701

Duration:

Adverse Reactions:

DEVICE FAILURE

INCORRECT DOSE ADMINISTERED

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5124620 Case Number: 6148888 I/F Code: I Report Date: 20061005  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007746685  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20070831  
Indication: PULMONARY CONGESTION  
Route: NASAL  
Dose: 2-5 PUFFS-INHALED 4-6 HOURS NASAL  
Event Date: 20061003  
FDA Date: 20061006  
Follow Number:  
Image ID: 5124620-4  
Age: 46 YR Gender: F Weight: 175 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: 20061004  
Therapy End: 20061002  
Duration:  
Adverse Reactions:  
DYSPHONIA  
FEELING ABNORMAL  
HEART RATE INCREASED  
INSOMNIA  
PALPITATIONS

ISR Number: 5125796 Case Number: 6149398 I/F Code: I Report Date: 20061008

Drug Name: **ALBUTEROL SULFATE HFA 108MCG PER ACTIVATION IVAX LABORATORIES INC., MI**

NDA Number:

Role Code: PS VAL/VBM: 2

Seq Number: 1007751367

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADF21A

Expiration Date: 20070630

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: SEE IMAGE

Event Date: 20060915

FDA Date: 20061010

Follow Number:

Image ID: 5125796-5

Age: Gender: M Weight: 115 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:

Therapy End:

Duration: 1 MON

Adverse Reactions:

- CONSTIPATION
- DISTURBANCE IN ATTENTION
- DRUG WITHDRAWAL SYNDROME
- ERECTILE DYSFUNCTION
- FEELING JITTERY
- HUNGER
- INCREASED APPETITE
- INSOMNIA
- METABOLIC DISORDER
- PHARMACEUTICAL PRODUCT COMPLAINT
- WEIGHT INCREASED

ISR Number: 5125807 Case Number: 6149551 I/F Code: I Report Date: 20061009

Drug Name: **ALBUTEROL SULFATE 108 MCG ALBUTEROL HFA IVAX PHARMACEUTICALS**

NDA Number:

Role Code: PS VAL/VBM: 2

Seq Number: 1007751396

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date: 20070801

Indication: ASTHMA

Route:

Dose:

Event Date: 20060910

FDA Date: 20061010

Follow Number:

Image ID: 5125807-7

Age: 41 YR Gender: F Weight: 180 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

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5159447 Case Number: 6178972 I/F Code: I Report Date: 20061121  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007887978  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADG18A  
Expiration Date: 20070831  
Indication: ASTHMA  
Route: ORAL  
Dose: 200 METERED INHALATIONS 2 PUFFS EVERY 4 H PO  
Event Date: 20061107  
FDA Date: 20061122  
Follow Number:  
Image ID: 5159447-0  
Age: Gender: Weight:  
Occupation: CN  
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: 20061107  
Therapy End: 20061107  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5159448 Case Number: 6178978 I/F Code: I Report Date: 20061121

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1007887979

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: NDC-59310-579-

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1 INHALED DOSE 2 TIMES DAILY

Event Date: 20061120

FDA Date: 20061122

Follow Number:

Image ID: 5159448-2

Age: 71 YR Gender: F Weight: 160 LBS

Occupation:

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:

Duration:

Adverse Reactions:

- ASTHMA
- CHEST PAIN
- MUSCLE TIGHTNESS
- REACTION TO DRUG EXCIPIENTS

ISR Number: 5167664 Case Number: 6186117 I/F Code: I Report Date: 20060103  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007919162  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date:  
FDA Date: 20061204  
Follow Number:  
Image ID: 5167664-9  
Age: Gender: Weight:  
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:  
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5195691 Case Number: 6237081 I/F Code: I Report Date: 20061224

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008000999

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: PP2113

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 90 MCG AS NEEDED INHAL

Event Date: 20061224

FDA Date: 20061226

Follow Number:

Image ID: 5195691-4

Age: Gender: F Weight: 145 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: 20061225

Therapy End: 20061224

Duration: 24 HR

Adverse Reactions:

DRUG HYPERSENSITIVITY

STOMACH DISCOMFORT

VOMITING PROJECTILE

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ISR Number: 5211676 Case Number: 6219298 I/F Code: I Report Date: 20070114  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008052533  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: PP2113  
Expiration Date: 20071231  
Indication: ASTHMA  
Route:  
Dose: 90 MCG 2XDAY  
Event Date: 20070102  
FDA Date: 20070117  
Follow Number:  
Image ID: 5211676-3  
Age: 55 YR Gender: F Weight: 174 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:  
Therapy End:  
Duration:  
Adverse Reactions:  
BLOOD PRESSURE INCREASED  
HEADACHE  
IMPAIRED WORK ABILITY  
MOVEMENT DISORDER  
MUSCULOSKELETAL STIFFNESS  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5221898 Case Number: 6237084 I/F Code: I Report Date: 20070125  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008089465  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADF40A  
Expiration Date: 20071229  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS AS NEEDED PO  
Event Date: 20061230  
FDA Date: 20070126  
Follow Number:  
Image ID: 5221898-3  
Age: 47 YR Gender: M Weight: 185 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: HO Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start: 20061231  
Therapy End: 20061215  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DEVICE FAILURE  
DRUG EFFECT DECREASED  
DYSGEUSIA  
LUNG DISORDER  
NASOPHARYNGITIS  
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5228265 Case Number: 6236527 I/F Code: I Report Date: 20070130

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008112892

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADG47A

Expiration Date: 20080831

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS PRN INHAL

Event Date: 20061229

FDA Date: 20070131

Follow Number:

Image ID: 5228265-7

Age: 28 YR Gender: F Weight: 135 LBS

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start: 20061228

Therapy End: 20060704

Duration:

Adverse Reactions:

- DEVICE FAILURE
- INCORRECT DOSE ADMINISTERED
- MEDICATION ERROR

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ISR Number: 5243593 Case Number: 6252765 I/F Code: I Report Date: 20070218  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008170743  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS PRN  
Event Date: 20070210  
FDA Date: 20070220  
Follow Number:  
Image ID: 5243593-7  
Age: 30 YR Gender: F Weight: 150 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: 20070221  
Therapy End: 20070201  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

ISR Number: 5246379 Case Number: 6253788 I/F Code: I Report Date: 20070221

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008180574

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1 TO 2 PUFFS EVERY 4 TO 6 HOURS INHAL

Event Date: 20070218

FDA Date: 20070222

Follow Number:

Image ID: 5246379-2

Age: 6 YR Gender: M Weight: 55 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20070221

Therapy End: 20070215

Duration:

Adverse Reactions:

APPARENT LIFE THREATENING EVENT

DRUG EFFECT DECREASED

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5246380 Case Number: 6253795 I/F Code: I Report Date: 20070221  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008180575  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070220  
FDA Date: 20070222  
Follow Number:  
Image ID: 5246380-9  
Age: Gender: F Weight: 200 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: LT Dechallenge Code: Y Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
BRONCHOSPASM  
DRUG INEFFECTIVE  
DYSPNOEA  
FEAR  
NERVOUSNESS  
OBSTRUCTIVE AIRWAYS DISORDER  
PAIN IN EXTREMITY

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ISR Number: 5247967 Case Number: 6256677 I/F Code: I Report Date: 20070223  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008186828  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADJ29A  
Expiration Date: 20071130  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 TO 4 PUFFS DAILY  
Event Date: 20070101  
FDA Date: 20070226  
Follow Number:  
Image ID: 5247967-X  
Age: 53 YR Gender: F Weight: 150 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: 20070223  
Therapy End: 20061101  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5252239 Case Number: 6257005 I/F Code: I Report Date: 20070226

Drug Name: **ALBUTERAL HFA INHALER 8.5 MG PROAIR**

NDA Number:

Role Code: PS VAL/VBM: 2

Seq Number: 1008199695

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS 4 TO 6 HOURS INHAL

Event Date:

FDA Date: 20070227

Follow Number:

Image ID: 5252239-3

Age: Gender: M Weight: 189 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
- PHARMACEUTICAL PRODUCT COMPLAINT
- WHEEZING

ISR Number: 5254823 Case Number: 6260172 I/F Code: I Report Date: 20070228

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008210388

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: OTHER

Dose: 2 PUFFS Q 4 TO 6 HR PRN OTHER

Event Date: 20070228

FDA Date: 20070301

Follow Number:

Image ID: 5254823-X

Age: Gender: F Weight: 360 LBS

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start: 20070228

Therapy End: 20070201

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5256960 Case Number: 6262871 I/F Code: I Report Date: 20070303  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008219532  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADH78A  
Expiration Date: 20071031  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 1-2 PUFFS EVERY 4-6HRS PRN INHAL  
Event Date: 20061017  
FDA Date: 20070305  
Follow Number:  
Image ID: 5256960-2  
Age: Gender: M Weight: 316 LBS  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: Dechallenge Code: Y Rechallenge Code: Y Death Date:  
Therapy Start: 20061020  
Therapy End: 20061017  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE  
DYSPNOEA  
THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5256961 Case Number: 6262897 I/F Code: I Report Date: 20070303

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008219533

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: BRONCHITIS

Route: RESPIRATORY (INHALATION)

Dose: 1-2 PUFFS EVERY 4-6 HRS PRN INHAL

Event Date: 20070126

FDA Date: 20070305

Follow Number:

Image ID: 5256961-4

Age: Gender: M Weight: 160 LBS

Occupation: PH

Country: UNITED STATES

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

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

Therapy Start: 20070226

Therapy End: 20070126

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

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ISR Number: 5258298 Case Number: 6262930 I/F Code: I Report Date: 20070305  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008224896  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADJ84A  
Expiration Date: 20071231  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS TWICE DAILY PO  
Event Date: 20070101  
FDA Date: 20070306  
Follow Number:  
Image ID: 5258298-6  
Age: 35 YR Gender: F Weight: 181 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:  
    DEVICE MALFUNCTION  
    DRUG EFFECT DECREASED  
    DYSPNOEA  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5263397 Case Number: 6267177 I/F Code: I Report Date: 20070308  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008242657  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADK24A  
Expiration Date: 20080130  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 SPRAYS AS REQUIRED UP TO 4X/DAY INHAL  
Event Date: 20070307  
FDA Date: 20070309  
Follow Number:  
Image ID: 5263397-9  
Age: 29 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: 20070308  
Therapy End: 20070307  
Duration: 1 DAY  
Adverse Reactions:  
DRUG EFFECT DECREASED  
INCORRECT DOSE ADMINISTERED  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5265834 Case Number: 6268685 I/F Code: I Report Date: 20070310  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008252099  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADM41A  
Expiration Date: 20080229  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS TWICE A DAY INHAL  
Event Date: 20070309  
FDA Date: 20070312  
Follow Number:  
Image ID: 5265834-2  
Age: 58 YR Gender: F Weight: 160 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: 20070310  
Therapy End: 20070309  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    ECONOMIC PROBLEM  
    INCORRECT DOSE ADMINISTERED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5277206 Case Number: 6278534 I/F Code: I Report Date: 20070321

Drug Name: **PRO-AIR HFA 8.5MG IVAX PHARMACEUTICALS**

NDA Number:

Role Code: PS VAL/VBM: 2

Seq Number: 1008297445

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADL63A

Expiration Date: 20080229

Indication: ASTHMA

Route: ORAL

Dose: 2 PUFFS 4 TIMES DAILY PO

Event Date: 20070314

FDA Date: 20070322

Follow Number:

Image ID: 5277206-5

Age: 43 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: 20070320

Therapy End: 20070314

Duration:

Adverse Reactions:

- DEVICE INEFFECTIVE
- DRUG INEFFECTIVE
- DYSGEUSIA
- THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION
- UNEVALUABLE EVENT

---

ISR Number: 5279844 Case Number: 6280235 I/F Code: I Report Date: 20070326  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008307197  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADM48A  
Expiration Date: 20080331  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS 2-4 HOURS INHAL  
Event Date: 20070308  
FDA Date: 20070327  
Follow Number:  
Image ID: 5279844-2  
Age: 46 YR Gender: F Weight: 83 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: 20070326  
Therapy End: 20070308  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    FEAR  
    WHEEZING

---

ISR Number: 5279858 Case Number: 6282841 I/F Code: I Report Date: 20070323

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008307219

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS QID INHALED

Event Date: 20070306

FDA Date: 20070326

Follow Number:

Image ID: 5279858-2

Age: 55 YR Gender: F Weight: 180 LBS

Occupation: MD

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: 20070307

Therapy End: 20070305

Duration:

Adverse Reactions:

- CHEST DISCOMFORT
- PHARMACEUTICAL PRODUCT COMPLAINT
- PHARYNGEAL OEDEMA
- RASH ERYTHEMATOUS

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ISR Number: 5282858 Case Number: 6284348 I/F Code: I Report Date: 20070324  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008318761  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070318  
FDA Date: 20070329  
Follow Number:  
Image ID: 5282858-X  
Age: 42 YR Gender: F Weight: 115 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:  
Therapy End: 20070319  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPTNOEA  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5287755 Case Number: 6287514 I/F Code: I Report Date: 20070401  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008334051  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date:  
FDA Date: 20070402  
Follow Number:  
Image ID: 5287755-1  
Age: 47 YR Gender: M Weight: 230 LBS  
Occupation:  
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 EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

---

ISR Number: 5287758 Case Number: 6448492 I/F Code: I Report Date: 20070331  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008334057  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN04A  
Expiration Date: 20080401  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: AS NEEDED VERY OFTEN INHAL  
Event Date: 20070316  
FDA Date: 20070402  
Follow Number:  
Image ID: 5287758-7  
Age: 35 YR Gender: F Weight: 180 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:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    DYSPNOEA  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5290563 Case Number: 6289532 I/F Code: I Report Date: 20070320

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008345180

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADM27A

Expiration Date: 20080201

Indication: ASTHMA

Route:

Dose: 2 INHALATIONS AS NEEDED

Event Date: 20070305

FDA Date: 20070405

Follow Number:

Image ID: 5290563-9

Age: Gender: M Weight: 300 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- CHEST DISCOMFORT
- CONDITION AGGRAVATED
- DRUG INEFFECTIVE
- PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5290964 Case Number: 6448511 I/F Code: I Report Date: 20070404  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008346681  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20080301  
Indication: ASTHMA  
Route:  
Dose: 200 METERED EVERY 4 HR  
Event Date:  
FDA Date: 20070405  
Follow Number:  
Image ID: 5290964-9  
Age: 15 YR Gender: M Weight: 225 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:  
Therapy End:  
Duration:  
Adverse Reactions:  
ECONOMIC PROBLEM

ISR Number: 5290967 Case Number: 6448513 I/F Code: I Report Date: 20070404

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008346688

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose: 2 PUFFS 4 TIMES DA

Event Date: 20070402

FDA Date: 20070405

Follow Number:

Image ID: 5290967-4

Age: 37 YR Gender: F Weight:

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:

- BURNING SENSATION
- CHEST PAIN
- COUGH
- DRUG INEFFECTIVE
- DYSPNOEA
- PHARMACEUTICAL PRODUCT COMPLAINT
- RESPIRATORY TRACT IRRITATION

---

ISR Number: 5294246 Case Number: 6290947 I/F Code: I Report Date: 20070408  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008358777  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: AS NEEDED  
Event Date: 20070408  
FDA Date: 20070409  
Follow Number:  
Image ID: 5294246-0  
Age: 31 YR Gender: F Weight: 167 LBS  
Occupation: CN  
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: 20070406  
Therapy End: 20070327  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5294396 Case Number: 6290856 I/F Code: I Report Date: 20070407  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008359330  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADJ64A  
Expiration Date: 20071101  
Indication: ASTHMA  
Route: ORAL  
Dose: 1 PUFF 3X/DAY PO  
Event Date: 20070129  
FDA Date: 20070409  
Follow Number:  
Image ID: 5294396-9  
Age: 34 YR Gender: F Weight: 147 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start: 20070407  
Therapy End: 20070129  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DECREASED ACTIVITY  
DRUG INEFFECTIVE  
FEAR  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5297513 Case Number: 6448516 I/F Code: I Report Date: 20070401  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008370824  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: HYPERSENSITIVITY  
Route:  
Dose: 1-2 PUFFS 4-6 HRS  
Event Date: 20070321  
FDA Date: 20070411  
Follow Number:  
Image ID: 5297513-X  
Age: 50 YR Gender: F Weight: 150 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: Rechallenge Code: Y Death Date:  
Therapy Start:  
Therapy End: 20070301  
Duration:  
Adverse Reactions:  
COUGH  
  
DRUG INEFFECTIVE  
  
PHARMACEUTICAL PRODUCT COMPLAINT  
  
STOMATITIS  
  
TONGUE DISORDER

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ISR Number: 5300329 Case Number: 6295425 I/F Code: I Report Date: 20070412  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008381306  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: TWO PUFFS 4-6 HOURS PRN INHAL  
Event Date:  
FDA Date: 20070413  
Follow Number:  
Image ID: 5300329-9  
Age: Gender: F Weight: 280 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: DS Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5302896 Case Number: 6303481 I/F Code: I Report Date: 20070324  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008390287  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070318  
FDA Date: 20070419  
Follow Number:  
Image ID: 5302896-8  
Age: 42 YR Gender: F Weight: 115 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: 20070318  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPTNOEA  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5304252 Case Number: 6448517 I/F Code: I Report Date: 20070418  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008396261  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN03A  
Expiration Date: 20080430  
Indication:  
Route:  
Dose: 2 ACTIVATIONS 4 X DAILY  
Event Date: 20070401  
FDA Date: 20070419  
Follow Number:  
Image ID: 5304252-5  
Age: 54 YR Gender: M Weight: 141 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: 20070418  
Therapy End: 20070315  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5308307 Case Number: 6301098 I/F Code: I Report Date: 20070421  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008411506  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20080430  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS EVERY 4-6 HOURS  
Event Date:  
FDA Date: 20070423  
Follow Number:  
Image ID: 5308307-0  
Age: Gender: F Weight: 130 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start: 20070401  
Therapy End: 20070301  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
COUGH  
DRUG INEFFECTIVE  
LOSS OF EMPLOYMENT  
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5309286 Case Number: 6448518 I/F Code: I Report Date: 20070423

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008415195

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: PP2113

Expiration Date: 20080430

Indication: MULTIPLE ALLERGIES

Route: ORAL

Dose: 90 MCG EVERY 1/2 HOUR PO

Event Date: 20070423

FDA Date: 20070424

Follow Number:

Image ID: 5309286-2

Age: 29 YR Gender: F Weight: 160 LBS

Occupation: OT

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: 20070423

Therapy End: 20070130

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

THROAT IRRITATION

WHEEZING

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ISR Number: 5309287 Case Number: 6302204 I/F Code: I Report Date: 20070423  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008415196  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS AS NEEDED INHAL  
Event Date: 20070420  
FDA Date: 20070424  
Follow Number:  
Image ID: 5309287-4  
Age: Gender: F Weight: 235 LBS  
Occupation:  
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: 20070420  
Therapy End: 20070418  
Duration:  
Adverse Reactions:  
ANXIETY  
CHEST DISCOMFORT  
DRUG INEFFECTIVE  
FEAR

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ISR Number: 5309591 Case Number: 6302571 I/F Code: I Report Date: 20070424  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008416142  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN79A  
Expiration Date: 20080531  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS 3 OR 4 HOURS PO  
Event Date: 20070402  
FDA Date: 20070425  
Follow Number:  
Image ID: 5309591-X  
Age: 47 DY Gender: F Weight: 155 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20070424  
Therapy End: 20070402  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPNOEA  
    WHEEZING

---

ISR Number: 5314500 Case Number: 6306695 I/F Code: I Report Date: 20070427  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008436109  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: PP2113  
Expiration Date: 20070901  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS AS NEEDED 15 MIN BEFORE EXERC  
Event Date:  
FDA Date: 20070430  
Follow Number:  
Image ID: 5314500-3  
Age: Gender: F Weight: 238 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:  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
INFLAMMATION  
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5318775 Case Number: 6448526 I/F Code: I Report Date: 20070503

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008454915

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADN20A

Expiration Date: 20080430

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS AS NEEDED

Event Date: 20070502

FDA Date: 20070504

Follow Number:

Image ID: 5318775-6

Age: Gender: F Weight: 145 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20070419

Therapy End: 20070404

Duration:

Adverse Reactions:

ASTHMA

CONDITION AGGRAVATED

DEPENDENCE

DRUG EFFECT DECREASED

PHARMACEUTICAL PRODUCT COMPLAINT

POOR QUALITY DRUG ADMINISTERED

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ISR Number: 5318936 Case Number: 6310714 I/F Code: I Report Date: 20070502  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008455432  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN63A  
Expiration Date: 20080430  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS 4X A DAY PRN PO  
Event Date: 20070420  
FDA Date: 20070503  
Follow Number:  
Image ID: 5318936-6  
Age: 25 YR Gender: F Weight: 136 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: 20070401  
Duration:  
Adverse Reactions:  
ANXIETY  
DRUG EFFECT DECREASED  
HEART RATE INCREASED  
INSOMNIA  
PHARMACEUTICAL PRODUCT COMPLAINT  
TREMOR  
VISUAL DISTURBANCE

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ISR Number: 5318938 Case Number: 6448528 I/F Code: I Report Date: 20070502  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008455439  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: PP2113  
Expiration Date: 20080401  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: AS NEEDED 4-6 TIMES A DAY INHAL  
Event Date: 20070420  
FDA Date: 20070503  
Follow Number:  
Image ID: 5318938-X  
Age: Gender: F Weight: 150 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: 2 MON  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5321909 Case Number: 6312088 I/F Code: I Report Date: 20070507  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008467438  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 1 PUFF AS NEEDED  
Event Date: 20070507  
FDA Date: 20070508  
Follow Number:  
Image ID: 5321909-0  
Age: 25 YR Gender: F Weight: 138 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:  
Therapy End:  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DRUG EFFECT DECREASED  
PHARMACEUTICAL PRODUCT COMPLAINT  
TREMOR

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ISR Number: 5323500 Case Number: 6314756 I/F Code: I Report Date: 20070508  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008473507  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADM45A  
Expiration Date: 20080331  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS AS NEEDED PO  
Event Date:  
FDA Date: 20070509  
Follow Number:  
Image ID: 5323500-9  
Age: 32 YR Gender: M Weight: 195 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: 20070507  
Therapy End: 20061120  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    DRUG EFFECT DECREASED

ISR Number: 5323508 Case Number: 6314762 I/F Code: I Report Date: 20070508

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008473524

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose: TWO PUFFS 4X DAY AS NEEDED OTHER

Event Date: 20070402

FDA Date: 20070509

Follow Number:

Image ID: 5323508-3

Age: 67 YR Gender: M Weight: 155 LBS

Occupation: OT

Country: UNITED STATES

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

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

Therapy Start: 20070402

Therapy End: 20070402

Duration:

Adverse Reactions:

- ASTHMA
- BLISTER
- BRONCHIAL DISORDER
- BRONCHOSPASM
- CONDITION AGGRAVATED
- DRUG EFFECT DECREASED
- DRUG HYPERSENSITIVITY
- DRUG INEFFECTIVE
- DYSPNOEA
- LIP BLISTER
- PHARMACEUTICAL PRODUCT COMPLAINT
- PO2 ABNORMAL
- REACTION TO DRUG EXCIPIENTS

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ISR Number: 5323885 Case Number: 6314486 I/F Code: I Report Date: 20070509  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008474957  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 1-2 PUFFS AS NEEDED  
Event Date: 20070419  
FDA Date: 20070510  
Follow Number:  
Image ID: 5323885-3  
Age: 45 YR Gender: F Weight: 160 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20070416  
Therapy End: 20070416  
Duration:  
Adverse Reactions:  
ASTHMA  
CHEST DISCOMFORT  
CHEST PAIN  
COUGH  
DRUG INEFFECTIVE  
FEELING ABNORMAL  
RESPIRATORY TRACT IRRITATION

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ISR Number: 5323888 Case Number: 6314602 I/F Code: I Report Date: 20070509  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008474962  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADM41A  
Expiration Date: 20080201  
Indication: LUNG DISORDER  
Route: ORAL  
Dose: 90MCG ONCE DAILY PO  
Event Date: 20070501  
FDA Date: 20070510  
Follow Number:  
Image ID: 5323888-9  
Age: 40 YR Gender: M Weight: 175 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: 20070501  
Therapy End: 20070409  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPTNOEA  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5325022 Case Number: 6313464 I/F Code: I Report Date: 20070510  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008479350  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070510  
FDA Date: 20070511  
Follow Number:  
Image ID: 5325022-8  
Age: 51 YR Gender: F Weight: 175 LBS  
Occupation: OT  
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:  
MEDICATION ERROR

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ISR Number: 5327221 Case Number: 6316399 I/F Code: I Report Date: 20070513

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008487777

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADN41A

Expiration Date: 20080401

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 200 METERED INHALATIONS 2X PER DAY PO

Event Date: 20070403

FDA Date: 20070514

Follow Number:

Image ID: 5327221-8

Age: 28 YR Gender: F Weight: 200 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20070513

Therapy End: 20070403

Duration:

Adverse Reactions:

- DRUG EFFECT DECREASED
- DRUG HYPERSENSITIVITY
- PAIN
- PHARMACEUTICAL PRODUCT COMPLAINT
- PRURITUS
- RASH GENERALISED
- THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION
- URTICARIA
- URTICARIA GENERALISED

ISR Number: 5328253 Case Number: 6316556 I/F Code: I Report Date: 20070515

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008492090

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: PP2113

Expiration Date: 20080430

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 4 PUFFS 4 TIMES DAILY INHAL

Event Date: 20070101

FDA Date: 20070516

Follow Number:

Image ID: 5328253-6

Age: Gender: F Weight: 118 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20070515

Therapy End: 20070101

Duration:

Adverse Reactions:

- DRUG EFFECT DECREASED
- INCORRECT DOSE ADMINISTERED
- PHARMACEUTICAL PRODUCT COMPLAINT
- POOR QUALITY DRUG ADMINISTERED

---

ISR Number: 5332398 Case Number: 6319989 I/F Code: I Report Date: 20070519  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008508666  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS EVERY 4-6 HOURS PO  
Event Date: 20070518  
FDA Date: 20070521  
Follow Number:  
Image ID: 5332398-4  
Age: Gender: M Weight: 160 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: 20070518  
Therapy End: 20070324  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5332414 Case Number: 6320007 I/F Code: I Report Date: 20070521  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008508684  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADJ31A 11/2007  
Expiration Date: 20071130  
Indication: ASTHMA  
Route: ORAL  
Dose: PO  
Event Date: 20070515  
FDA Date: 20070522  
Follow Number:  
Image ID: 5332414-X  
Age: 60 YR Gender: F Weight:  
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: 20070518  
Therapy End: 20070104  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5350368 Case Number: 6329958 I/F Code: I Report Date: 20070604

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008563520

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADP21A

Expiration Date: 20080531

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: EVERY 4 HRS AS NEEDED 4 TIMES A DAY INHAL

Event Date: 20070102

FDA Date: 20070605

Follow Number:

Image ID: 5350368-7

Age: 69 YR Gender: F Weight: 173 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: 20070604

Therapy End: 20070101

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5350369 Case Number: 6448494 I/F Code: I Report Date: 20070605  
Drug Name: **PROAIR HFA MDI IVAX**  
NDA Number:  
Role Code: PS VAL/VBM: 2  
Seq Number: 1008563521  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: HYPERSENSITIVITY  
Route: RESPIRATORY (INHALATION)  
Dose: 2 INHALATIONS EVERY 4 TO 6 HOURS INHAL  
Event Date: 20061225  
FDA Date: 20070606  
Follow Number:  
Image ID: 5350369-9  
Age: Gender: F Weight: 175. LBS  
Occupation: MD  
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: 20061220  
Therapy End: 20060916  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    DEVICE MALFUNCTION  
    DRUG INEFFECTIVE  
    INCORRECT DOSE ADMINISTERED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5350370 Case Number: 6329966 I/F Code: I Report Date: 20070604  
Drug Name: **PORAIR HFA 90MCG ALBUTEROL/PUFF - IVAX**  
NDA Number:  
Role Code: PS VAL/VBM: 2  
Seq Number: 1008563522  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN40A  
Expiration Date: 20080430  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY 4 TO 6 HOURS INHAL  
Event Date: 20070525  
FDA Date: 20070605  
Follow Number:  
Image ID: 5350370-5  
Age: Gender: F Weight: 172 LBS  
Occupation: MD  
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: 20070525  
Therapy End: 20061215  
Duration:  
Adverse Reactions:  
ASTHMA  
DEVICE MALFUNCTION  
DRUG INEFFECTIVE

---

ISR Number: 5353933 Case Number: 6333967 I/F Code: I Report Date: 20070607  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008576080  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADP13A  
Expiration Date: 20080531  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 INHALATIONS 3 TIMES DAILY PO  
Event Date: 20070507  
FDA Date: 20070608  
Follow Number:  
Image ID: 5353933-6  
Age: 62 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: D Rechallenge Code: D Death Date:  
Therapy Start: 20070605  
Therapy End: 20070605  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    DRUG EFFECT DECREASED  
    OBSTRUCTIVE AIRWAYS DISORDER

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ISR Number: 5355296 Case Number: 6335437 I/F Code: I Report Date: 20070531  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008580661  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADM48A  
Expiration Date: 20080301  
Indication:  
Route:  
Dose: 2 PUFFS EVERY 4 TO 6 HOURS  
Event Date: 20070530  
FDA Date: 20070611  
Follow Number:  
Image ID: 5355296-9  
Age: Gender: Weight:  
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: 20070530  
Therapy End: 20070517  
Duration:  
Adverse Reactions:  
CHEST PAIN  
PHARMACEUTICAL PRODUCT COMPLAINT  
POOR QUALITY DRUG ADMINISTERED  
WHEEZING

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ISR Number: 5355403 Case Number: 6336187 I/F Code: I Report Date: 20070525

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008580926

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADM48A

Expiration Date: 20080301

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFF EVERY 4 HRS 4 HRS INHALER

Event Date: 20070301

FDA Date: 20070611

Follow Number:

Image ID: 5355403-8

Age: Gender: F Weight: 135 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20070501

Therapy End: 20070301

Duration:

Adverse Reactions:

- BRONCHOSPASM
- DRUG INEFFECTIVE
- DYSPNOEA
- WHEEZING

---

ISR Number: 5355831 Case Number: 6335104 I/F Code: I Report Date: 20070608  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008581931  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADP13A  
Expiration Date: 20080501  
Indication: ASTHMA  
Route:  
Dose: 90 MCG FOUR TIMES DAILY  
Event Date: 20070305  
FDA Date: 20070611  
Follow Number:  
Image ID: 5355831-0  
Age: 33 YR Gender: F Weight: 150 LBS  
Occupation: CN  
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: 20070608  
Therapy End: 20060901  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5356982 Case Number: 6337333 I/F Code: I Report Date: 20070605  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008586615  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADL86A  
Expiration Date: 20080201  
Indication: HYPERSENSITIVITY  
Route: RESPIRATORY (INHALATION)  
Dose: 90 MG Q4HOURS INHALED  
Event Date: 20070603  
FDA Date: 20070612  
Follow Number:  
Image ID: 5356982-7  
Age: Gender: F Weight: 151 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: RI Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End: 20070401  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    DRUG INEFFECTIVE

ISR Number: 5357320 Case Number: 6337249 I/F Code: I Report Date: 20070611

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008587702

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADN81A

Expiration Date: 20080531

Indication: EMPHYSEMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS 4X A DAY INHAL

Event Date:

FDA Date: 20070612

Follow Number:

Image ID: 5357320-6

Age: Gender: F Weight: 124 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20070601

Therapy End: 20070201

Duration:

Adverse Reactions:

- BLOOD PRESSURE INCREASED
- DEVICE MALFUNCTION
- DRUG INEFFECTIVE
- HEART RATE INCREASED
- HEART RATE IRREGULAR
- PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5357325 Case Number: 6337254 I/F Code: I Report Date: 20070611  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008587732  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 1 TO 2 INHALATIONS PRN INHAL  
Event Date:  
FDA Date: 20070612  
Follow Number:  
Image ID: 5357325-5  
Age: Gender: Weight:  
Occupation: CN  
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: 20070610  
Therapy End: 20070101  
Duration:  
Adverse Reactions:  
DRUG EFFECT DECREASED  
INCORRECT DOSE ADMINISTERED  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5357386 Case Number: 6343726 I/F Code: I Report Date: 20070611  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008587960  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date:  
FDA Date: 20070612  
Follow Number:  
Image ID: 5357386-3  
Age: 44 YR Gender: F Weight: 145 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y  
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5363537 Case Number: 6343472 I/F Code: I Report Date: 20070616  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008608455  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN42A  
Expiration Date: 20080430  
Indication: ASTHMA  
Route: ENDOTRACHEAL  
Dose: 90MCG PRN ENDOTRACHEA  
Event Date: 20070322  
FDA Date: 20070618  
Follow Number:  
Image ID: 5363537-7  
Age: 36 YR Gender: F Weight: 160 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: OT Dechallenge Code: N Rechallenge Code: Y Death Date:  
Therapy Start: 20070615  
Therapy End: 20070420  
Duration:  
Adverse Reactions:  
    ASPHYXIA  
    DRUG INEFFECTIVE  
    WHEEZING

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ISR Number: 5366238 Case Number: 6345412 I/F Code: I Report Date: 20070620  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008616662  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: PP2113  
Expiration Date: 20071231  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS AS NEEDED  
Event Date: 20070618  
FDA Date: 20070621  
Follow Number:  
Image ID: 5366238-4  
Age: 39 YR Gender: F Weight: 200 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: 20070620  
Therapy End: 20070601  
Duration:  
Adverse Reactions:  
DYSпноEA  
HEADACHE  
IMPAIRED WORK ABILITY

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ISR Number: 5368240 Case Number: 6346803 I/F Code: I Report Date: 20070610  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008624701  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADH70A  
Expiration Date: 20071001  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route:  
Dose: 2 PUFFS EVERY 4 HRS 054  
Event Date: 20070101  
FDA Date: 20070622  
Follow Number:  
Image ID: 5368240-5  
Age: Gender: F Weight: 200 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: 1 MON  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5374375 Case Number: 6349108 I/F Code: I Report Date: 20070627  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645717  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN42A  
Expiration Date: 20080430  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: INHALATIONS FOR WHEEZING 2 PUFFS AS NEEDED INHAL  
Event Date: 20070515  
FDA Date: 20070628  
Follow Number:  
Image ID: 5374375-3  
Age: 39 YR Gender: F Weight: 135 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: Y Rechallenge Code: Y Death Date:  
Therapy Start: 20070515  
Therapy End: 20070515  
Duration:  
Adverse Reactions:  
ASTHMA  
BRONCHOSPASM  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
HEADACHE  
PHARMACEUTICAL PRODUCT COMPLAINT  
STOMACH DISCOMFORT

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ISR Number: 5374376 Case Number: 6349109 I/F Code: I Report Date: 20070627  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645718  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN39A  
Expiration Date: 20080401  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 1-2 PUFFS EVERY 4-6 H PRN INHAL  
Event Date: 20070627  
FDA Date: 20070628  
Follow Number:  
Image ID: 5374376-5  
Age: 23 YR Gender: F Weight: 120 LBS  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: Y Death Date:  
Therapy Start: 20070627  
Therapy End: 20070530  
Duration:  
Adverse Reactions:  
    DEVICE OCCLUSION  
    DRUG EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5374377 Case Number: 6349112 I/F Code: I Report Date: 20070627  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645719  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070624  
FDA Date: 20070628  
Follow Number:  
Image ID: 5374377-7  
Age: 54 YR Gender: F Weight: 130 LBS  
Occupation: CN  
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: 20070627  
Therapy End: 20070624  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5375975 Case Number: 6350419 I/F Code: I Report Date: 20070626  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008652288  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20080101  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 1-2X PUFFS 4 TO 6 HOURS INHAL  
Event Date: 20070625  
FDA Date: 20070627  
Follow Number:  
Image ID: 5375975-7  
Age: 49 YR Gender: M 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: D Death Date:  
Therapy Start: 20070626  
Therapy End: 20070401  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    DRUG INEFFECTIVE  
    HEART RATE ABNORMAL  
    WHEEZING

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ISR Number: 5376715 Case Number: 6352139 I/F Code: I Report Date: 20070628  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008655643  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS EVERY 4-6 HOURS PO  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5376715-8  
Age: 36 YR Gender: F Weight: 240 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  
    NAUSEA  
    THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

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ISR Number: 5376716 Case Number: 6352140 I/F Code: I Report Date: 20070628  
Drug Name: **PROAIR HFA METERD DOSE INHALER IVAX**  
NDA Number:  
Role Code: PS VAL/VBM: 2  
Seq Number: 1008655645  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20080606  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS Q4-6HRS, AS NEEDED INHAL  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5376716-X  
Age: 53 YR Gender: F Weight: 165 LBS  
Occupation:  
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  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5378088 Case Number: 6353301 I/F Code: I Report Date: 20070612  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008661667  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 1 TO 2 PUFFS EVERY 4 HOURS INHALATION  
Event Date:  
FDA Date: 20070702  
Follow Number:  
Image ID: 5378088-3  
Age: 20 YR Gender: F Weight:  
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:  
Therapy End: 20070501  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

---

ISR Number: 5378089 Case Number: 6353297 I/F Code: I Report Date: 20070612  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008661668  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY FOUR HOURS INHALATION  
Event Date: 20070521  
FDA Date: 20070702  
Follow Number:  
Image ID: 5378089-5  
Age: 11 YR Gender: M Weight:  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: Y Death Date:  
Therapy Start:  
Therapy End: 20070501  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    INCORRECT DOSE ADMINISTERED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5378354 Case Number: 6355318 I/F Code: I Report Date: 20070630  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008662801  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20080630  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS EVERY SIX HOURS  
Event Date: 20070630  
FDA Date: 20070702  
Follow Number:  
Image ID: 5378354-1  
Age: Gender: M Weight: 135 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start: 20070630  
Therapy End: 20070626  
Duration:  
Adverse Reactions:  
DEPRESSION  
DRUG INEFFECTIVE  
DYSPNOEA  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5378685 Case Number: 6448499 I/F Code: I Report Date: 20070629  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008663880  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN64A  
Expiration Date: 20080430  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS 4 TIMES/DAY OR AS INHAL  
Event Date: 20070628  
FDA Date: 20070702  
Follow Number:  
Image ID: 5378685-5  
Age: 67 YR Gender: M Weight: 202 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20070628  
Therapy End: 20070626  
Duration:  
Adverse Reactions:  
DYSпноEA  
MEDICAL DEVICE COMPLICATION  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5385457 Case Number: 6448548 I/F Code: I Report Date: 20070708  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008690796  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: PP21193  
Expiration Date: 20071231  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: ORAL  
Dose: 2 PUFFS 4 TIMES/AS NEEDED PO  
Event Date: 20070301  
FDA Date: 20070709  
Follow Number:  
Image ID: 5385457-4  
Age: 55 YR Gender: M Weight: 173 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: 20070315  
Therapy End: 20070301  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPTNOEA  
    PHARMACEUTICAL PRODUCT COMPLAINT

---

ISR Number: 5386216 Case Number: 6359279 I/F Code: I Report Date: 20070709  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008694059  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADNO3A  
Expiration Date: 20080401  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY 4 TO 6 HOURS INHAL  
Event Date: 20070705  
FDA Date: 20070710  
Follow Number:  
Image ID: 5386216-9  
Age: 36 YR 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: N Rechallenge Code: Y Death Date:  
Therapy Start: 20070705  
Therapy End: 20070621  
Duration:  
Adverse Reactions:  
ACTIVITIES OF DAILY LIVING IMPAIRED  
ASTHMA  
CHEST PAIN  
CONDITION AGGRAVATED  
COUGH  
DRUG INEFFECTIVE  
DYSPNOEA  
FATIGUE  
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5387436 Case Number: 6360514 I/F Code: I Report Date: 20070710

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008699780

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADN04A

Expiration Date: 20080430

Indication:

Route:

Dose:

Event Date: 20070705

FDA Date: 20070711

Follow Number:

Image ID: 5387436-X

Age: 61 YR Gender: F Weight:

Occupation: OT

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DEVICE FAILURE
- INCORRECT DOSE ADMINISTERED
- PHARMACEUTICAL PRODUCT COMPLAINT

---

ISR Number: 5392094 Case Number: 6365478 I/F Code: I Report Date: 20070717

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008717651

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADP27B

Expiration Date: 20080630

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2-3 X DAILY INHAL

Event Date: 19970510

FDA Date: 20070718

Follow Number:

Image ID: 5392094-4

Age: 15 YR Gender: F Weight: 103 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20070510

Therapy End: 20070510

Duration:

Adverse Reactions:

- ANAPHYLACTIC REACTION
- DIZZINESS
- ILL-DEFINED DISORDER
- OBSTRUCTIVE AIRWAYS DISORDER
- OXYGEN SATURATION DECREASED
- PHARMACEUTICAL PRODUCT COMPLAINT
- THROAT IRRITATION
- THROAT TIGHTNESS

---

ISR Number: 5397880 Case Number: 6371149 I/F Code: I Report Date: 20070720  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008741003  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN80A  
Expiration Date: 20080501  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS 4 TIMES OR AS NEED  
Event Date: 20070714  
FDA Date: 20070723  
Follow Number:  
Image ID: 5397880-2  
Age: 36 YR Gender: F Weight: 160 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: 20070720  
Therapy End: 20070626  
Duration:  
Adverse Reactions:  
ASTHMA  
DRUG INEFFECTIVE

---

ISR Number: 5397884 Case Number: 6371184 I/F Code: I Report Date: 20070722

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008741014

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS AS NEEDED INHAL

Event Date: 20070704

FDA Date: 20070723

Follow Number:

Image ID: 5397884-X

Age: 76 YR Gender: F Weight: 170 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20070704

Therapy End: 20070624

Duration:

Adverse Reactions:

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5397902 Case Number: 6372316 I/F Code: I Report Date: 20070721  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008741078  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20080430  
Indication: BRONCHITIS  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS 4 TIMES A DAY INHAL  
Event Date: 20070710  
FDA Date: 20070723  
Follow Number:  
Image ID: 5397902-9  
Age: 61 YR Gender: F Weight: 145 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20070722  
Therapy End: 20070710  
Duration:  
Adverse Reactions:  
BRONCHITIS  
DRUG EFFECT DECREASED  
PHARMACEUTICAL PRODUCT COMPLAINT  
WHEEZING  
WRONG TECHNIQUE IN DRUG USAGE PROCESS

---

ISR Number: 5397906 Case Number: 6372350 I/F Code: I Report Date: 20070720  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008741082  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 90MCG ALBUTEROL PER ACUATION EVERY 4 HOURS INHAL  
Event Date: 20070515  
FDA Date: 20070723  
Follow Number:  
Image ID: 5397906-6  
Age: 31 YR Gender: F Weight: 240 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start: 20070615  
Therapy End: 20070515  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

---

ISR Number: 5402335 Case Number: 6373813 I/F Code: I Report Date: 20070728  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008761148  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADP27C  
Expiration Date: 20080630  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 INHALATIONS EVERY 4 HOURS INHAL  
Event Date: 20070728  
FDA Date: 20070730  
Follow Number:  
Image ID: 5402335-2  
Age: 56 YR Gender: F Weight: 171 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: 20070728  
Therapy End: 20070726  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

---

ISR Number: 5404907 Case Number: 6377606 I/F Code: I Report Date: 20070731

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008770046

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADP29A

Expiration Date: 20090630

Indication: ASTHMA

Route: ORAL

Dose: 2 PUFFS -216MCG- Q 4-6 H PRN PO

Event Date: 20070730

FDA Date: 20070801

Follow Number:

Image ID: 5404907-8

Age: 24 YR Gender: M Weight: 300 LBS

Occupation: OT

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration: 8 MON

Adverse Reactions:

- DEVICE MALFUNCTION
- DRUG EFFECT DECREASED
- DYSPNOEA
- PHARMACEUTICAL PRODUCT COMPLAINT
- PULMONARY FUNCTION TEST DECREASED
- SUFFOCATION FEELING
- WHEEZING

---

ISR Number: 5406008 Case Number: 6378746 I/F Code: I Report Date: 20070711

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008775567

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date:

FDA Date: 20070802

Follow Number:

Image ID: 5406008-1

Age: Gender: Weight:

Occupation: MD

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 MALFUNCTION
- DRUG INEFFECTIVE
- EXERCISE TOLERANCE DECREASED
- PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5406136 Case Number: 6378866 I/F Code: I Report Date: 20070801  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008776013  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADM01A  
Expiration Date: 20080229  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS 4 X DAY INHAL 2-3 MONTHS  
Event Date: 20070730  
FDA Date: 20070802  
Follow Number:  
Image ID: 5406136-0  
Age: 75 YR Gender: F Weight: 170 LBS  
Occupation:  
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:  
Therapy End:  
Duration: 10 DAY  
Adverse Reactions:  
DYSпноEA  
MEDICAL DEVICE COMPLICATION  
PHARMACEUTICAL PRODUCT COMPLAINT  
STRESS

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ISR Number: 5406161 Case Number: 6378736 I/F Code: I Report Date: 20070731  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008776053  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADP13A  
Expiration Date: 20080531  
Indication: NASOPHARYNGITIS  
Route:  
Dose: TWO PUFFS EVERY FOUR HOURS  
Event Date: 20070626  
FDA Date: 20070802  
Follow Number:  
Image ID: 5406161-X  
Age: Gender: F Weight: 62 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: Dechallenge Code: Y Rechallenge Code: D Death Date:  
Therapy Start: 20070626  
Therapy End: 20070625  
Duration:  
Adverse Reactions:  
NAUSEA  
VOMITING

---

ISR Number: 5407159 Case Number: 6380178 I/F Code: I Report Date: 20070802  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008780839  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADP23A  
Expiration Date: 20080531  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 ACTUATIONS 4 HRS. OR AS NEED INHAL  
Event Date:  
FDA Date: 20070803  
Follow Number:  
Image ID: 5407159-8  
Age: Gender: M Weight: 215 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start: 20070801  
Therapy End: 20070531  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    PHARMACEUTICAL PRODUCT COMPLAINT  
    POOR QUALITY DRUG ADMINISTERED

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ISR Number: 5409208 Case Number: 6381062 I/F Code: I Report Date: 20070626

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008788925

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date:

FDA Date: 20070807

Follow Number:

Image ID: 5409208-X

Age: Gender: Weight:

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 EFFECT DECREASED
- INCORRECT DOSE ADMINISTERED
- MEDICATION ERROR
- PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5409461 Case Number: 6381855 I/F Code: I Report Date: 20070806  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008789938  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN64A  
Expiration Date: 20080430  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS 4-6 HOURS INHAL  
Event Date:  
FDA Date: 20070807  
Follow Number:  
Image ID: 5409461-2  
Age: 54 YR Gender: F Weight: 130 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: 20070806  
Therapy End: 20070720  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5409596 Case Number: 6381858 I/F Code: I Report Date: 20070806

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008790386

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADP29A

Expiration Date: 20080630

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY 4 HOURS INHAL

Event Date: 20070501

FDA Date: 20070807

Follow Number:

Image ID: 5409596-4

Age: 24 YR Gender: F Weight: 130 LBS

Occupation: CN

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: 20070806

Therapy End: 20070503

Duration:

Adverse Reactions:

- ANXIETY
- DEVICE OCCLUSION
- DYSGEUSIA
- PHARMACEUTICAL PRODUCT COMPLAINT
- STRESS

---

ISR Number: 5415396 Case Number: 6385551 I/F Code: I Report Date: 20070812  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008811124  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS PRN PO  
Event Date: 20070315  
FDA Date: 20070813  
Follow Number:  
Image ID: 5415396-1  
Age: 32 YR Gender: F Weight: 140 LBS  
Occupation:  
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: 20070731  
Therapy End: 20070305  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5416452 Case Number: 6386179 I/F Code: I Report Date: 20070812

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008814490

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS Q. 4 H

Event Date: 20070725

FDA Date: 20070813

Follow Number:

Image ID: 5416452-4

Age: 36 YR Gender: F Weight: 175 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: 20070801

Therapy End: 20070501

Duration:

Adverse Reactions:

- ASTHMA
- CONTRAINDICATION TO MEDICAL TREATMENT
- DRUG HYPERSENSITIVITY
- DYSPNOEA
- OEDEMA
- PHARMACEUTICAL PRODUCT COMPLAINT
- SWELLING

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ISR Number: 5420951 Case Number: 6389591 I/F Code: I Report Date: 20070816  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008831130  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date:  
FDA Date: 20070817  
Follow Number:  
Image ID: 5420951-9  
Age: Gender: Weight:  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5420952 Case Number: 6389604 I/F Code: I Report Date: 20070816  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008831131  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date: 20070816  
FDA Date: 20070817  
Follow Number:  
Image ID: 5420952-0  
Age: 58 YR Gender: F Weight: 229 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DEVICE INEFFECTIVE  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5420957 Case Number: 6389618 I/F Code: I Report Date: 20070816  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008831147  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ12A  
Expiration Date: 20080731  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS 4 TIMES DAY INHAL  
Event Date: 20070815  
FDA Date: 20070817  
Follow Number:  
Image ID: 5420957-X  
Age: 44 YR Gender: F Weight: 170 LBS  
Occupation:  
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: 20070815  
Therapy End: 20061201  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5422275 Case Number: 6392198 I/F Code: I Report Date: 20070817  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008835205  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: NDC 59310-579-  
Expiration Date: 20080814  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY 4 TO 6 HOURS 1 OR 2 A DAY INHAL  
Event Date:  
FDA Date: 20070820  
Follow Number:  
Image ID: 5422275-2  
Age: 8 YR Gender: M Weight: 53 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: 20070101  
Therapy End: 20010101  
Duration:  
Adverse Reactions:  
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5423531 Case Number: 6391860 I/F Code: I Report Date: 20070820  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008839519  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date: 19870819  
FDA Date: 20070821  
Follow Number:  
Image ID: 5423531-4  
Age: Gender: F Weight: 135 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:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5427097 Case Number: 6404656 I/F Code: I Report Date: 20070822  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008851499  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS FOUR TIMES DAILY  
Event Date:  
FDA Date: 20070823  
Follow Number:  
Image ID: 5427097-4  
Age: 35 YR Gender: F Weight: 120 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start: 20070822  
Therapy End: 20070101  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5427098 Case Number: 6404659 I/F Code: I Report Date: 20070822  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008851500  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route: RESPIRATORY (INHALATION)  
Dose: PROAIR PRN INHAL  
Event Date: 20070815  
FDA Date: 20070823  
Follow Number:  
Image ID: 5427098-6  
Age: 49 YR Gender: F Weight: 150 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: LT Dechallenge Code: N Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5427100 Case Number: 6404662 I/F Code: I Report Date: 20070822  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008851502  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADP28A  
Expiration Date: 20080630  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 8.5GM AS NEEDED INHAL  
Event Date: 20070821  
FDA Date: 20070823  
Follow Number:  
Image ID: 5427100-1  
Age: 59 YR Gender: F Weight: 190 LBS  
Occupation: CN  
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: 20070821  
Therapy End: 20070620  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5428759 Case Number: 6405846 I/F Code: I Report Date: 20070827

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008856391

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: BRONCHITIS

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY 4-6 HOURS INHAL

Event Date: 20070807

FDA Date: 20070827

Follow Number:

Image ID: 5428759-5

Age: 47 YR Gender: F Weight: 140 LBS

Occupation: OT

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20070601

Duration:

Adverse Reactions:

- BRONCHOSPASM
- DEVICE FAILURE
- DRUG INEFFECTIVE
- PARAESTHESIA
- PHARMACEUTICAL PRODUCT COMPLAINT
- WHEEZING

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ISR Number: 5433027 Case Number: 6405857 I/F Code: I Report Date: 20070827  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008869117  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS PRN PO  
Event Date:  
FDA Date: 20070828  
Follow Number:  
Image ID: 5433027-1  
Age: Gender: Weight:  
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:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

ISR Number: 5441778 Case Number: 6408020 I/F Code: I Report Date: 20070829

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008883972

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: PP2113

Expiration Date: 20070930

Indication: ASTHMA

Route: ORAL

Dose: TWICE A DAY PO

Event Date: 20061007

FDA Date: 20070830

Follow Number:

Image ID: 5441778-8

Age: 32 YR Gender: F Weight: 165 LBS

Occupation: CN

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: 20061007

Therapy End: 20061005

Duration: 2 DAY

Adverse Reactions:

- ASTHMA
- CHEST PAIN
- CONDITION AGGRAVATED
- DRUG EFFECT DECREASED
- DRUG HYPERSENSITIVITY
- DRUG INEFFECTIVE
- HYPOAESTHESIA
- INFLAMMATION
- LUNG DISORDER
- MYOCARDIAL INFARCTION

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ISR Number: 5444216 Case Number: 6410477 I/F Code: I Report Date: 20070831  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008892465  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADP88A  
Expiration Date: 20080814  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 METERED DOSES 1 TIME A DAY INHAL  
Event Date:  
FDA Date: 20070904  
Follow Number:  
Image ID: 5444216-4  
Age: 9 YR Gender: M Weight: 53 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: 20070815  
Therapy End: 20070607  
Duration:  
Adverse Reactions:  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5452344 Case Number: 6418815 I/F Code: I Report Date: 20070911  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008922318  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN39A  
Expiration Date: 20080430  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 INHALATIONS P.R.N. PO  
Event Date: 20070801  
FDA Date: 20070912  
Follow Number:  
Image ID: 5452344-2  
Age: Gender: F Weight: 190 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: 20070911  
Therapy End: 20070712  
Duration:  
Adverse Reactions:  
DRUG EFFECT DECREASED

ISR Number: 5455814 Case Number: 6421446 I/F Code: I Report Date: 20070912  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008936437  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 1-2 PUFFS 4 TIMES DAILY PO  
Event Date: 20070912  
FDA Date: 20070913  
Follow Number:  
Image ID: 5455814-6  
Age: 57 YR Gender: F Weight: 209 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:  
Duration:  
Adverse Reactions:  
DRUG EFFECT DECREASED

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ISR Number: 5455820 Case Number: 6421577 I/F Code: I Report Date: 20070912  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008936444  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: PP2295  
Expiration Date: 20071031  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS EVERY 4 HOURS PO  
Event Date: 20070801  
FDA Date: 20070913  
Follow Number:  
Image ID: 5455820-1  
Age: 66 YR Gender: F Weight: 155 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: 20070712  
Therapy End: 20070701  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5466959 Case Number: 6429747 I/F Code: I Report Date: 20070831  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008970049  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ81B  
Expiration Date: 20080801  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route:  
Dose: INHALE 2 PUFFS FOUR TIMES DAILY AS NEEDED  
Event Date: 20070822  
FDA Date: 20070921  
Follow Number:  
Image ID: 5466959-9  
Age: 71 YR Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration: 1 MON  
Adverse Reactions:  
    DEVICE FAILURE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5466991 Case Number: 6433373 I/F Code: I Report Date: 20070921  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008970135  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS WHEN NEEDED INHAL  
Event Date: 20070802  
FDA Date: 20070924  
Follow Number:  
Image ID: 5466991-5  
Age: 59 YR Gender: F Weight: 150 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: 20070920  
Therapy End: 20070802  
Duration: 2 MON  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5470531 Case Number: 6439435 I/F Code: I Report Date: 20070926

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008982875

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADQ13A

Expiration Date: 20080731

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 4 PUFFS 6 HOURS INHAL

Event Date: 20070926

FDA Date: 20070927

Follow Number:

Image ID: 5470531-4

Age: Gender: F Weight: 103 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: 20070926

Therapy End: 20070710

Duration:

Adverse Reactions:

- DEVICE FAILURE
- DRUG INEFFECTIVE
- PANIC ATTACK
- PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5476865 Case Number: 6448500 I/F Code: I Report Date: 20070924

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009005488

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date: 20070101

FDA Date: 20071002

Follow Number:

Image ID: 5476865-1

Age: Gender: F Weight: 269 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:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- DEVICE MALFUNCTION
- DRUG EFFECT DECREASED
- DRUG LEVEL DECREASED
- PHARMACEUTICAL PRODUCT COMPLAINT
- STRESS

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ISR Number: 5476967 Case Number: 6439526 I/F Code: I Report Date: 20071002  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009005833  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: BRONCHITIS  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY 4-6 HOURS INHAL  
Event Date: 20070807  
FDA Date: 20071003  
Follow Number:  
Image ID: 5476967-X  
Age: 47 YR Gender: F Weight: 140 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: LT Dechallenge Code: N Rechallenge Code: Y Death Date:  
Therapy Start:  
Therapy End: 20070601  
Duration:  
Adverse Reactions:  
BRONCHOSPASM  
DRUG INEFFECTIVE  
PARAESTHESIA ORAL  
PHARMACEUTICAL PRODUCT COMPLAINT  
PHARYNGOLARYNGEAL PAIN  
WHEEZING

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ISR Number: 5480427 Case Number: 6441689 I/F Code: I Report Date: 20071001  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009020255  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ60A  
Expiration Date: 20080801  
Indication: DYSPNOEA  
Route: RESPIRATORY (INHALATION)  
Dose: 90MCG INHALER PRN INHALED  
Event Date: 20070901  
FDA Date: 20071004  
Follow Number:  
Image ID: 5480427-X  
Age: 43 YR Gender: F Weight:  
Occupation: OT  
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:  
Therapy End: 20070901  
Duration:  
Adverse Reactions:  
BRONCHIAL IRRITATION  
DRUG INEFFECTIVE

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ISR Number: 5483637 Case Number: 6442859 I/F Code: I Report Date: 20071004  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009033250  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date: 20071003  
FDA Date: 20071005  
Follow Number:  
Image ID: 5483637-0  
Age: Gender: F Weight: 350 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
DYSPNOEA  
MUSCLE SPASMS  
POOR QUALITY SLEEP

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ISR Number: 5485498 Case Number: 6445845 I/F Code: I Report Date: 20071009  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009040254  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ60A  
Expiration Date: 20080831  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 90 MCG /INHALATION PRN INHAL  
Event Date:  
FDA Date: 20071010  
Follow Number:  
Image ID: 5485498-2  
Age: Gender: Weight:  
Occupation: PH  
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:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5485539 Case Number: 6445212 I/F Code: I Report Date: 20071011  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009040392  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route:  
Dose: 2 PUFFS 4 DAILY OR AS NEEDED  
Event Date:  
FDA Date: 20071011  
Follow Number:  
Image ID: 5485539-2  
Age: 72 YR Gender: F Weight: 155 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20070501  
Therapy End: 20070221  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5485545 Case Number: 6444737 I/F Code: I Report Date: 20071010  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009040398  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN79A  
Expiration Date: 20080531  
Indication: ASTHMA  
Route: ORAL  
Dose: PO  
Event Date: 20070425  
FDA Date: 20071011  
Follow Number:  
Image ID: 5485545-8  
Age: 55 YR Gender: F Weight: 145 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: 20070630  
Therapy End: 20070416  
Duration: 2 MON  
Adverse Reactions:  
APHONIA  
LARYNGITIS

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ISR Number: 5487662 Case Number: 6451922 I/F Code: I Report Date: 20071012  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009048111  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ60C  
Expiration Date: 20080831  
Indication: DYSPNOEA  
Route: RESPIRATORY (INHALATION)  
Dose: USE 1-2 PUFFS EVERY 6 HOURS INHAL  
Event Date: 20071011  
FDA Date: 20071015  
Follow Number:  
Image ID: 5487662-5  
Age: 67 YR Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20071012  
Therapy End: 20071010  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5490445 Case Number: 6455823 I/F Code: I Report Date: 20071016  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009057442  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: AS NEEDED  
Event Date:  
FDA Date: 20071017  
Follow Number:  
Image ID: 5490445-3  
Age: 15 YR Gender: M Weight: 115 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 INEFFECTIVE  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5494739 Case Number: 6455089 I/F Code: I Report Date: 20071022  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009073802  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ60A  
Expiration Date: 20080831  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS FOUR TIMES DAILY PO  
Event Date: 20071022  
FDA Date: 20071023  
Follow Number:  
Image ID: 5494739-7  
Age: Gender: M Weight: 180 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration: 6 MON  
Adverse Reactions:  
DRUG INEFFECTIVE  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5494741 Case Number: 6455091 I/F Code: I Report Date: 20071022  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009073804  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ40A  
Expiration Date: 20080731  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 EVERY FOUR HOURS INHAL  
Event Date:  
FDA Date: 20071023  
Follow Number:  
Image ID: 5494741-5  
Age: 79 YR Gender: M Weight: 151 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20071022  
Therapy End: 20071002  
Duration:  
Adverse Reactions:  
MEDICAL DEVICE COMPLICATION  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5498520 Case Number: 6458476 I/F Code: I Report Date: 20071023  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009087506  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR14A  
Expiration Date: 20080801  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS PRN INHAL  
Event Date: 20071023  
FDA Date: 20071024  
Follow Number:  
Image ID: 5498520-4  
Age: 33 YR Gender: F Weight: 125 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20071023  
Therapy End: 20070521  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    RESPIRATORY DISORDER

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ISR Number: 5500359 Case Number: 6459507 I/F Code: I Report Date: 20071024  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009095759  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR14B  
Expiration Date: 20080801  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 1 BEFORE EXERCISE INHAL SINCE AUGUST  
Event Date: 20071023  
FDA Date: 20071025  
Follow Number:  
Image ID: 5500359-8  
Age: 36 YR Gender: F Weight: 135 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: Y Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5501699 Case Number: 6457031 I/F Code: I Report Date: 20071025  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009100554  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADP90A  
Expiration Date: 20080731  
Indication: WHEEZING  
Route: ORAL  
Dose: 2 PUFFS TWICE DAILY PO  
Event Date: 20071010  
FDA Date: 20071026  
Follow Number:  
Image ID: 5501699-9  
Age: Gender: F Weight: 130 LBS  
Occupation: CN  
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: 3 MON  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DEVICE BREAKAGE  
DRUG EFFECT DECREASED  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5503764 Case Number: 6461232 I/F Code: I Report Date: 20071029  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009109338  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS AS NEEDED  
Event Date:  
FDA Date: 20071030  
Follow Number:  
Image ID: 5503764-9  
Age: 52 YR Gender: F Weight: 130 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: 20071001  
Therapy End: 20070901  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5503766 Case Number: 6461237 I/F Code: I Report Date: 20071029  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009109348  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: PRN/2 PUFFS  
Event Date: 20070501  
FDA Date: 20071030  
Follow Number:  
Image ID: 5503766-2  
Age: Gender: F Weight: 150 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: Y Rechallenge Code: Y Death Date:  
Therapy Start: 20070501  
Therapy End: 20060101  
Duration:  
Adverse Reactions:  
CHEMICAL BURN OF SKIN  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
NAUSEA  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5504804 Case Number: 6462221 I/F Code: I Report Date: 20071030  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009112593  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN20A  
Expiration Date: 20080430  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 1-2 PUFFS EVERY 4 TO 6 HRS INHAL  
Event Date: 20071011  
FDA Date: 20071031  
Follow Number:  
Image ID: 5504804-3  
Age: 77 YR Gender: M Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20071011  
Therapy End: 20070829  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5504805 Case Number: 6462226 I/F Code: I Report Date: 20071030  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009112594  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR 14 A  
Expiration Date: 20080801  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20071029  
FDA Date: 20071031  
Follow Number:  
Image ID: 5504805-5  
Age: Gender: F Weight: 155 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20071001  
Therapy End: 20070201  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    FEAR  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5508869 Case Number: 6471774 I/F Code: I Report Date: 20071005  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009127584  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS AS NEEDED INHALATION  
Event Date: 20070605  
FDA Date: 20071105  
Follow Number:  
Image ID: 5508869-4  
Age: 24 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: D Rechallenge Code: Death Date:  
Therapy Start: 20070619  
Therapy End: 20070605  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5509607 Case Number: 6471775 I/F Code: I Report Date: 20071105  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009130113  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: PP2356  
Expiration Date: 20080831  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 90MCG PRN INHAL  
Event Date: 20070617  
FDA Date: 20071106  
Follow Number:  
Image ID: 5509607-1  
Age: 25 YR Gender: F Weight: 223 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20071105  
Therapy End: 20071028  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5509694 Case Number: 6469653 I/F Code: I Report Date: 20071106  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009130291  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route: ORAL  
Dose: 2 PUFFS AM AND 1 PUFF PM QD-BID PO  
Event Date:  
FDA Date: 20071107  
Follow Number:  
Image ID: 5509694-0  
Age: 58 YR Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start: 20071106  
Therapy End: 20070328  
Duration:  
Adverse Reactions:  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5509713 Case Number: 6469664 I/F Code: I Report Date: 20071106

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009130363

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADQ81B

Expiration Date: 20080831

Indication: ASTHMA

Route: ORAL

Dose: 4-6 PUFFS 10 + TIMES A DAY PO

Event Date: 20070501

FDA Date: 20071107

Follow Number:

Image ID: 5509713-1

Age: 22 YR Gender: F Weight: 110 LBS

Occupation: OT

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: 6 MON

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DRUG INEFFECTIVE
- HEADACHE
- INCORRECT DOSE ADMINISTERED
- LUNG DISORDER
- PAIN
- PHARMACEUTICAL PRODUCT COMPLAINT
- THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

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ISR Number: 5510932 Case Number: 6470667 I/F Code: I Report Date: 20071105  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009134940  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route: ORAL  
Dose: 2 PUFFS AS NEEDED PO  
Event Date: 20071104  
FDA Date: 20071106  
Follow Number:  
Image ID: 5510932-9  
Age: 45 YR Gender: M Weight: 185 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:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5513716 Case Number: 6471769 I/F Code: I Report Date: 20071106  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009145872  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route: ORAL  
Dose: 1-2 SPRAYS EVERY 4 HRS PRN ORAL  
Event Date: 20071106  
FDA Date: 20071109  
Follow Number:  
Image ID: 5513716-0  
Age: 48 YR Gender: M Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20071108  
Therapy End: 20070908  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5518998 Case Number: 6475062 I/F Code: I Report Date: 20071113  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009165407  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADP 90 A  
Expiration Date: 20080731  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: OTHER  
Dose: 200 METERED INHALATIONS Q6H, PRN OTHER  
Event Date:  
FDA Date: 20071114  
Follow Number:  
Image ID: 5518998-7  
Age: 76 YR Gender: F Weight: 145 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: 20071101  
Therapy End: 20070927  
Duration:  
Adverse Reactions:  
PRURITUS GENERALISED  
SWOLLEN TONGUE  
TONGUE BLISTERING  
TONGUE DISORDER

ISR Number: 5525217 Case Number: 6478295 I/F Code: I Report Date: 20071117  
 Drug Name: **PROAIR HFA**  
 NDA Number:  
 Role Code: PS VAL/VBM: 1  
 Seq Number: 1009191526  
 Mfg. Date:  
 Mfg. Number:  
 Mfg. Sender:  
 Lot Number:  
 Expiration Date:  
 Indication:  
 Route:  
 Dose:  
 Event Date: 20071117  
 FDA Date: 20071119  
 Follow Number:  
 Image ID: 5525217-4  
 Age: 39 YR Gender: M Weight: 200 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:  
     BRONCHOSPASM  
     DYSPTNOEA

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ISR Number: 5525705 Case Number: 6478951 I/F Code: I Report Date: 20071119  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009193123  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20090731  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 90 MCG PER INHALATION EVERY 2-4 HOURS INHAL  
Event Date: 20071101  
FDA Date: 20071120  
Follow Number:  
Image ID: 5525705-0  
Age: 23 YR Gender: F Weight: 130 LBS  
Occupation: OT  
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: 20071115  
Therapy End: 20071101  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PEAK EXPIRATORY FLOW RATE DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5526346 Case Number: 6480308 I/F Code: I Report Date: 20071120  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009195947  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADJ40A  
Expiration Date: 20071231  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2-4 PUFFS Q 4 H PRN INHAL  
Event Date: 20070601  
FDA Date: 20071121  
Follow Number:  
Image ID: 5526346-1  
Age: 43 YR Gender: F Weight: 210 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: 20071120  
Therapy End: 20070601  
Duration:  
Adverse Reactions:  
COUGH  
DRUG EFFECT DECREASED  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5528050 Case Number: 6495692 I/F Code: I Report Date: 20071108  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009202152  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ60A  
Expiration Date: 20080831  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route:  
Dose: INHALE 1 PUFF EVERY FOUR TO SIX HOURS AS NEEDED  
Event Date: 20071108  
FDA Date: 20071126  
Follow Number:  
Image ID: 5528050-2  
Age: 68 YR Gender: M Weight: 220 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: 20070409  
Duration:  
Adverse Reactions:  
    DEVICE MALFUNCTION  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5528066 Case Number: 6480132 I/F Code: I Report Date: 20071125  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009202181  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADM43A  
Expiration Date: 20080331  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS AS NEEDED INHAL  
Event Date: 20071124  
FDA Date: 20071126  
Follow Number:  
Image ID: 5528066-6  
Age: Gender: F Weight: 118 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: DS Dechallenge Code: D Rechallenge Code: Y Death Date:  
Therapy Start: 20071124  
Therapy End: 20071101  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5528124 Case Number: 6495694 I/F Code: I Report Date: 20071121  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009202340  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: OTHER  
Dose: 2 PUFFS 5-10 X A DAY OTHER  
Event Date: 20071010  
FDA Date: 20071126  
Follow Number:  
Image ID: 5528124-6  
Age: 35 YR Gender: F Weight: 180 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start: 20071121  
Therapy End: 20060102  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

ISR Number: 5531567 Case Number: 6495695 I/F Code: I Report Date: 20071126

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009215618

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADQ87C

Expiration Date: 20080831

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS PRN INHAL

Event Date: 20071101

FDA Date: 20071127

Follow Number:

Image ID: 5531567-8

Age: 29 YR Gender: F Weight: 150 LBS

Occupation: OT

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: 20071126

Therapy End: 20071008

Duration:

Adverse Reactions:

- DRUG INEFFECTIVE
- PHARMACEUTICAL PRODUCT COMPLAINT
- TREMOR

ISR Number: 5534193 Case Number: 6491095 I/F Code: I Report Date: 20071129

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009224686

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADP13A

Expiration Date: 20080531

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY 4-6 HOURS PRN INHAL

Event Date: 20071126

FDA Date: 20071130

Follow Number:

Image ID: 5534193-X

Age: 54 YR 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: Y Rechallenge Code: Y Death Date:

Therapy Start: 20071126

Therapy End: 20071126

Duration: 1 DAY

Adverse Reactions:

- ASTHMA
- CHOKING
- COUGH
- OXYGEN SATURATION DECREASED
- PHARMACEUTICAL PRODUCT COMPLAINT
- SKIN DISCOLOURATION
- WHEEZING

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ISR Number: 5534239 Case Number: 6491174 I/F Code: I Report Date: 20071129  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009224833  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR69A  
Expiration Date: 20081031  
Indication: ASTHMA  
Route: ORAL  
Dose: 1 OR 2 PUFFS AS NEEDED PO  
Event Date: 20071126  
FDA Date: 20071130  
Follow Number:  
Image ID: 5534239-9  
Age: 58 YR Gender: F Weight: 105 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: 20070201  
Duration:  
Adverse Reactions:  
ASTHMA  
DEVICE FAILURE  
DRUG INEFFECTIVE  
EMOTIONAL DISTRESS  
PHARMACEUTICAL PRODUCT COMPLAINT  
THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

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ISR Number: 5535289 Case Number: 6554094 I/F Code: I Report Date: 20071202  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009228360  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: RESPIRATORY DISTRESS  
Route: RESPIRATORY (INHALATION)  
Dose: 2 INHALATIONS Q 5 MINUTES PRN INHAL  
Event Date: 20071024  
FDA Date: 20071204  
Follow Number:  
Image ID: 5535289-9  
Age: 51 YR Gender: F Weight: 250 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: LT Dechallenge Code: Y Rechallenge Code: D Death Date:  
Therapy Start: 20071024  
Therapy End: 20071024  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    RESPIRATORY DISTRESS

ISR Number: 5535709 Case Number: 6507761 I/F Code: I Report Date: 20071203

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009229820

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADN 80A

Expiration Date: 20080531

Indication: ASTHMA

Route: ORAL

Dose: 2 INHALATIONS AS NEEDED Q.4H PO

Event Date: 20070801

FDA Date: 20071204

Follow Number:

Image ID: 5535709-X

Age: 73 YR Gender: F Weight: 175 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: 20071203

Therapy End: 20070701

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5542614 Case Number: 6509085 I/F Code: I Report Date: 20071205  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009247697  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ81A  
Expiration Date: 20080831  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY 4 HOURS INHAL  
Event Date: 20071201  
FDA Date: 20071206  
Follow Number:  
Image ID: 5542614-1  
Age: 25 YR Gender: F Weight: 250 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20071205  
Therapy End: 20070601  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT  
    RESPIRATORY DISORDER

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ISR Number: 5542618 Case Number: 6500482 I/F Code: I Report Date: 20071205  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009247711  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR15B  
Expiration Date: 20080801  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 90MCG PRN INHAL  
Event Date: 20071129  
FDA Date: 20071206  
Follow Number:  
Image ID: 5542618-9  
Age: 6 YR Gender: M Weight: 45 LBS  
Occupation: OT  
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: 20071204  
Therapy End: 20071120  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPTNOEA  
    OXYGEN SATURATION DECREASED

---

ISR Number: 5556836 Case Number: 6508659 I/F Code: I Report Date: 20071209  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009278994  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20071101  
FDA Date: 20071210  
Follow Number:  
Image ID: 5556836-7  
Age: 34 YR Gender: F Weight: 250 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:  
ASTHMA  
BLOOD PRESSURE INCREASED  
CONDITION AGGRAVATED  
DRUG EFFECT DECREASED  
DRY THROAT  
DYSPHONIA  
MUSCLE SPASMS  
NASAL DRYNESS

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ISR Number: 5556864 Case Number: 6511828 I/F Code: I Report Date: 20071211  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009279028  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route:  
Dose:  
Event Date:  
FDA Date: 20071212  
Follow Number:  
Image ID: 5556864-1  
Age: 66 YR Gender: M Weight: 175 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: Dechallenge Code: Y Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5562684 Case Number: 6511728 I/F Code: I Report Date: 20071210  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009296093  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: AS NEEDED PO  
Event Date: 20070324  
FDA Date: 20071211  
Follow Number:  
Image ID: 5562684-4  
Age: 23 YR Gender: F Weight: 125 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: 20071201  
Therapy End: 20070301  
Duration:  
Adverse Reactions:  
    COMPLICATION OF PREGNANCY  
    DRUG EFFECT DECREASED  
    DRUG EXPOSURE DURING PREGNANCY  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5562690 Case Number: 6511974 I/F Code: I Report Date: 20071208  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009296108  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADH92A  
Expiration Date: 20071130  
Indication: ASTHMA  
Route:  
Dose: METERED APPLICATION USE AS NEEDED  
Event Date: 20070928  
FDA Date: 20071211  
Follow Number:  
Image ID: 5562690-X  
Age: 45 YR Gender: F Weight: 125 LBS  
Occupation: CN  
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: 20070801  
Therapy End: 20070601  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
COUGH  
DRUG INEFFECTIVE  
NO THERAPEUTIC RESPONSE  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5562754 Case Number: 6513569 I/F Code: I Report Date: 20071210  
Drug Name: **ALBUTEROL SULFATE HFA INHALER 200 METERED INHALATIONS PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 2  
Seq Number: 1009296284  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR160  
Expiration Date: 20080901  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY 4-6 HOURS INHAL  
Event Date: 20071210  
FDA Date: 20071211  
Follow Number:  
Image ID: 5562754-0  
Age: 34 YR Gender: M Weight: 150 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: 20071210  
Therapy End: 20060601  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE  
HYPERTENSION  
PAIN  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5565176 Case Number: 6514296 I/F Code: I Report Date: 20071212  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009305275  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date: 20071210  
FDA Date: 20071213  
Follow Number:  
Image ID: 5565176-1  
Age: 24 YR Gender: M Weight: 170 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 HYPERSENSITIVITY  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5566114 Case Number: 6515561 I/F Code: I Report Date: 20071217  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009308436  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADM44A  
Expiration Date: 20080331  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS Q 4-6 HRS PO  
Event Date: 20071217  
FDA Date: 20071218  
Follow Number:  
Image ID: 5566114-8  
Age: 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: D Death Date:  
Therapy Start: 20071217  
Therapy End: 20070602  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5566400 Case Number: 6554096 I/F Code: I Report Date: 20071214  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009309205  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADL05A  
Expiration Date: 20080131  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: WHEN NEEDED WHEN NEEDED INHAL  
Event Date: 20071214  
FDA Date: 20071217  
Follow Number:  
Image ID: 5566400-1  
Age: 33 YR Gender: F Weight: 100 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: 20071214  
Therapy End: 20071214  
Duration:  
Adverse Reactions:  
ASTHMA  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5566401 Case Number: 6517772 I/F Code: I Report Date: 20071214  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009309206  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 2-3 BUFFS 8 TIMES A DAY PO  
Event Date: 20071110  
FDA Date: 20071217  
Follow Number:  
Image ID: 5566401-3  
Age: 41 YR Gender: M Weight: 210 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: LT Dechallenge Code: N Rechallenge Code: Death Date:  
Therapy Start: 20071214  
Therapy End: 20071110  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    INCORRECT DOSE ADMINISTERED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5566431 Case Number: 6554098 I/F Code: I Report Date: 20071215  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009309334  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 SPRAYS 3-4 TIMES DAILY INHAL  
Event Date:  
FDA Date: 20071218  
Follow Number:  
Image ID: 5566431-1  
Age: Gender: F Weight: 265 LBS  
Occupation: CN  
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: 20071215  
Therapy End: 20071004  
Duration:  
Adverse Reactions:  
ASTHMA  
DRUG EFFECT DECREASED  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5574387 Case Number: 6517642 I/F Code: I Report Date: 20071221  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009337643  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR15B  
Expiration Date: 20080831  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 INHALATIONS AS NEEDED INHAL  
Event Date:  
FDA Date: 20071226  
Follow Number:  
Image ID: 5574387-0  
Age: Gender: Weight:  
Occupation: CN  
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: 20071221  
Therapy End: 20070601  
Duration:  
Adverse Reactions:  
PHARMACEUTICAL PRODUCT COMPLAINT  
WHEEZING

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ISR Number: 5574709 Case Number: 6518346 I/F Code: I Report Date: 20071220  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009338616  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20071220  
FDA Date: 20071221  
Follow Number:  
Image ID: 5574709-0  
Age: 44 YR Gender: M Weight: 245 LBS  
Occupation: CN  
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:  
Therapy End:  
Duration:  
Adverse Reactions:  
BRONCHIAL SECRETION RETENTION  
CONDITION AGGRAVATED  
DYSPNOEA  
PHARMACEUTICAL PRODUCT COMPLAINT  
REACTION TO DRUG EXCIPIENTS

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ISR Number: 5578613 Case Number: 6520040 I/F Code: I Report Date: 20071226  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009352165  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR16C  
Expiration Date: 20080930  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS PRN INHAL  
Event Date: 20071221  
FDA Date: 20071227  
Follow Number:  
Image ID: 5578613-3  
Age: Gender: M Weight: 191 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20071226  
Therapy End: 20071221  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5578772 Case Number: 6520157 I/F Code: I Report Date: 20071226  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009352698  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route:  
Dose: OTIC  
Event Date:  
FDA Date: 20071227  
Follow Number:  
Image ID: 5578772-2  
Age: 76 YR Gender: M Weight: 140 LBS  
Occupation:  
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 INEFFECTIVE  
    DRUG EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5578778 Case Number: 6520164 I/F Code: I Report Date: 20071226  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009352713  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR15B  
Expiration Date: 20080808  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY 4 HOURS INHAL  
Event Date: 20071212  
FDA Date: 20071227  
Follow Number:  
Image ID: 5578778-3  
Age: 64 YR Gender: F Weight: 172 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: 20071104  
Therapy End: 20071029  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPTNOEA  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5578786 Case Number: 6554099 I/F Code: I Report Date: 20071226

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009352757

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: HYPERSENSITIVITY

Route:

Dose: 4 DOSES 24 HOURS

Event Date: 20071226

FDA Date: 20071227

Follow Number:

Image ID: 5578786-2

Age: 57 YR Gender: M Weight: 164 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: 20071201

Therapy End: 20071001

Duration:

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DRUG INEFFECTIVE
- PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5578787 Case Number: 6554100 I/F Code: I Report Date: 20071226  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009352758  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS 4HRS  
Event Date: 20071225  
FDA Date: 20071227  
Follow Number:  
Image ID: 5578787-4  
Age: 55 YR Gender: F Weight: 250 LBS  
Occupation: CN  
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: 20071226  
Therapy End: 20071201  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
HYPERSENSITIVITY  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5580440 Case Number: 6520185 I/F Code: I Report Date: 20071228  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009358445  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADP91A  
Expiration Date: 20080731  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 1 INHALATION AS NEEDED INHAL  
Event Date: 20071228  
FDA Date: 20071231  
Follow Number:  
Image ID: 5580440-8  
Age: Gender: F Weight: 180 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:  
Adverse Reactions:  
    DIZZINESS  
    LOSS OF CONSCIOUSNESS  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5585155 Case Number: 6525429 I/F Code: I Report Date: 20080103  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009374801  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR15C  
Expiration Date: 20080930  
Indication: ASTHMA  
Route:  
Dose: 90MCG PER DOSE  
Event Date: 20080102  
FDA Date: 20080104  
Follow Number:  
Image ID: 5585155-8  
Age: 51 YR Gender: F Weight: 145 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: 20071231  
Therapy End: 20071211  
Duration:  
Adverse Reactions:  
DYSпноEA  
PHARMACEUTICAL PRODUCT COMPLAINT  
RASH

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ISR Number: 5586308 Case Number: 6526740 I/F Code: I Report Date: 20080104  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009378666  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS 3-4 HRS INHAL  
Event Date: 20080104  
FDA Date: 20080107  
Follow Number:  
Image ID: 5586308-5  
Age: Gender: M Weight: 235 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
PHARMACEUTICAL PRODUCT COMPLAINT  
PULMONARY FUNCTION TEST DECREASED  
RESPIRATORY DISORDER

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ISR Number: 5586313 Case Number: 6526753 I/F Code: I Report Date: 20080105  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009378692  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20090401  
Indication: ASTHMA  
Route: ORAL  
Dose: TWO PUFFS EVERY FOUR HOURS PO  
Event Date: 20071201  
FDA Date: 20080107  
Follow Number:  
Image ID: 5586313-9  
Age: 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: N Rechallenge Code: Y Death Date:  
Therapy Start: 20071212  
Therapy End: 20071201  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    MEDICAL DEVICE COMPLICATION  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5586328 Case Number: 6528179 I/F Code: I Report Date: 20080106  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009378729  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS 4 X PER DAY INHAL  
Event Date:  
FDA Date: 20080107  
Follow Number:  
Image ID: 5586328-0  
Age: Gender: F Weight: 145 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:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5586333 Case Number: 6527944 I/F Code: I Report Date: 20080106

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009378771

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADR16A

Expiration Date: 20080930

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS 4HOURS INHAL

Event Date: 20080106

FDA Date: 20080107

Follow Number:

Image ID: 5586333-4

Age: Gender: F Weight: 200 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: 2 MON

Adverse Reactions:

- DRUG EFFECT DECREASED
- ECONOMIC PROBLEM
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5587964 Case Number: 6527984 I/F Code: I Report Date: 20070828

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009384042

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADP21A

Expiration Date: 20080501

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 90 MCG AS NEEDED INHALATION AEROSOL

Event Date: 20070816

FDA Date: 20080108

Follow Number:

Image ID: 5587964-8

Age: 57 YR Gender: F Weight: 280 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: 20070819

Therapy End: 20070816

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5591272 Case Number: 6531130 I/F Code: I Report Date: 20080108  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009396021  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 90MCG WHEN NEEDED  
Event Date:  
FDA Date: 20080110  
Follow Number:  
Image ID: 5591272-9  
Age: 27 YR Gender: M Weight: 195 LBS  
Occupation: OT  
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: 20070630  
Therapy End: 20070601  
Duration: 1 MON  
Adverse Reactions:  
THERAPEUTIC PRODUCT INEFFECTIVE

ISR Number: 5591443 Case Number: 6530764 I/F Code: I Report Date: 20080110

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009396533

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose: 2 PUFFS EVERY 4 HRS OR AS

Event Date: 20080109

FDA Date: 20080111

Follow Number:

Image ID: 5591443-1

Age: 27 YR Gender: F Weight: 185 LBS

Occupation: CN

Country: UNITED STATES

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:

- COLD SWEAT
- CONFUSIONAL STATE
- DIZZINESS
- DRUG INEFFECTIVE
- HEADACHE
- NAUSEA
- NONSPECIFIC REACTION
- TREMOR
- VISION BLURRED
- VOMITING

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ISR Number: 5595483 Case Number: 6535853 I/F Code: I Report Date: 20080115  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009410345  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR16C  
Expiration Date: 20080901  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: AS NEEDED 1 PUFF EVERY 6 HRS INHAL  
Event Date: 20080110  
FDA Date: 20080116  
Follow Number:  
Image ID: 5595483-8  
Age: 42 YR Gender: M Weight: 165 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Y Death Date:  
Therapy Start: 20071210  
Therapy End: 20071101  
Duration:  
Adverse Reactions:  
DYSпноEA  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5595541 Case Number: 6536025 I/F Code: I Report Date: 20080115  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009410557  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: PP2113  
Expiration Date: 20080630  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: ONE -1- PUFF OF 90 MCG AS RESCUE INHALER INHAL  
Event Date: 20070903  
FDA Date: 20080116  
Follow Number:  
Image ID: 5595541-8  
Age: Gender: F Weight: 180 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: Y Rechallenge Code: Y Death Date:  
Therapy Start:  
Therapy End:  
Duration: 4 MON  
Adverse Reactions:  
BRONCHIAL IRRITATION  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
PHARMACEUTICAL PRODUCT COMPLAINT  
THROAT IRRITATION

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ISR Number: 5599779 Case Number: 6537215 I/F Code: I Report Date: 20080117  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009426212  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20080831  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS AS NEEDED PO  
Event Date: 20071215  
FDA Date: 20080118  
Follow Number:  
Image ID: 5599779-5  
Age: 10 YR Gender: M Weight: 72 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: 20080118  
Therapy End: 20080116  
Duration:  
Adverse Reactions:  
ANXIETY  
ASTHMA  
DRUG INEFFECTIVE  
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5600160 Case Number: 6538863 I/F Code: I Report Date: 20080116  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009427474  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 EVERY 4 HOURS PO  
Event Date: 20080116  
FDA Date: 20080117  
Follow Number:  
Image ID: 5600160-0  
Age: 26 YR Gender: M Weight: 145 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start: 20080116  
Therapy End: 20080113  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5600164 Case Number: 6537894 I/F Code: I Report Date: 20080116  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009427488  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS AS NEEDED PO  
Event Date: 20071126  
FDA Date: 20080117  
Follow Number:  
Image ID: 5600164-8  
Age: 12 YR Gender: F Weight: 120 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: 20080116  
Therapy End: 20070801  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5600169 Case Number: 6537932 I/F Code: I Report Date: 20080116  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009427496  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS AS NEEDED PO  
Event Date: 20071213  
FDA Date: 20080117  
Follow Number:  
Image ID: 5600169-7  
Age: 32 YR Gender: F Weight: 156 LBS  
Occupation: LW  
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: 20071231  
Therapy End: 20071106  
Duration: 2 MON  
Adverse Reactions:  
DRUG INEFFECTIVE  
DYSPNOEA  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5601193 Case Number: 6538460 I/F Code: I Report Date: 20080121

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009432186

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADQ87 A

Expiration Date: 20080831

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: METERED DOSE AS NEEDED INHAL

Event Date: 20080119

FDA Date: 20080122

Follow Number:

Image ID: 5601193-0

Age: 36 YR Gender: F Weight: 250 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: 20080121

Therapy End: 20080115

Duration:

Adverse Reactions:

- APHTHOUS STOMATITIS
- CHEILITIS
- ERYTHEMA
- GINGIVAL SWELLING
- GINGIVITIS
- STOMATITIS

ISR Number: 5602063 Case Number: 6538413 I/F Code: I Report Date: 20080118

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009435831

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose:

Event Date: 20080118

FDA Date: 20080122

Follow Number:

Image ID: 5602063-4

Age: 31 YR Gender: M Weight: 175 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: 20071201

Therapy End: 20071101

Duration:

Adverse Reactions:

DRUG EFFECT DECREASED

ECONOMIC PROBLEM

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5606022 Case Number: 6542129 I/F Code: I Report Date: 20080120  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009449861  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR14B  
Expiration Date: 20080331  
Indication: BRONCHITIS CHRONIC  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY 4 TO 6 HOURS INHAL  
Event Date: 20080104  
FDA Date: 20080123  
Follow Number:  
Image ID: 5606022-7  
Age: 42 YR Gender: F Weight: 228 LBS  
Occupation: CN  
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: 20080120  
Therapy End: 20071118  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPNOEA  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5608733 Case Number: 6554101 I/F Code: I Report Date: 20080125  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009459214  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20071231  
Indication: ASTHMA  
Route:  
Dose:  
Event Date:  
FDA Date: 20080128  
Follow Number:  
Image ID: 5608733-6  
Age: 43 YR Gender: F Weight: 140 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: 20071217  
Therapy End: 20050605  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5608854 Case Number: 6554102 I/F Code: I Report Date: 20080124  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009459709  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070929  
FDA Date: 20080128  
Follow Number:  
Image ID: 5608854-8  
Age: 15 YR Gender: F Weight: 110 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20070829  
Therapy End: 20070713  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5612033 Case Number: 6551745 I/F Code: I Report Date: 20080128  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009470514  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY 4 HOURS INHAL  
Event Date: 20080108  
FDA Date: 20080129  
Follow Number:  
Image ID: 5612033-8  
Age: Gender: F Weight: 150 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: DS Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start: 20080116  
Therapy End: 20080108  
Duration:  
Adverse Reactions:  
CHEST PAIN  
DRUG INEFFECTIVE  
DYSPNOEA  
PALPITATIONS  
PHARMACEUTICAL PRODUCT COMPLAINT  
STRESS

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ISR Number: 5612038 Case Number: 6550484 I/F Code: I Report Date: 20080127  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009470534  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20080701  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS AS NEEDED PO  
Event Date:  
FDA Date: 20080129  
Follow Number:  
Image ID: 5612038-7  
Age: 30 YR Gender: M Weight: 180 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20080115  
Therapy End: 20071101  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5612462 Case Number: 6551330 I/F Code: I Report Date: 20080129  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009472136  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR168  
Expiration Date: 20080930  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS 4 TIMES DAILY AS NEEDS PO  
Event Date:  
FDA Date: 20080131  
Follow Number:  
Image ID: 5612462-2  
Age: Gender: F Weight: 165 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: 20080129  
Therapy End: 20070910  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5612466 Case Number: 6673397 I/F Code: I Report Date: 20080129  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009472141  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: TWO PUFFS 4 HOURS AS NEEDED PO  
Event Date:  
FDA Date: 20080131  
Follow Number:  
Image ID: 5612466-X  
Age: 34 YR Gender: F Weight: 165 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:  
Therapy End:  
Duration: 1 MON  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5616659 Case Number: 6561635 I/F Code: I Report Date: 20080205  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009486416  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 90 MCG 2 PUFFS AS NEEDED INHAL  
Event Date: 20071020  
FDA Date: 20080206  
Follow Number:  
Image ID: 5616659-7  
Age: 44 YR Gender: F Weight: 230 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: DS Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End: 20071001  
Duration:  
Adverse Reactions:  
COUGH  
DYSPNOEA  
WHEEZING

ISR Number: 5618320 Case Number: 6554832 I/F Code: I Report Date: 20080204  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009488880  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20080930  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 ACTUATIONS AS NEEDED INHAL  
Event Date: 20080204  
FDA Date: 20080205  
Follow Number:  
Image ID: 5618320-1  
Age: Gender: F Weight: 158 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: 20080204  
Therapy End: 20080204  
Duration:  
Adverse Reactions:  
PARAESTHESIA ORAL  
URTICARIA

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ISR Number: 5618620 Case Number: 6555673 I/F Code: I Report Date: 20080204  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009489870  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR14B  
Expiration Date: 20100831  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS 3X DAILY INHAL  
Event Date:  
FDA Date: 20080205  
Follow Number:  
Image ID: 5618620-5  
Age: 70 YR Gender: F Weight: 125 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: 20071220  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE  
DYSPNOEA  
IMPAIRED WORK ABILITY  
PHARMACEUTICAL PRODUCT COMPLAINT  
RESPIRATORY DISORDER

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ISR Number: 5622646 Case Number: 6558644 I/F Code: I Report Date: 20080209  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009504918  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20080111  
FDA Date: 20080211  
Follow Number:  
Image ID: 5622646-5  
Age: Gender: F Weight: 122 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Y Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5624545 Case Number: 6560030 I/F Code: I Report Date: 20080206  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009511314  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADM45A  
Expiration Date: 20080331  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS AS NEEDED  
Event Date: 20080204  
FDA Date: 20080207  
Follow Number:  
Image ID: 5624545-1  
Age: 37 YR Gender: F Weight: 210 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: DS Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20080204  
Therapy End: 20070414  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5634174 Case Number: 6567608 I/F Code: I Report Date: 20080215  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009546817  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070301  
FDA Date: 20080221  
Follow Number:  
Image ID: 5634174-1  
Age: Gender: F Weight: 135 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:  
Therapy End: 20070301  
Duration:  
Adverse Reactions:  
ASTHMA  
COUGH

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ISR Number: 5634765 Case Number: 6567872 I/F Code: I Report Date: 20080220  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009548870  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR14A  
Expiration Date: 20080808  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS QID INHAL  
Event Date: 20080126  
FDA Date: 20080221  
Follow Number:  
Image ID: 5634765-8  
Age: Gender: F Weight: 220 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: 20080220  
Therapy End: 20070901  
Duration:  
Adverse Reactions:  
BRONCHOSPASM  
DRUG EFFECT DECREASED  
INCORRECT DOSE ADMINISTERED  
MEDICAL DEVICE COMPLICATION  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5636179 Case Number: 6568903 I/F Code: I Report Date: 20080212  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009553974  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: WHEEZING  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS Q4-6 HRS INHALED  
Event Date: 20080123  
FDA Date: 20080212  
Follow Number:  
Image ID: 5636179-3  
Age: Gender: F Weight: 38 LBS  
Occupation: MD  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: Y Rechallenge Code: Y Death Date:  
Therapy Start: 20080208  
Therapy End: 20080123  
Duration:  
Adverse Reactions:  
URTICARIA

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ISR Number: 5637190 Case Number: 6570201 I/F Code: I Report Date: 20080219  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009557374  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date: 20080801  
Indication: ASTHMA  
Route: ORAL  
Dose: 90 MCG AS NEEDED PO  
Event Date: 20080213  
FDA Date: 20080220  
Follow Number:  
Image ID: 5637190-9  
Age: 28 YR Gender: F Weight: 140 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y  
Outcome Code: LT Dechallenge Code: N Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE

ISR Number: 5638881 Case Number: 6570509 I/F Code: I Report Date: 20080221

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009562843

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADR15C

Expiration Date: 20080831

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY 4 HOURS INHAL

Event Date: 20070201

FDA Date: 20080222

Follow Number:

Image ID: 5638881-6

Age: 52 YR Gender: M Weight: 232 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: 20080221

Therapy End: 20070916

Duration:

Adverse Reactions:

ASTHMA

CONDITION AGGRAVATED

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5639944 Case Number: 6572313 I/F Code: I Report Date: 20080222  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009566115  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADN42A  
Expiration Date: 20080430  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS Q 4-6 HOURS INHAL  
Event Date: 20080221  
FDA Date: 20080225  
Follow Number:  
Image ID: 5639944-1  
Age: 48 YR Gender: F Weight: 250 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration: 1 WK  
Adverse Reactions:  
    CONDITION AGGRAVATED  
    DRUG EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5646807 Case Number: 6577823 I/F Code: I Report Date: 20080228  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009589278  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 1 INHALATION EVERY 4 HOURS/ NEED PO  
Event Date:  
FDA Date: 20080229  
Follow Number:  
Image ID: 5646807-4  
Age: 59 YR Gender: M Weight: 215 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: 20080227  
Therapy End: 20071220  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5648339 Case Number: 6578397 I/F Code: I Report Date: 20080302  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009593860  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ14A  
Expiration Date: 20080731  
Indication: VIRAL UPPER RESPIRATORY TRACT INFECTION  
Route: ORAL  
Dose: 2 PUFFS Q 4 HOURS PO  
Event Date: 20080302  
FDA Date: 20080303  
Follow Number:  
Image ID: 5648339-6  
Age: 53 YR Gender: F Weight: 221 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: 20080302  
Therapy End: 20080226  
Duration:  
Adverse Reactions:  
    CONDITION AGGRAVATED  
    DEVICE FAILURE  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5648355 Case Number: 6578400 I/F Code: I Report Date: 20080302  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009593888  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADS56C  
Expiration Date: 20081130  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS BY MOUTH AS NEEDED INHAL  
Event Date: 20080301  
FDA Date: 20080303  
Follow Number:  
Image ID: 5648355-4  
Age: 39 YR 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: N Rechallenge Code: D Death Date:  
Therapy Start: 20080301  
Therapy End: 20080301  
Duration:  
Adverse Reactions:  
CYANOSIS  
DRUG HYPERSENSITIVITY  
DRUG INEFFECTIVE  
PHARMACEUTICAL PRODUCT COMPLAINT  
POOR PERIPHERAL CIRCULATION  
PULMONARY OEDEMA  
RHINORRHOEA  
SINUSITIS NONINFECTIVE

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ISR Number: 5648730 Case Number: 6580679 I/F Code: I Report Date: 20080229  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009594903  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADS56B  
Expiration Date: 20081130  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: TWO PUFFS Q 4-6 HOURS INHAL  
Event Date: 20080228  
FDA Date: 20080303  
Follow Number:  
Image ID: 5648730-8  
Age: Gender: M Weight: 150 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration: 6 MON  
Adverse Reactions:  
DRUG EFFECT DECREASED  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5648833 Case Number: 6579840 I/F Code: I Report Date: 20080301  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009595171  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADQ87B  
Expiration Date: 20080831  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 200 METERED INHALATIONS 4 X DAY OR PRN INHAL  
Event Date: 20080227  
FDA Date: 20080203  
Follow Number:  
Image ID: 5648833-8  
Age: 42 YR Gender: F Weight: 185 LBS  
Occupation:  
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: 20080229  
Therapy End: 20080201  
Duration:  
Adverse Reactions:  
ASTHMA  
DRUG INEFFECTIVE  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5650534 Case Number: 6580814 I/F Code: I Report Date: 20080303  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009600238  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR688  
Expiration Date: 20081031  
Indication: BRONCHITIS  
Route: ORAL  
Dose: TWO PUFFS TWICE A DAY PO  
Event Date: 20080222  
FDA Date: 20080304  
Follow Number:  
Image ID: 5650534-7  
Age: 56 YR Gender: F Weight: 120 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: LT Dechallenge Code: Y Rechallenge Code: D Death Date:  
Therapy Start: 20080222  
Therapy End: 20080221  
Duration:  
Adverse Reactions:  
    DRUG HYPERSENSITIVITY  
    DRUG INEFFECTIVE

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ISR Number: 5652756 Case Number: 6585245 I/F Code: I Report Date: 20080304  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009606045  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 1 PUFF PRN PO  
Event Date: 20071215  
FDA Date: 20080305  
Follow Number:  
Image ID: 5652756-8  
Age: 53 YR Gender: M Weight: 220 LBS  
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: 20080304  
Therapy End: 20071201  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5662782 Case Number: 6589245 I/F Code: I Report Date: 20080310  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009641548  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: DYSPNOEA  
Route: ORAL  
Dose: 2 PUFFS 4 TIMES PER DAY PO  
Event Date: 20071001  
FDA Date: 20080311  
Follow Number:  
Image ID: 5662782-0  
Age: 37 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: Y Rechallenge Code: D Death Date:  
Therapy Start: 20071001  
Therapy End: 20070901  
Duration:  
Adverse Reactions:  
COUGH  
PHARMACEUTICAL PRODUCT COMPLAINT  
THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

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ISR Number: 5668973 Case Number: 6597529 I/F Code: I Report Date: 20080311  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009662104  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADR64B  
Expiration Date: 20080930  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS, 4 TIMES DAILY INHAL  
Event Date: 20080311  
FDA Date: 20080312  
Follow Number:  
Image ID: 5668973-7  
Age: 67 YR Gender: M Weight: 197 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: 20080311  
Therapy End: 20080311  
Duration:  
Adverse Reactions:  
COUGH  
HEADACHE  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5672165 Case Number: 6597013 I/F Code: I Report Date: 20080314  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009673188  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: NUMEROUS PUFFS INHAL  
Event Date: 20080310  
FDA Date: 20080317  
Follow Number:  
Image ID: 5672165-5  
Age: 40 YR Gender: M Weight: 155 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: HO Dechallenge Code: N Rechallenge Code: Death Date:  
Therapy Start: 20080310  
Therapy End: 20080310  
Duration: 30 MIN  
Adverse Reactions:  
DRUG INEFFECTIVE

ISR Number: 5672228 Case Number: 6597022 I/F Code: I Report Date: 20080315

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009673419

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date: 20081101

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS BY MOUTH EVERY 4 HOURS AS NEEDED INHAL AS PERSCRIBED

Event Date: 20080310

FDA Date: 20080317

Follow Number:

Image ID: 5672228-4

Age: Gender: M Weight: 65 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20080315

Therapy End: 20071201

Duration:

Adverse Reactions:

DEVICE INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5674720 Case Number: 6600897 I/F Code: I Report Date: 20080318  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009681851  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: WHEEZING  
Route: ORAL  
Dose: ONE PUFF EV 4 HOURS AS NEED PO  
Event Date: 20070701  
FDA Date: 20080319  
Follow Number:  
Image ID: 5674720-5  
Age: 50 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: N Rechallenge Code: Death Date:  
Therapy Start: 20080317  
Therapy End: 20070701  
Duration:  
Adverse Reactions:  
    APNOEA  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5674742 Case Number: 6600937 I/F Code: I Report Date: 20080318  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009681953  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADS97C  
Expiration Date: 20081231  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: WHEN EVER NEEDED INHAL  
Event Date: 20080105  
FDA Date: 20080319  
Follow Number:  
Image ID: 5674742-4  
Age: 34 YR Gender: M Weight: 210 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: 6 MON  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    FEAR  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5676670 Case Number: 6602358 I/F Code: I Report Date: 20080319

Drug Name: **NEW INHALER PROAIR**

NDA Number:

Role Code: PS VAL/VBM: 2

Seq Number: 1009690156

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date: 20080101

FDA Date: 20080320

Follow Number:

Image ID: 5676670-7

Age: 20 YR Gender: M Weight: 170 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:

DRUG INEFFECTIVE

FEAR

MORBID THOUGHTS

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ISR Number: 5678120 Case Number: 6603749 I/F Code: I Report Date: 20080322  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009694888  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ADRR15C  
Expiration Date: 20080804  
Indication: BRONCHIAL HYPERREACTIVITY  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFF AS NEEDED INHAL  
Event Date: 20070210  
FDA Date: 20080324  
Follow Number:  
Image ID: 5678120-3  
Age: 4 YR Gender: F Weight: 38 LBS  
Occupation:  
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: 20080320  
Therapy End: 20060101  
Duration:  
Adverse Reactions:  
OBSTRUCTIVE AIRWAYS DISORDER

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ISR Number: 5680012 Case Number: 6604778 I/F Code: I Report Date: 20080324  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009700626  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date:  
FDA Date: 20080325  
Follow Number:  
Image ID: 5680012-0  
Age: Gender: Weight:  
Occupation: CN  
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: 20080301  
Therapy End: 20070501  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5682737 Case Number: 6605514 I/F Code: I Report Date: 20080325

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009708348

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADT69A

Expiration Date: 20090131

Indication: BRONCHOSPASM

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS Q 4 HOURS INHAL

Event Date: 20080325

FDA Date: 20080326

Follow Number:

Image ID: 5682737-X

Age: 56 YR Gender: F Weight: 116 LBS

Occupation: OT

Country: UNITED STATES

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

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

Therapy Start: 20080325

Therapy End: 20080325

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5682738 Case Number: 6605519 I/F Code: I Report Date: 20080325

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009708349

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADS56A

Expiration Date: 20081130

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS AS NEEDED AS NEEDED INHAL

Event Date:

FDA Date: 20080326

Follow Number:

Image ID: 5682738-1

Age: 38 YR Gender: F Weight: 190 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20080325

Therapy End: 20071001

Duration:

Adverse Reactions:

DEVICE FAILURE

DRUG EFFECT DECREASED

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5688334 Case Number: 6606988 I/F Code: I Report Date: 20080327  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009724894  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20080115  
FDA Date: 20080328  
Follow Number:  
Image ID: 5688334-4  
Age: 29 YR Gender: M Weight: 195 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: 20080115  
Therapy End: 20070101  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5690603 Case Number: 6607763 I/F Code: I Report Date: 20080329  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009732669  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 90 MCG, PUFFS Q4 INHAL  
Event Date: 20080120  
FDA Date: 20080331  
Follow Number:  
Image ID: 5690603-9  
Age: 45 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: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration: 1 MON  
Adverse Reactions:  
    DEVICE OCCLUSION  
    DRUG INEFFECTIVE  
    INCORRECT DOSE ADMINISTERED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5690624 Case Number: 6614921 I/F Code: I Report Date: 20080330  
Drug Name: **PROAIR HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009732715  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS EVERY 4 HRS. INHAL  
Event Date: 20070606  
FDA Date: 20080331  
Follow Number:  
Image ID: 5690624-6  
Age: Gender: F Weight: 95 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: 20080329  
Therapy End: 20070606  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE  
DYSPNOEA  
THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION