

ISR Number: 6158249 Case Number: 6973751 I/F Code: I Report Date: 20090413

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011441512

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEA89B

Expiration Date: 20100731

Indication: ASTHMA

Route:

Dose: ONE PUFF

Event Date: 20090413

FDA Date: 20090413

Follow Number:

Image ID: 6158249-6

Age: 34 Gender: F Weight: 170 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: 20090413

Therapy End: 20090413

Duration:

Adverse Reactions:

- ABDOMINAL DISCOMFORT
- ASTHMA
- CONDITION AGGRAVATED
- HEADACHE
- PRODUCT QUALITY ISSUE
- RESPIRATORY TRACT IRRITATION

ISR Number: 6159263 Case Number: 6972007 I/F Code: I Report Date: 20090416

Drug Name: **SALBUTAMOL**

NDA Number: 21457

Role Code: PS VAL/VBM: 2

Seq Number: 1011445607

Mfg. Date: 20090407

Mfg. Number: NL-TEVA-191158ISR

Mfg. Sender: TEVA

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070601

FDA Date: 20090417

Follow Number:

Image ID: 6159263-7

Age: 15 Gender: M Weight: 52 KG

Occupation: PH

Country: NETHERLANDS

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

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

Therapy Start:

Therapy End: 20070327

Duration:

Adverse Reactions:

ENAMEL ANOMALY

TOOTH DISORDER

ISR Number: 6160311 Case Number: 6990064 I/F Code: I Report Date: 20090404
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011450211
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADQ81B
Expiration Date: 20080801
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 90 MCG (2 PUFFS) 3X DAY
Event Date:
FDA Date: 20090416
Follow Number:
Image ID: 6160311-9
Age: Gender: M Weight: 280 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: 20070101
Duration:
Adverse Reactions:
PRODUCT QUALITY ISSUE

ISR Number: 6163565 Case Number: 6978781 I/F Code: I Report Date: 20090418

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011463118

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEA56A

Expiration Date: 20100701

Indication: ASTHMA

Route: ORAL

Dose: 2-3 INHALATIONS 4 TIMES A DAY PO

Event Date: 20090305

FDA Date: 20090420

Follow Number:

Image ID: 6163565-8

Age: 28 YR Gender: M Weight: 245 LBS

Occupation: CN

Country: GUAM

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

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

Therapy Start: 20090418

Therapy End: 20081208

Duration:

Adverse Reactions:

- DECREASED ACTIVITY
- DEVICE MALFUNCTION
- DRUG INEFFECTIVE
- FEAR
- PRODUCT SUBSTITUTION ISSUE
- WEIGHT INCREASED

ISR Number: 6163963 Case Number: 6975314 I/F Code: I Report Date: 20090422

Drug Name: **SALBUTAMOL SULFATE INHALATION, 0.09 MG**

NDA Number: 21457

Role Code: PS VAL/VBM: 2

Seq Number: 1011464638

Mfg. Date: 20090416

Mfg. Number: US-TEVA-191810USA

Mfg. Sender: TEVA

Lot Number:

Expiration Date:

Indication: OESOPHAGEAL SPASM

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS PRN AS RESCUE

Event Date: 20090410

FDA Date: 20090422

Follow Number:

Image ID: 6163963-2

Age: 64 Gender: F Weight: 56.7 KG

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20081201

Duration:

Adverse Reactions:

- CHRONIC OBSTRUCTIVE PULMONARY DISEASE
- DEVICE CONNECTION ISSUE
- DYSPNOEA
- PNEUMONIA

ISR Number: 6167270 Case Number: 6977589 I/F Code: I Report Date: 20090424
Drug Name: **SALBUTAMOL**
NDA Number: 21457
Role Code: PS VAL/VBM: 2
Seq Number: 1011477222
Mfg. Date: 20090417
Mfg. Number: GB-TEVA-192063ISR
Mfg. Sender: TEVA
Lot Number: ADU84A
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090424
Follow Number:
Image ID: 6167270-3
Age: Gender: F Weight:
Occupation: OT
Country: UNITED KINGDOM
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: Rechallenge Code: Death Date: 20080507
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA

ISR Number: 6168649 Case Number: 6990089 I/F Code: I Report Date: 20090420

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011483176

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date: 20100620

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20090101

FDA Date: 20090424

Follow Number:

Image ID: 6168649-6

Age: 63 YR Gender: M Weight: 210 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:

Therapy End:

Duration:

Adverse Reactions:

- DEVICE MALFUNCTION
- DRUG INEFFECTIVE
- OROPHARYNGITIS FUNGAL
- PRODUCT QUALITY ISSUE
- PRODUCT SUBSTITUTION ISSUE

ISR Number: 6170230 Case Number: 6985863 I/F Code: I Report Date: 20090426
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011489460
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: PP2472
Expiration Date: 20070701
Indication: COUGH
Route: RESPIRATORY (INHALATION)
Dose: TWO PUFFS Q 6 HRS PRN INHALE
Event Date: 20090325
FDA Date: 20090427
Follow Number:
Image ID: 6170230-X
Age: 56 Gender: F Weight: 200 LBS
Occupation: OT
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: 20090325
Duration:
Adverse Reactions:
APHONIA
IMPAIRED WORK ABILITY
LARYNGITIS
THERMAL BURN
VOCAL CORD DISORDER

ISR Number: 6170984 Case Number: 6980310 I/F Code: I Report Date: 20090428

Drug Name: **SALBUTAMOL**

NDA Number: 21457

Role Code: PS VAL/VBM: 2

Seq Number: 1011492533

Mfg. Date: 20090422

Mfg. Number: FR-TEVA-192787ISR

Mfg. Sender: TEVA

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20090218

FDA Date: 20090429

Follow Number:

Image ID: 6170984-2

Age: 22 Gender: M Weight:

Occupation: OT

Country: FRANCE

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

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

Therapy Start: 20090220

Therapy End: 20090219

Duration:

Adverse Reactions:

- ASTHMATIC CRISIS
- BLOOD PHOSPHORUS DECREASED
- DYSPNOEA
- FATIGUE
- GLYCOSURIA
- HYPERGLYCAEMIA
- HYPOKALAEMIA
- MYALGIA
- RESPIRATORY DISORDER
- VOMITING

ISR Number: 6171131 Case Number: 6988099 I/F Code: I Report Date: 20090427
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011493098
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose:
Event Date: 20090403
FDA Date: 20090428
Follow Number:
Image ID: 6171131-3
Age: 20 YR Gender: M Weight: 138 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG EFFECT DECREASED

ISR Number: 6172145 Case Number: 6987476 I/F Code: I Report Date: 20090426

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011496614

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: MDI PRN INHAL

Event Date: 20090425

FDA Date: 20090427

Follow Number:

Image ID: 6172145-X

Age: 25 YR Gender: M Weight: 200 LBS

Occupation:

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: 20090426

Therapy End: 20090122

Duration:

Adverse Reactions:

DRUG EFFECT DECREASED

PRODUCT QUALITY ISSUE

PRODUCT SUBSTITUTION ISSUE

ISR Number: 6173917 Case Number: 6988226 I/F Code: I Report Date: 20090428
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011503262
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1-2PUFFS AS NEEDED INHAL
Event Date: 20090420
FDA Date: 20090429
Follow Number:
Image ID: 6173917-8
Age: 41 Gender: F 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
DEVICE MALFUNCTION
DRUG INEFFECTIVE
PRODUCT SUBSTITUTION ISSUE

ISR Number: 6173925 Case Number: 6988297 I/F Code: I Report Date: 20090428

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011503281

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEB73C

Expiration Date: 20100930

Indication: ASTHMA

Route:

Dose: 1 INHALATIONS Q4H PRN

Event Date: 20090101

FDA Date: 20090429

Follow Number:

Image ID: 6173925-7

Age: 18 YR Gender: F Weight: 110 LBS

Occupation: PH

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: 20090420

Therapy End: 20090101

Duration:

Adverse Reactions:

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

ISR Number: 6180308 Case Number: 6992428 I/F Code: I Report Date: 20090502

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011532227

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEA56A

Expiration Date: 20100731

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 90MCG/INHALATION 2 PUFFS Q4H PRN INHAL

Event Date: 20081228

FDA Date: 20090504

Follow Number:

Image ID: 6180308-2

Age: 31 Gender: M Weight: 160 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: 20090501

Therapy End: 20090101

Duration:

Adverse Reactions:

ASTHMA

DRUG EFFECT DECREASED

PRODUCT QUALITY ISSUE

ISR Number: 6180309 Case Number: 6992436 I/F Code: I Report Date: 20090502
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011532228
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA12C
Expiration Date: 20100731
Indication: EMPHYSEMA
Route:
Dose:
Event Date: 20090301
FDA Date: 20090504
Follow Number:
Image ID: 6180309-4
Age: 59 YR Gender: F Weight: 142 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start: 20090425
Therapy End: 20090210
Duration:
Adverse Reactions:
 DEVICE MALFUNCTION
 INCORRECT DOSE ADMINISTERED
 PRODUCT QUALITY ISSUE

ISR Number: 6181098 Case Number: 6993013 I/F Code: I Report Date: 20090503

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011535059

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY SIX HOURS INHAL

Event Date: 20090101

FDA Date: 20090504

Follow Number:

Image ID: 6181098-X

Age: 32 YR Gender: F Weight: 140 LBS

Occupation: CN

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: 20090401

Therapy End: 20081001

Duration:

Adverse Reactions:

ASTHMA

CONDITION AGGRAVATED

DRUG INEFFECTIVE

ISR Number: 6182201 Case Number: 6992902 I/F Code: I Report Date: 20090504
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011539167
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEB73B
Expiration Date: 20100407
Indication: ASTHMA
Route:
Dose: 90 MCG 3X DAILY INHAL
Event Date: 20090430
FDA Date: 20090505
Follow Number:
Image ID: 6182201-8
Age: 40 YR Gender: M Weight: 198 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: N Rechallenge Code: D Death Date:
Therapy Start: 20090430
Therapy End: 20090407
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT SUBSTITUTION ISSUE
 PRODUCT TASTE ABNORMAL

ISR Number: 6183701 Case Number: 6989785 I/F Code: I Report Date: 20090507
Drug Name: **SALBUTAMOL**
NDA Number: 21457
Role Code: PS VAL/VBM: 2
Seq Number: 1011545005
Mfg. Date: 20090430
Mfg. Number: GB-TEVA-193497ISR
Mfg. Sender: TEVA
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090508
Follow Number:
Image ID: 6183701-7
Age: 13 MON 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:
HYPERGLYCAEMIA

ISR Number: 6184175 Case Number: 6993587 I/F Code: I Report Date: 20090505

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011546655

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA EXERCISE INDUCED

Route: ORAL

Dose: REGULAR 2XMTHS SINCE 2/09 PO

Event Date: 20090425

FDA Date: 20090506

Follow Number:

Image ID: 6184175-2

Age: 32 YR Gender: F Weight: 150 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20090425

Therapy End: 20090201

Duration:

Adverse Reactions:

- ASTHENIA
- ASTHMA
- CONDITION AGGRAVATED
- COUGH
- DRUG EFFECT DECREASED
- DRUG INEFFECTIVE
- DYSPHAGIA
- EAR PAIN
- INFLUENZA
- OROPHARYNGEAL PAIN
- PRODUCT QUALITY ISSUE
- PRODUCT SUBSTITUTION ISSUE
- QUALITY OF LIFE DECREASED
- THROAT IRRITATION

ISR Number: 6184180 Case Number: 6993699 I/F Code: I Report Date: 20090505
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011546662
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose: 8 DOSES/DAY
Event Date: 20090505
FDA Date: 20090508
Follow Number:
Image ID: 6184180-6
Age: 72 Gender: M Weight: 175 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:
 PRODUCT DOSAGE FORM ISSUE

ISR Number: 6184187 Case Number: 6993724 I/F Code: I Report Date: 20090505

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011546689

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEC12A

Expiration Date: 20101031

Indication: CYSTIC FIBROSIS

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS TWICE DAILY INHAL

Event Date: 20090421

FDA Date: 20090506

Follow Number:

Image ID: 6184187-9

Age: 31 Gender: M 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: 20090418

Therapy End: 20090401

Duration:

Adverse Reactions:

- BACTERIA SPUTUM IDENTIFIED
- CHILLS
- COUGH
- DEVICE MALFUNCTION
- DYSPNOEA
- MALAISE
- NIGHT SWEATS
- PRODUCT QUALITY ISSUE
- PYREXIA

ISR Number: 6186972 Case Number: 6995507 I/F Code: I Report Date: 20090507

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011559063

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: MULTIPLE ALLERGIES

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS 4 HOURS INHAL

Event Date: 20090427

FDA Date: 20090508

Follow Number:

Image ID: 6186972-6

Age: 8 YR Gender: M Weight: 83 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20090427

Therapy End: 20080925

Duration:

Adverse Reactions:

- ASTHMA
- DEVICE OCCLUSION
- GENERAL PHYSICAL HEALTH DETERIORATION
- INCORRECT DOSE ADMINISTERED
- MALAISE
- OROPHARYNGEAL PAIN
- PRODUCT QUALITY ISSUE
- RHINORRHOEA
- VIRAL INFECTION

ISR Number: 6189937 Case Number: 6998200 I/F Code: I Report Date: 20090510
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011571651
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA56A
Expiration Date: 20100227
Indication: ASTHMA
Route:
Dose: 1 PUFF EVERY 4 HR
Event Date: 20090321
FDA Date: 20090512
Follow Number:
Image ID: 6189937-3
Age: 45 YR Gender: M Weight: 295 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: RI Dechallenge Code: Y Rechallenge Code: Y Death Date:
Therapy Start: 20090321
Therapy End: 20090227
Duration:
Adverse Reactions:
LUNG INFECTION
PULMONARY OEDEMA

ISR Number: 6196566 Case Number: 7003186 I/F Code: I Report Date: 20090516

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011600761

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEA13B

Expiration Date: 20100630

Indication: ASTHMA

Route:

Dose: INHALE 2 PUFFS 4 HRS AS NEEDED

Event Date: 20090426

FDA Date: 20090518

Follow Number:

Image ID: 6196566-4

Age: 15 YR Gender: M Weight: 198 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20090430

Therapy End: 20090426

Duration:

Adverse Reactions:

APPARENT LIFE THREATENING EVENT

PRODUCT QUALITY ISSUE

THERAPEUTIC RESPONSE DECREASED

ISR Number: 6196717 Case Number: 7002771 I/F Code: I Report Date: 20090515
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011601284
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEB19A
Expiration Date: 20100204
Indication:
Route:
Dose:
Event Date: 20090301
FDA Date: 20090518
Follow Number:
Image ID: 6196717-1
Age: 81 Gender: M Weight:
Occupation: PH
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: HO Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
THROAT IRRITATION

ISR Number: 6199670 Case Number: 7008828 I/F Code: I Report Date: 20090505
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011613299
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose: AS REQUIRED
Event Date: 20081201
FDA Date: 20090520
Follow Number:
Image ID: 6199670-X
Age: 54 Gender: M Weight: 235 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6202419 Case Number: 7007580 I/F Code: I Report Date: 20090513
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011626569
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: ADV555C
Expiration Date: 20091201
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route:
Dose: 90 MCG 2 PUFFS 4 TIMES DAILY
Event Date:
FDA Date: 20090521
Follow Number:
Image ID: 6202419-5
Age: 68 YR Gender: M Weight: 230 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Rechallenge Code: Y Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DYSпноEA
 MUCOUS MEMBRANE DISORDER

ISR Number: 6202611 Case Number: 7007120 I/F Code: I Report Date: 20090520
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011627149
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose: 100MG
Event Date: 20090520
FDA Date: 20090521
Follow Number:
Image ID: 6202611-X
Age: 38 YR Gender: M Weight: 165 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG HYPERSENSITIVITY
 WHEEZING

ISR Number: 6203337 Case Number: 7007832 I/F Code: I Report Date: 20090521

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011630123

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date:

FDA Date: 20090522

Follow Number:

Image ID: 6203337-9

Age: 26 YR Gender: F Weight: 150 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DEVICE FAILURE
- DRUG INEFFECTIVE
- NERVOUSNESS
- PARANOIA
- PRODUCT QUALITY ISSUE

ISR Number: 6203340 Case Number: 7007853 I/F Code: I Report Date: 20090521

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011630129

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date:

FDA Date: 20090522

Follow Number:

Image ID: 6203340-9

Age: Gender: M Weight: 180 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 EFFECT DECREASED

PRODUCT QUALITY ISSUE

PRODUCT SUBSTITUTION ISSUE

ISR Number: 6203346 Case Number: 7007881 I/F Code: I Report Date: 20090521

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011630146

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEC23C

Expiration Date: 20101031

Indication: ASTHMA

Route: ORAL

Dose: 2 PUFFS EVERY 4 HOURS PO 1 TIME

Event Date: 20090520

FDA Date: 20090522

Follow Number:

Image ID: 6203346-X

Age: 50 YR Gender: F Weight: 200 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: 20090520

Therapy End: 20090520

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PRODUCT SUBSTITUTION ISSUE

ISR Number: 6204042 Case Number: 7008283 I/F Code: I Report Date: 20090522

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011632518

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: BUCCAL

Dose: 108 MCG PRN BUCCAL

Event Date: 20090101

FDA Date: 20090526

Follow Number:

Image ID: 6204042-5

Age: 58 YR Gender: M Weight: 250 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20090515

Therapy End: 20090101

Duration:

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DRUG EFFECT DECREASED
- PRODUCT SUBSTITUTION ISSUE

ISR Number: 6204116 Case Number: 7007428 I/F Code: I Report Date: 20090525

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011632872

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEC24A

Expiration Date: 20101101

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: TWO PUFFS AS NEEDED INHAL

Event Date: 20090524

FDA Date: 20090526

Follow Number:

Image ID: 6204116-9

Age: 47 YR Gender: M Weight: 180 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: 20090524

Therapy End: 20090521

Duration:

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DRUG INEFFECTIVE
- DYSPHONIA
- LARYNGITIS

ISR Number: 6204135 Case Number: 7008120 I/F Code: I Report Date: 20090523

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011632912

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: ADZ291C

Expiration Date: 20100501

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: @ PUFFS 4 TIMES A DAY INHAL

Event Date:

FDA Date: 20090526

Follow Number:

Image ID: 6204135-2

Age: 73 YR Gender: M Weight: 185 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: 20090523

Therapy End: 20080314

Duration: 15 MON

Adverse Reactions:

PRODUCT QUALITY ISSUE

PRODUCT SUBSTITUTION ISSUE

ISR Number: 6206397 Case Number: 7009120 I/F Code: I Report Date: 20090526
 Drug Name: **PROAIR HFA**
 NDA Number:
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011642630
 Mfg. Date:
 Mfg. Number:
 Mfg. Sender:
 Lot Number:
 Expiration Date:
 Indication: ASTHMA
 Route:
 Dose: 2 PUFFS EVERY 4 HOURS INHAL
 Event Date:
 FDA Date: 20090527
 Follow Number:
 Image ID: 6206397-4
 Age: 37 YR Gender: F Weight: 135 LBS
 Occupation:
 Country: UNITED STATES
 Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
 Outcome Code: HO Dechallenge Code: D Rechallenge Code: Y Death Date:
 Therapy Start: 20090526
 Therapy End: 20080916
 Duration:
 Adverse Reactions:
 DRUG INEFFECTIVE

ISR Number: 6206402 Case Number: 7009139 I/F Code: I Report Date: 20090526
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011642638
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: TWO INHALATIONS AS NEEDED PO
Event Date: 20090526
FDA Date: 20090527
Follow Number:
Image ID: 6206402-5
Age: 29 YR Gender: F Weight: 127 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: 20090526
Therapy End: 20081118
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DRUG DELIVERY SYSTEM MALFUNCTION
DRUG INEFFECTIVE
PRODUCT QUALITY ISSUE

ISR Number: 6207362 Case Number: 7009510 I/F Code: I Report Date: 20090526
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011646348
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEB85A
Expiration Date: 20101001
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PRN INHAL
Event Date: 20090526
FDA Date: 20090527
Follow Number:
Image ID: 6207362-3
Age: 15 YR Gender: M Weight: 150 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: 20090526
Therapy End: 20090101
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 6207423 Case Number: 7009551 I/F Code: I Report Date: 20090526

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011646576

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: AEC03A

Expiration Date: 20101031

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS 4 TIMES DAILY INHAL

Event Date: 20090430

FDA Date: 20090527

Follow Number:

Image ID: 6207423-9

Age: 52 Gender: Weight: 165 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: 20090525

Therapy End: 20081219

Duration:

Adverse Reactions:

DRUG EFFECT DECREASED

HERNIA

ISR Number: 6216762 Case Number: 7015059 I/F Code: I Report Date: 20090602

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011682480

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 3 DIFFERENT LO

Expiration Date: 20100606

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 200 METERED INHALATIONS

Event Date: 20090515

FDA Date: 20090603

Follow Number:

Image ID: 6216762-7

Age: 51 YR Gender: F Weight: 120 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: 20090602

Therapy End: 20090515

Duration:

Adverse Reactions:

- DRUG INEFFECTIVE
- DYSPNOEA
- OROPHARYNGEAL PAIN

ISR Number: 6216822 Case Number: 7016357 I/F Code: I Report Date: 20090603
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011682634
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20100428
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS 4-6 A DAY ORAL
Event Date: 20090428
FDA Date: 20090603
Follow Number:
Image ID: 6216822-0
Age: 74 Gender: F Weight: 201 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:
Therapy End: 20090428
Duration:
Adverse Reactions:
ASTHMA
DEVICE FAILURE
DRUG EFFECT DECREASED

ISR Number: 6217933 Case Number: 7016814 I/F Code: I Report Date: 20090603
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011686552
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEA56A
Expiration Date: 20100731
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: FEW PUFFS 2XDAY INHAL
Event Date: 20090603
FDA Date: 20090604
Follow Number:
Image ID: 6217933-6
Age: 33 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: 20090603
Therapy End: 20090602
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 HEADACHE

ISR Number: 6219173 Case Number: 7018447 I/F Code: I Report Date: 20090604
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011691778
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20100331
Indication: ASTHMA
Route: ORAL
Dose: 1 INHALATION ONCE PO
Event Date: 20090527
FDA Date: 20090605
Follow Number:
Image ID: 6219173-3
Age: 40 YR Gender: F Weight: 117 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: 20090528
Therapy End: 20090103
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT SUBSTITUTION ISSUE

ISR Number: 6222051 Case Number: 7022609 I/F Code: I Report Date: 20090605

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011703885

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: ORAL

Dose: 2 PUFFS 4X AS NEEDED PO

Event Date: 20080925

FDA Date: 20090608

Follow Number:

Image ID: 6222051-7

Age: 61 YR Gender: M Weight: 300 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20080901

Therapy End: 20080901

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PRODUCT SUBSTITUTION ISSUE

ISR Number: 6222055 Case Number: 7022612 I/F Code: I Report Date: 20090605
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011703903
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4 X ADAY 4X A DAY INHAL
Event Date: 20080509
FDA Date: 20090608
Follow Number:
Image ID: 6222055-4
Age: 53 YR Gender: F Weight: 160 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: HO Dechallenge Code: Y Rechallenge Code: Y Death Date:
Therapy Start: 20081026
Therapy End: 20080125
Duration:
Adverse Reactions:
 DEVICE MALFUNCTION
 DRUG INEFFECTIVE
 DYSPNOEA

ISR Number: 6222547 Case Number: 7022767 I/F Code: I Report Date: 20090608

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011705754

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 108 MCG 12-15 INHAL

Event Date:

FDA Date: 20090609

Follow Number:

Image ID: 6222547-8

Age: 59 YR Gender: M Weight: 200 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20090606

Therapy End: 20080615

Duration:

Adverse Reactions:

ASTHMA

CONDITION AGGRAVATED

DRUG INEFFECTIVE

PRODUCT QUALITY ISSUE

ISR Number: 6231436 Case Number: 7026610 I/F Code: I Report Date: 20090610
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011738329
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: ORAL
Dose: 2 PUFFFS 4/DAY PO MONTHS
Event Date: 20090603
FDA Date: 20090611
Follow Number:
Image ID: 6231436-4
Age: 52 YR Gender: F Weight: 250 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DEVICE FAILURE

ISR Number: 6231818 Case Number: 7032184 I/F Code: I Report Date: 20090610

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011739784

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date:

FDA Date: 20090611

Follow Number:

Image ID: 6231818-0

Age: 39 YR Gender: F Weight: 195 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:

COUGH

DRUG INEFFECTIVE

INCORRECT DOSE ADMINISTERED

WHEEZING

ISR Number: 6234600 Case Number: 7030133 I/F Code: I Report Date: 20090610
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011749745
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date:
FDA Date: 20090616
Follow Number:
Image ID: 6234600-3
Age: 39 YR Gender: F Weight: 195 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 INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6241163 Case Number: 7036436 I/F Code: I Report Date: 20090617

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011773346

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date: 20090315

FDA Date: 20090619

Follow Number:

Image ID: 6241163-5

Age: 52 Gender: M Weight: 160 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG DELIVERY SYSTEM MALFUNCTION

PRODUCT QUALITY ISSUE

ISR Number: 6243289 Case Number: 7038706 I/F Code: I Report Date: 20090621

Drug Name: **PROAIR HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011785351

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS AS NEEDED EVERY 4 HRS INHAL

Event Date: 20080701

FDA Date: 20090622

Follow Number:

Image ID: 6243289-9

Age: 37 YR Gender: F Weight:

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: 20090621

Therapy End: 20080701

Duration:

Adverse Reactions:

- DECREASED ACTIVITY
- DRUG EFFECT DECREASED
- PRODUCT QUALITY ISSUE
- PRODUCT SUBSTITUTION ISSUE
- QUALITY OF LIFE DECREASED

ISR Number: 6247507 Case Number: 7034741 I/F Code: I Report Date: 20090626
Drug Name: **ALBUTEROL**
NDA Number: 21457
Role Code: PS VAL/VBM: 1
Seq Number: 1011800141
Mfg. Date: 20090617
Mfg. Number: GB-TEVA-198697ISR
Mfg. Sender: TEVA
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090626
Follow Number:
Image ID: 6247507-2
Age: 41 YR Gender: F Weight:
Occupation:
Country: UNITED KINGDOM
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
HYPOKALAEMIA
MYOCARDIAL INFARCTION

ISR Number: 6248534 Case Number: 7046817 I/F Code: I Report Date: 20090609
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011804994
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: XE074C
Expiration Date: 20100901
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS BY MOUTH 4X DAY
Event Date: 20090524
FDA Date: 20090624
Follow Number:
Image ID: 6248534-1
Age: 83 Gender: M 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: D Death Date:
Therapy Start:
Therapy End: 20090524
Duration:
Adverse Reactions:
TREMOR

ISR Number: 6249087 Case Number: 7040564 I/F Code: I Report Date: 20090623
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011806830
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEC23A
Expiration Date: 20101031
Indication: ASTHMA
Route: ORAL
Dose: 90 MCG 1-2 PUFFS Q 4 HRS PO ONE DOSE
Event Date: 20090622
FDA Date: 20090624
Follow Number:
Image ID: 6249087-4
Age: 51 YR Gender: F Weight: 228 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: 20090622
Therapy End: 20090622
Duration:
Adverse Reactions:
TINNITUS

ISR Number: 6253167 Case Number: 7045107 I/F Code: I Report Date: 20090626
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011824525
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: AEC57A
Expiration Date: 20101130
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS EVERY 6 HOURS PO
Event Date: 20090625
FDA Date: 20090629
Follow Number:
Image ID: 6253167-7
Age: 32 Gender: M Weight: 220 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: 20090626
Therapy End: 20090106
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DEVICE OCCLUSION

ISR Number: 6253810 Case Number: 7045768 I/F Code: I Report Date: 20090627
Drug Name: **PROAIR HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011827456
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20100531
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS 4 A DAY AS NEEDED PROAIR
Event Date: 20090623
FDA Date: 20090629
Follow Number:
Image ID: 6253810-2
Age: 50 YR Gender: F Weight: 155 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: RI Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start: 20090630
Therapy End: 20081030
Duration:
Adverse Reactions:
DRUG INEFFECTIVE
IMPAIRED WORK ABILITY
MALAISE
PNEUMONIA
QUALITY OF LIFE DECREASED