
ISR Number: 6030248 Case Number: 6880238 I/F Code: I Report Date: 20090101
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010960163
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20100430
Indication: WHEEZING
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4 TIMES PER DAY INHAL
Event Date: 20090101
FDA Date: 20090105
Follow Number:
Image ID: 6030248-4
Age: 6 YR Gender: M Weight: 38 KG
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: HO Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20080101
Therapy End: 20080101
Duration: 1 DAY
Adverse Reactions:
CHEST PAIN
DRUG INEFFECTIVE
PALPITATIONS

ISR Number: 6030488 Case Number: 6881537 I/F Code: I Report Date: 20090105
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010960913
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose:
Event Date:
FDA Date: 20090106
Follow Number:
Image ID: 6030488-4
Age: 30 YR Gender: M Weight: 160 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6034690 Case Number: 6885177 I/F Code: I Report Date: 20090108
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010975506
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADZ39C
Expiration Date: 20100501
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 90 MCG/PUFF 4X DAILY INHAL
Event Date: 20090108
FDA Date: 20090109
Follow Number:
Image ID: 6034690-7
Age: 32 YR 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: N Rechallenge Code: Y Death Date:
Therapy Start:
Therapy End:
Duration: 4 YR
Adverse Reactions:
CHEST PAIN
DEVICE MALFUNCTION
DRUG EFFECT DECREASED
DYSPNOEA
FEELING ABNORMAL
PRODUCT QUALITY ISSUE

ISR Number: 6034983 Case Number: 6885770 I/F Code: I Report Date: 20090107
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010976350
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20100531
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS AS NEEDED -OFTEN- INHAL
Event Date: 20090105
FDA Date: 20090108
Follow Number:
Image ID: 6034983-3
Age: 25 YR 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: Death Date:
Therapy Start: 20081231
Therapy End: 20080901
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6035463 Case Number: 6888470 I/F Code: I Report Date: 20090109

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010977989

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADZ550

Expiration Date: 20100531

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 INHALATIONS TWICE A DAYADZ

Event Date: 20080131

FDA Date: 20090112

Follow Number:

Image ID: 6035463-1

Age: 52 YR Gender: F Weight: 128 LBS

Occupation: CN

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: 20081231

Therapy End: 20080131

Duration:

Adverse Reactions:

- DEVICE MALFUNCTION
- DEVICE OCCLUSION
- DRUG EFFECT DECREASED
- PRODUCT QUALITY ISSUE

ISR Number: 6037854 Case Number: 6889048 I/F Code: I Report Date: 20090113
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010987903
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date:
FDA Date: 20090114
Follow Number:
Image ID: 6037854-1
Age: 65 YR Gender: F Weight: 132 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:
 DRUG INEFFECTIVE
 POOR QUALITY DRUG ADMINISTERED

ISR Number: 6037963 Case Number: 6888842 I/F Code: I Report Date: 20090112
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010988242
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date:
FDA Date: 20090113
Follow Number:
Image ID: 6037963-7
Age: 44 YR Gender: F Weight: 115 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6038964 Case Number: 6888981 I/F Code: I Report Date: 20090113
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010991169
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADZ39B
Expiration Date: 20100531
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1 PUFF PRN INHAL
Event Date: 20090101
FDA Date: 20090114
Follow Number:
Image ID: 6038964-5
Age: 8 YR Gender: M Weight: 70 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: 20090101
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 PRODUCT QUALITY ISSUE

ISR Number: 6044996 Case Number: 6894666 I/F Code: I Report Date: 20090116
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011012925
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADY53C
Expiration Date: 20100401
Indication:
Route:
Dose: 2 PUFFS TWICE A DAY
Event Date:
FDA Date: 20090116
Follow Number:
Image ID: 6044996-3
Age: 73 YR Gender: F Weight: 119 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: 20090101
Duration:
Adverse Reactions:
HEADACHE
OROPHARYNGEAL PAIN
PRODUCT QUALITY ISSUE

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ISR Number: 6045431 Case Number: 6892625 I/F Code: I Report Date: 20090115
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011014431
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20090110
FDA Date: 20090116
Follow Number:
Image ID: 6045431-1
Age: 27 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: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6048290 Case Number: 6893020 I/F Code: I Report Date: 20090116
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011026382
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route: ORAL
Dose: 1-2 PUFFS AS NECESSARY PO
Event Date: 20090116
FDA Date: 20090121
Follow Number:
Image ID: 6048290-6
Age: 41 YR Gender: M Weight: 230 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DEVICE MALFUNCTION
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6048303 Case Number: 6893046 I/F Code: I Report Date: 20090116
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011026432
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS QID AND PRN PO
Event Date: 20090115
FDA Date: 20090121
Follow Number:
Image ID: 6048303-1
Age: 36 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: N Rechallenge Code: Y Death Date:
Therapy Start: 20081231
Therapy End: 20080715
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DRUG EFFECT DECREASED
PRODUCT QUALITY ISSUE

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ISR Number: 6048553 Case Number: 6896191 I/F Code: I Report Date: 20090121
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011027379
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS 4 TIMES A DAY PO
Event Date: 20090121
FDA Date: 20090122
Follow Number:
Image ID: 6048553-4
Age: 22 YR Gender: F Weight: 128 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:
 DEVICE FAILURE

ISR Number: 6050168 Case Number: 6896254 I/F Code: I Report Date: 20090121
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011032425
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: ORAL
Dose: 2 INHALATIONS AS NEEDED PO
Event Date: 20081218
FDA Date: 20090122
Follow Number:
Image ID: 6050168-9
Age: 71 YR Gender: M Weight: 205 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: 20081216
Therapy End: 20081216
Duration: 1 DAY
Adverse Reactions:
BLOOD PRESSURE INCREASED
DRUG INEFFECTIVE
FLUSHING
LUNG DISORDER

ISR Number: 6050648 Case Number: 6897858 I/F Code: I Report Date: 20090119

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011033754

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: ORAL

Dose: PO

Event Date: 20080315

FDA Date: 20090121

Follow Number:

Image ID: 6050648-6

Age: 15 YR Gender: M Weight: 165 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- CHEST DISCOMFORT
- DRUG INEFFECTIVE
- PAIN
- PRODUCT QUALITY ISSUE
- RETCHING

ISR Number: 6051734 Case Number: 6897876 I/F Code: I Report Date: 20090119
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011036723
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: OTHER
Dose: 2PUFFS EVERY 4-6 HOURS OTHER
Event Date:
FDA Date: 20090121
Follow Number:
Image ID: 6051734-7
Age: 9 YR Gender: M Weight: 145 LBS
Occupation: OT
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: Y Death Date:
Therapy Start: 20080501
Therapy End: 20080201
Duration:
Adverse Reactions:
 MANIA
 PRODUCT QUALITY ISSUE

ISR Number: 6051837 Case Number: 6896367 I/F Code: I Report Date: 20090120

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011037036

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date: 20081001

FDA Date: 20090121

Follow Number:

Image ID: 6051837-7

Age: 36 YR Gender: M Weight: 225 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG EFFECT DECREASED

HEADACHE

INSOMNIA

PRODUCT QUALITY ISSUE

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ISR Number: 6051838 Case Number: 6900119 I/F Code: I Report Date: 20090120
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011037037
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADZO5A
Expiration Date: 20100501
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1-10 PUFFS PRN INHAL
Event Date: 20090119
FDA Date: 20090121
Follow Number:
Image ID: 6051838-9
Age: 27 Gender: F Weight: 136 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: 3 MON
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 6051848 Case Number: 6896372 I/F Code: I Report Date: 20090118
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011037064
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20090117
FDA Date: 20090121
Follow Number:
Image ID: 6051848-1
Age: 65 YR Gender: F Weight: 131 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:
COUGH
DEVICE INEFFECTIVE
DRUG EFFECT DECREASED
ECONOMIC PROBLEM
PRODUCT QUALITY ISSUE

ISR Number: 6056237 Case Number: 6899685 I/F Code: I Report Date: 20090122
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011051210
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20090118
FDA Date: 20090123
Follow Number:
Image ID: 6056237-1
Age: 49 Gender: M Weight: 200 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 HEADACHE
 INCORRECT DOSE ADMINISTERED
 PRODUCT QUALITY ISSUE

ISR Number: 6056241 Case Number: 6899720 I/F Code: I Report Date: 20090122

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011051221

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: ORAL

Dose: TWO PUFFS BY MOUTH TWICE DAILY PO

Event Date: 20090102

FDA Date: 20090123

Follow Number:

Image ID: 6056241-3

Age: 48 YR Gender: F Weight: 152 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- DRUG EFFECT DECREASED
- DRUG INEFFECTIVE
- ECONOMIC PROBLEM
- PRODUCT QUALITY ISSUE

ISR Number: 6056770 Case Number: 6903203 I/F Code: I Report Date: 20090124

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011052606

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 200 METERED DOSE INHALER INHAL

Event Date: 20090121

FDA Date: 20090126

Follow Number:

Image ID: 6056770-2

Age: 34 YR Gender: F Weight: 180 LBS

Occupation: OT

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: 20090124

Therapy End: 20080101

Duration:

Adverse Reactions:

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

ISR Number: 6056777 Case Number: 6900222 I/F Code: I Report Date: 20090123
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011052616
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20081218
FDA Date: 20090126
Follow Number:
Image ID: 6056777-5
Age: 40 YR Gender: F Weight: 160 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ABDOMINAL PAIN UPPER
CHEST PAIN
COLD SWEAT
DRUG ADMINISTRATION ERROR
DRUG INEFFECTIVE
HYPERHIDROSIS
PALPITATIONS
PRODUCT QUALITY ISSUE
VOMITING

AERS Reports - January 2009 - March 2009

ISR Number: 6056785 Case Number: 6900239 I/F Code: I Report Date: 20090123
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011052625
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: REV 0707
Expiration Date: 20091126
Indication: ASTHMA
Route: ORAL
Dose: 2 INHALATIONS ONCE A WEEK PO
Event Date: 20081215
FDA Date: 20090126
Follow Number:
Image ID: 6056785-4
Age: 27 Gender: M Weight: 160 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: 20090121
Therapy End: 20081215
Duration:
Adverse Reactions:
CHEST PAIN
PRODUCT QUALITY ISSUE

ISR Number: 6057072 Case Number: 6900274 I/F Code: I Report Date: 20090124
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011053657
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADY 53C
Expiration Date: 20100401
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4 X DAY INHAL
Event Date: 20090124
FDA Date: 20090126
Follow Number:
Image ID: 6057072-0
Age: 36 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: 20090123
Therapy End: 20090101
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 NAUSEA
 PRODUCT QUALITY ISSUE

ISR Number: 6057529 Case Number: 6901279 I/F Code: I Report Date: 20090126
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011054888
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA56A
Expiration Date: 20100731
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: AS NEEDED INHAL
Event Date: 20090123
FDA Date: 20090127
Follow Number:
Image ID: 6057529-2
Age: 50 YR Gender: F Weight: 175 LBS
Occupation:
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: 20090123
Therapy End: 20081223
Duration:
Adverse Reactions:
 OVERDOSE
 PRODUCT QUALITY ISSUE

ISR Number: 6060663 Case Number: 6904676 I/F Code: I Report Date: 20090119

Drug Name: **PROAIR**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011066147

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AFA16C

Expiration Date: 20100601

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 90MCG INHALATION EVERY 6 HRS

Event Date: 20090109

FDA Date: 20090130

Follow Number:

Image ID: 6060663-4

Age: 17 YR Gender: F Weight: 170 LBS

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: 20090109

Therapy End: 20090108

Duration:

Adverse Reactions:

- CHEST PAIN
- SYNCOPE
- TACHYCARDIA
- VOMITING

ISR Number: 6061505 Case Number: 6904592 I/F Code: I Report Date: 20090129
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011069150
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS AS NEEDED ALL DAY LONG PO
Event Date: 20081015
FDA Date: 20090130
Follow Number:
Image ID: 6061505-3
Age: 30 YR Gender: M Weight: 200 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: 20090129
Therapy End: 20081015
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DRUG EFFECT DECREASED
EXERCISE TOLERANCE DECREASED
MIDDLE INSOMNIA
PRODUCT QUALITY ISSUE

ISR Number: 6062148 Case Number: 6904665 I/F Code: I Report Date: 20090128
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011072135
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADZ 05B
Expiration Date: 20100531
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS EVERY 4-6 HOURS INHAL
Event Date: 20090127
FDA Date: 20090129
Follow Number:
Image ID: 6062148-8
Age: 4 YR Gender: M Weight: 35 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: 20090128
Therapy End: 20081120
Duration:
Adverse Reactions:
CONDITION AGGRAVATED
COUGH
DRUG INEFFECTIVE
INSOMNIA
PRODUCT QUALITY ISSUE
VOMITING

ISR Number: 6062567 Case Number: 6904899 I/F Code: I Report Date: 20090201
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011073461
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADZ39B
Expiration Date: 20100531
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 90 MCG EVERY 4 HOURS INHAL
Event Date: 20090131
FDA Date: 20090202
Follow Number:
Image ID: 6062567-X
Age: 6 YR Gender: M Weight: 51 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: 20090131
Therapy End: 20080401
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DEVICE MALFUNCTION
POOR QUALITY DRUG ADMINISTERED
PRODUCT QUALITY ISSUE

ISR Number: 6064868 Case Number: 6907084 I/F Code: I Report Date: 20090202
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011081399
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA16C
Expiration Date: 20100606
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1 PUFF 1X INHAL
Event Date: 20090201
FDA Date: 20090203
Follow Number:
Image ID: 6064868-8
Age: 52 YR Gender: F Weight: 180 LBS
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: 20090201
Therapy End: 20090201
Duration:
Adverse Reactions:
ASPHYXIA
ASTHMA
CONDITION AGGRAVATED
DIZZINESS
DRUG INEFFECTIVE
DRY MOUTH
HEAD BANGING

ISR Number: 6064881 Case Number: 6908712 I/F Code: I Report Date: 20090202
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011081422
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA EXERCISE INDUCED
Route:
Dose:
Event Date: 20090121
FDA Date: 20090203
Follow Number:
Image ID: 6064881-0
Age: 33 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: Y Rechallenge Code: Y Death Date:
Therapy Start: 20090130
Therapy End: 20090120
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 PRODUCT QUALITY ISSUE

ISR Number: 6065797 Case Number: 6904154 I/F Code: I Report Date: 20090119
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011084959
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date:
FDA Date: 20090121
Follow Number:
Image ID: 6065797-6
Age: 37 YR Gender: M Weight: 185 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: RI Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6069522 Case Number: 6908022 I/F Code: I Report Date: 20090203
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011098400
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4H INHAL
Event Date: 20090130
FDA Date: 20090204
Follow Number:
Image ID: 6069522-4
Age: 8 Gender: F Weight: 24.9 KG
Occupation: MD
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: 20090130
Therapy End: 20090130
Duration:
Adverse Reactions:
 PRODUCT QUALITY ISSUE
 TYPE I HYPERSENSITIVITY

ISR Number: 6072388 Case Number: 6911084 I/F Code: I Report Date: 20090207
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011108661
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADZ91C
Expiration Date: 20100531
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS 4 TIMES DAILY PO
Event Date: 20090207
FDA Date: 20090209
Follow Number:
Image ID: 6072388-X
Age: 27 YR Gender: M Weight: 150 LBS
Occupation:
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: 20090207
Therapy End: 20081001
Duration:
Adverse Reactions:
 ANGINA PECTORIS
 BURNING SENSATION
 DRUG INEFFECTIVE
 DYSPNOEA
 EXERCISE TOLERANCE DECREASED
 PRODUCT QUALITY ISSUE
 WEIGHT INCREASED

ISR Number: 6072428 Case Number: 6913442 I/F Code: I Report Date: 20090208

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011108800

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY 4 HRS INHAL

Event Date: 20080120

FDA Date: 20090209

Follow Number:

Image ID: 6072428-8

Age: 41 Gender: F Weight: 210 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: 20080120

Therapy End: 20080120

Duration:

Adverse Reactions:

- DRUG INEFFECTIVE
- EXPIRED DRUG ADMINISTERED
- PRODUCT QUALITY ISSUE

ISR Number: 6075550 Case Number: 6915494 I/F Code: I Report Date: 20090209
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011119897
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: INHALATION THERAPY
Route:
Dose:
Event Date:
FDA Date: 20090210
Follow Number:
Image ID: 6075550-5
Age: Gender: F 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:
Therapy End:
Duration:
Adverse Reactions:
CHEST DISCOMFORT
CONDITION AGGRAVATED
DYSPNOEA
HEADACHE
PRODUCT QUALITY ISSUE
THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 6075556 Case Number: 6915501 I/F Code: I Report Date: 20090209
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011119921
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA57A538660
Expiration Date: 20100731
Indication: ASTHMA
Route: ORAL
Dose: 2 INHALATIONS PO
Event Date: 20070207
FDA Date: 20090210
Follow Number:
Image ID: 6075556-6
Age: 29 Gender: F Weight: 180 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: 20090208
Therapy End: 20090101
Duration:
Adverse Reactions:
CHEST DISCOMFORT
DRUG EFFECT DECREASED
DYSPNOEA
THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 6076914 Case Number: 6915983 I/F Code: I Report Date: 20090211
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011124941
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose: 2-4 PUFFS AS NEEDED 4-10 TIMES DAILY INHAL
Event Date: 20081224
FDA Date: 20090212
Follow Number:
Image ID: 6076914-6
Age: 34 YR Gender: M Weight: 200 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: 20090211
Therapy End: 20081224
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DRUG INEFFECTIVE
PRODUCT QUALITY ISSUE

ISR Number: 6084052 Case Number: 6920392 I/F Code: I Report Date: 20090214
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011151101
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEB2BC
Expiration Date: 20100801
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4 HOURS INHAL
Event Date: 20090212
FDA Date: 20090217
Follow Number:
Image ID: 6084052-1
Age: 20 YR Gender: F Weight: 160 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: 20090214
Therapy End: 20090101
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6085649 Case Number: 6923352 I/F Code: I Report Date: 20090216

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011157303

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEA57A

Expiration Date: 20100731

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1 TO 2 PUFFS 4 TO 6 HOURS AS NEEDED INHAL

Event Date: 20090212

FDA Date: 20090217

Follow Number:

Image ID: 6085649-5

Age: 59 Gender: F Weight: 130 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- CONDITION AGGRAVATED
- DYSPNOEA
- PRODUCT QUALITY ISSUE
- PULMONARY CONGESTION

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ISR Number: 6085654 Case Number: 6923386 I/F Code: I Report Date: 20090216
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011157317
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20090210
FDA Date: 20090217
Follow Number:
Image ID: 6085654-9
Age: 76 YR Gender: M Weight: 165 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
 PRODUCT QUALITY ISSUE

ISR Number: 6085686 Case Number: 6921290 I/F Code: I Report Date: 20090215
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011157505
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: PP2355
Expiration Date: 20091212
Indication: ASTHMA
Route: ORAL
Dose: 90 MG 8 TIMES DAILY PO
Event Date: 20090215
FDA Date: 20090217
Follow Number:
Image ID: 6085686-0
Age: 53 YR Gender: F Weight: 130 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: LT Dechallenge Code: N Rechallenge Code: D Death Date:
Therapy Start: 20090215
Therapy End: 20090101
Duration:
Adverse Reactions:
 DEVICE FAILURE
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6085778 Case Number: 6920850 I/F Code: I Report Date: 20090215
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011157827
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose: 10 INHALATIONS DAILY
Event Date: 20090101
FDA Date: 20090217
Follow Number:
Image ID: 6085778-6
Age: 62 YR Gender: F Weight: 155 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:
Adverse Reactions:
 PRODUCT QUALITY ISSUE
 QUALITY OF LIFE DECREASED

ISR Number: 6087664 Case Number: 6924416 I/F Code: I Report Date: 20090217

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011165468

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEA89C

Expiration Date: 20100730

Indication: BRONCHITIS

Route:

Dose: 2 PUFFS INHAED BY MOUTH 4 TIMES/DAY PRN 8.5 HOURS

Event Date: 20090216

FDA Date: 20090218

Follow Number:

Image ID: 6087664-4

Age: 26 YR Gender: F Weight: 162 LBS

Occupation: OT

Country: UNITED STATES

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

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

Therapy Start: 20090216

Therapy End: 20090216

Duration:

Adverse Reactions:

- ORAL MUCOSAL ERYTHEMA
- ORAL PAIN
- PETECHIAE
- SWOLLEN TONGUE
- TONGUE DISCOLOURATION
- TONGUE DISORDER
- TONGUE HAEMORRHAGE

ISR Number: 6088636 Case Number: 6924003 I/F Code: I Report Date: 20090213

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011168719

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEA16C

Expiration Date: 20100630

Indication: ASTHMA

Route:

Dose: TWO PUFFS EVERY 6 HOURS

Event Date: 20090122

FDA Date: 20090218

Follow Number:

Image ID: 6088636-6

Age: 58 YR Gender: F Weight: 156 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20090122

Therapy End: 20090101

Duration:

Adverse Reactions:

- CHEST PAIN
- DIZZINESS
- DYSPNOEA
- HYPERHIDROSIS
- MYOCARDIAL INFARCTION

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ISR Number: 6088729 Case Number: 6924599 I/F Code: I Report Date: 20090219
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011169055
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20100702
Indication: ASTHMA
Route:
Dose:
Event Date:
FDA Date: 20090220
Follow Number:
Image ID: 6088729-3
Age: Gender: F Weight: 114 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: 20090211
Therapy End: 20090210
Duration:
Adverse Reactions:
URTICARIA

ISR Number: 6088817 Case Number: 6924461 I/F Code: I Report Date: 20090219
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011169311
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA13C
Expiration Date: 20100630
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 90 MCG 2 PUFFS 4 TIMES INHAL
Event Date: 20090218
FDA Date: 20090220
Follow Number:
Image ID: 6088817-1
Age: 49 Gender: F Weight: 250 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: N Rechallenge Code: Death Date:
Therapy Start: 20090218
Therapy End: 20090218
Duration:
Adverse Reactions:
BRONCHOSPASM
DRUG INEFFECTIVE

ISR Number: 6093759 Case Number: 6928419 I/F Code: I Report Date: 20090222

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011187887

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose: 200 METERED DOSES

Event Date: 20081110

FDA Date: 20090223

Follow Number:

Image ID: 6093759-1

Age: 60 Gender: F Weight: 110 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- DRUG INEFFECTIVE
- PRODUCT QUALITY ISSUE
- TINNITUS

ISR Number: 6097328 Case Number: 6929040 I/F Code: I Report Date: 20090225
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011199338
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA 8 98
Expiration Date: 20100731
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS EVERY 4-6 HRS. INHAL
Event Date: 20090101
FDA Date: 20090226
Follow Number:
Image ID: 6097328-9
Age: 55 YR Gender: F Weight: 175 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20090222
Therapy End: 20090101
Duration:
Adverse Reactions:
 CONDITION AGGRAVATED
 DYSPNOEA
 OXYGEN SATURATION DECREASED
 PRODUCT QUALITY ISSUE

ISR Number: 6100143 Case Number: 6933095 I/F Code: I Report Date: 20090227
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011211666
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS EVERY 4 HRS INHAL ON GOING
Event Date:
FDA Date: 20090302
Follow Number:
Image ID: 6100143-0
Age: Gender: F Weight: 175 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
PRODUCT QUALITY ISSUE
QUALITY OF LIFE DECREASED

ISR Number: 6100232 Case Number: 6933523 I/F Code: I Report Date: 20090227
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011212016
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADU88C
Expiration Date: 20090228
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS 4 TIMES DAILY PO
Event Date: 20090225
FDA Date: 20090302
Follow Number:
Image ID: 6100232-0
Age: 51 YR Gender: F Weight: 150 LBS
Occupation: OT
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: 20090125
Therapy End: 20090120
Duration:
Adverse Reactions:
BRONCHOSPASM
CHOKING SENSATION
COUGH
DRUG INEFFECTIVE
DYSPNOEA
PRODUCT QUALITY ISSUE
THROAT TIGHTNESS
WHEEZING

ISR Number: 6100451 Case Number: 6931278 I/F Code: I Report Date: 20090226
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011212892
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: TWO INHALATIONS 3 HOURS INHAL
Event Date: 20090218
FDA Date: 20090227
Follow Number:
Image ID: 6100451-3
Age: 66 YR Gender: F Weight: 175 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: D Rechallenge Code: Y Death Date:
Therapy Start: 20090226
Therapy End: 20090217
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DRUG INEFFECTIVE

ISR Number: 6111299 Case Number: 6945900 I/F Code: I Report Date: 20090309
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011252249
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20090301
FDA Date: 20090310
Follow Number:
Image ID: 6111299-8
Age: 61 YR Gender: M Weight: 215 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA
DEVICE INEFFECTIVE
DRUG INEFFECTIVE
PRODUCT QUALITY ISSUE

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ISR Number: 6111744 Case Number: 6945499 I/F Code: I Report Date: 20090309
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011253608
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose:
Event Date:
FDA Date: 20090310
Follow Number:
Image ID: 6111744-8
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: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 6112388 Case Number: 6945219 I/F Code: I Report Date: 20090303
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011256322
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEB19B
Expiration Date: 20100801
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS EVERY 2.4 HRS INHALED
Event Date: 20090101
FDA Date: 20090311
Follow Number:
Image ID: 6112388-4
Age: 51 Gender: M Weight: 230 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: LT Dechallenge Code: N Rechallenge Code: Y Death Date:
Therapy Start: 20090303
Therapy End: 20090101
Duration:
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE
PRODUCT QUALITY ISSUE

ISR Number: 6120605 Case Number: 6949272 I/F Code: I Report Date: 20090219
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011286798
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA12C
Expiration Date: 20100731
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: INHALE 2 PUFFS EVERY 4 HOURS
Event Date: 20090202
FDA Date: 20090312
Follow Number:
Image ID: 6120605-X
Age: 72 YR Gender: M Weight:
Occupation: PH
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: 20090130
Duration:
Adverse Reactions:
CHEST DISCOMFORT
CONDITION AGGRAVATED
FEELING ABNORMAL
PRODUCT QUALITY ISSUE
WHEEZING

ISR Number: 6121491 Case Number: 6948042 I/F Code: I Report Date: 20090312
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011289916
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADY53C
Expiration Date: 20100401
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 TO 3 PUFFS EVERY 4 HOURS INHAL
Event Date: 20090101
FDA Date: 20090313
Follow Number:
Image ID: 6121491-4
Age: 55 YR Gender: F Weight: 180 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20090312
Therapy End: 20090101
Duration: 3 MON
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

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ISR Number: 6121496 Case Number: 6948044 I/F Code: I Report Date: 20090312
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011289924
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA26C
Expiration Date: 20100630
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS 4 TIMES A DAY PO
Event Date:
FDA Date: 20090313
Follow Number:
Image ID: 6121496-3
Age: Gender: Weight:
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: 20090312
Therapy End: 20080901
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6124332 Case Number: 6951641 I/F Code: I Report Date: 20090317
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011301626
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEB74B
Expiration Date: 20100901
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: ORAL
Dose: 90MCG 4 TIMES DAILY PO
Event Date: 20090317
FDA Date: 20090318
Follow Number:
Image ID: 6124332-4
Age: 42 YR Gender: M Weight: 182 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: 20090317
Therapy End: 20090115
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 FEAR
 PRESYNCOPE
 PRODUCT QUALITY ISSUE

ISR Number: 6126948 Case Number: 6947637 I/F Code: I Report Date: 20090319
Drug Name: **SALBUTAMOL**
NDA Number: 21457
Role Code: PS VAL/VBM: 2
Seq Number: 1011311539
Mfg. Date: 20090309
Mfg. Number: GB-TEVA-187232ISR
Mfg. Sender: TEVA
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date:
FDA Date: 20090320
Follow Number:
Image ID: 6126948-8
Age: 13 YR Gender: M Weight:
Occupation:
Country: UNITED KINGDOM
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 INTENTIONAL DRUG MISUSE
 THERMAL BURN

ISR Number: 6128226 Case Number: 6954132 I/F Code: I Report Date: 20090226
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011316439
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AFA
Expiration Date: 20100701
Indication: ASTHMA
Route:
Dose: 200 @6 HOURS A DAY
Event Date: 20090101
FDA Date: 20090320
Follow Number:
Image ID: 6128226-X
Age: Gender: Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
PRODUCT QUALITY ISSUE

ISR Number: 6129197 Case Number: 6956244 I/F Code: I Report Date: 20090317

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011320049

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEB19B

Expiration Date: 20100831

Indication: DYSPNOEA

Route:

Dose: INHALER

Event Date: 20090212

FDA Date: 20090323

Follow Number:

Image ID: 6129197-2

Age: 73 YR Gender: M Weight:

Occupation: PH

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- DEVICE FAILURE
- DRUG INEFFECTIVE
- DYSPNOEA

ISR Number: 6130622 Case Number: 6950596 I/F Code: I Report Date: 20090323

Drug Name: **SALBUTAMOL**

NDA Number: 21457

Role Code: PS VAL/VBM: 2

Seq Number: 1011325938

Mfg. Date: 20090313

Mfg. Number: FR-TEVA-187018ISR

Mfg. Sender: TEVA

Lot Number:

Expiration Date:

Indication: BRONCHITIS

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20090325

Follow Number:

Image ID: 6130622-1

Age: Gender: F Weight:

Occupation: MD

Country: FRANCE

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

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

Therapy Start: 20090221

Therapy End: 20090217

Duration:

Adverse Reactions:

- ASTHENIA
- EUPHORIC MOOD
- TACHYCARDIA

ISR Number: 6138328 Case Number: 6961493 I/F Code: I Report Date: 20090326

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011357181

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: ENDOTRACHEAL

Dose: AS NEEDED ENDOTRACHEA

Event Date:

FDA Date: 20090330

Follow Number:

Image ID: 6138328-X

Age: Gender: Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20090326

Therapy End: 20090101

Duration:

Adverse Reactions:

- CONDITION AGGRAVATED
- DYSPNOEA
- ILL-DEFINED DISORDER
- PRODUCT QUALITY ISSUE
- WHEEZING

ISR Number: 6138348 Case Number: 6960899 I/F Code: I Report Date: 20090326
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011357254
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose: 4 TIMES DAILY
Event Date: 20080201
FDA Date: 20090327
Follow Number:
Image ID: 6138348-5
Age: 61 YR Gender: F Weight: 165 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: 20080205
Therapy End: 20080202
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 NO THERAPEUTIC RESPONSE
 PRODUCT QUALITY ISSUE

ISR Number: 6140676 Case Number: 6962089 I/F Code: I Report Date: 20090330
Drug Name: **PROAIR**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011367091
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA13A
Expiration Date: 20100601
Indication:
Route: RESPIRATORY (INHALATION)
Dose: 90MCG/PUFF AS NEEDED INHALED
Event Date:
FDA Date: 20090331
Follow Number:
Image ID: 6140676-4
Age: Gender: F Weight: 165 LBS
Occupation: MD
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: 20090330
Therapy End: 20090105
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 PRODUCT QUALITY ISSUE

ISR Number: 6141191 Case Number: 6964620 I/F Code: I Report Date: 20090329

Drug Name: **PROAIR**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011368704

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: DRUG HYPERSENSITIVITY

Route:

Dose: 2 PUFFS EVERY 6 HOURS

Event Date: 20080430

FDA Date: 20090330

Follow Number:

Image ID: 6141191-4

Age: 41 YR Gender: F Weight: 200 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20081102

Therapy End: 20080930

Duration:

Adverse Reactions:

- ASTHMA
- CHOKING
- CONDITION AGGRAVATED
- DIZZINESS
- DRUG DEPENDENCE
- DRUG INEFFECTIVE
- FEELING ABNORMAL
- HEADACHE
- INSOMNIA
- LUNG DISORDER
- MALAISE
- NAUSEA
- PALPITATIONS
- PRODUCT QUALITY ISSUE
- SPEECH DISORDER