

ISR Number: 4701878 Case Number: 5831245 I/F Code: I Report Date: 20050623

Drug Name: **LEVALBUTEROL MDI-HFA (TARTRATE) (90 UG)**

NDA Number: 21730

Role Code: PS VAL/VBM: 2

Seq Number: 1006154270

Mfg. Date: 20050610

Mfg. Number: 2005SP001129

Mfg. Sender: SEPRACOR INC.

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 90 UG; INHALATION

Event Date: 20050608

FDA Date: 20050627

Follow Number:

Image ID: 4701878-4

Age: 15 YR Gender: M Weight: 58.2 KG

Occupation: MD

Country:

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

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

Therapy Start: 20050608

Therapy End: 20041227

Duration:

Adverse Reactions:

BLOOD PH DECREASED

SOMNOLENCE

STATUS ASTHMATICUS

THERAPY NON-RESPONDER

ISR Number: 4967505 Case Number: 6026394 I/F Code: I Report Date: 20060406
Drug Name: **XOPENEX HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1007147674
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: LUNG DISORDER
Route:
Dose:
Event Date:
FDA Date: 20060407
Follow Number:
Image ID: 4967505-6
Age: 60 YR Gender: M Weight: 100 LBS
Occupation: MD
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: 20060406
Therapy End: 20060101
Duration:
Adverse Reactions:
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR
MEDICATION ERROR
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5073203 Case Number: 6072509 I/F Code: I Report Date: 20060706
Drug Name: **XOPENEX HFA**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1007552505
Mfg. Date: 20060525
Mfg. Number: 2006SP002068
Mfg. Sender: SEPRACOR INC.
Lot Number:
Expiration Date:
Indication:
Route:
Dose: INHALATION
Event Date: 20060501
FDA Date: 20060710
Follow Number:
Image ID: 5073203-3
Age: Gender: F Weight:
Occupation: PH
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: U Rechallenge Code: D Death Date:
Therapy Start: 20060501
Therapy End: 20060425
Duration:
Adverse Reactions:
CARDIAC DISORDER

ISR Number: 5078703 Case Number: 6110020 I/F Code: I Report Date: 20060807

Drug Name: **XOPENEX HFA**

NDA Number: 21730

Role Code: PS VAL/VBM: 1

Seq Number: 1007572320

Mfg. Date: 20060802

Mfg. Number: 2006SP002754

Mfg. Sender: SEPRACOR INC.

Lot Number: 50626

Expiration Date: 20070501

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 90 UG; BID; INHALATION

Event Date: 20060101

FDA Date: 20060808

Follow Number:

Image ID: 5078703-8

Age: 65 YR Gender: F Weight:

Occupation: PH

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20060101

Duration:

Adverse Reactions:

ASTHENIA

COUGH

FEELING ABNORMAL

INTERVERTEBRAL DISC PROTRUSION

ISR Number: 5114892 Case Number: 6141762 I/F Code: I Report Date: 20060921

Drug Name: **XOPENEX**

NDA Number: 21730

Role Code: PS VAL/VBM: 1

Seq Number: 1007705084

Mfg. Date: 20060913

Mfg. Number: 2006SP003269

Mfg. Sender: SEPRACOR INC.

Lot Number: 50702

Expiration Date: 20070701

Indication: BRONCHITIS

Route: RESPIRATORY (INHALATION)

Dose: 45 UG; INHALATION

Event Date: 20060913

FDA Date: 20060922

Follow Number:

Image ID: 5114892-4

Age: Gender: F Weight:

Occupation: PH

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20060913

Duration:

Adverse Reactions:

- CHOKING
- FOREIGN BODY ASPIRATION
- SENSATION OF FOREIGN BODY

ISR Number: 5139538 Case Number: 6164546 I/F Code: I Report Date: 20061023

Drug Name: **XOPENEX HFA**

NDA Number: 20837

Role Code: PS VAL/VBM: 1

Seq Number: 1007806233

Mfg. Date: 20061009

Mfg. Number: 2006SP003658

Mfg. Sender: SEPRACOR INC

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 90 UG; QID; INHALATION

Event Date: 20060921

FDA Date: 20061024

Follow Number:

Image ID: 5139538-0

Age: 71 YR Gender: M Weight: 91.3 KG

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20060601

Duration:

Adverse Reactions:

- BLOOD PRESSURE INCREASED
- BUNDLE BRANCH BLOCK LEFT
- BUNDLE BRANCH BLOCK RIGHT
- CHEST DISCOMFORT
- CHRONIC OBSTRUCTIVE PULMONARY DISEASE
- CONDITION AGGRAVATED
- ELECTROCARDIOGRAM ST-T CHANGE
- INTERNATIONAL NORMALISED RATIO INCREASED
- PROTHROMBIN TIME PROLONGED
- SPUTUM DISCOLOURED

ISR Number: 5147262 Case Number: 6171541 I/F Code: I Report Date: 20061102
Drug Name: **XOPENEX**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1007837410
Mfg. Date: 20061027
Mfg. Number: 2006SP003860
Mfg. Sender: SEPRACOR INC.
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: INHALATION
Event Date:
FDA Date: 20061103
Follow Number:
Image ID: 5147262-3
Age: Gender: M Weight:
Occupation: MD
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 STATUS ASTHMATICUS

ISR Number: 5186527 Case Number: 6206957 I/F Code: I Report Date: 20061212

Drug Name: **XOPENEX**

NDA Number: 21730

Role Code: PS VAL/VBM: 1

Seq Number: 1007968105

Mfg. Date: 20061130

Mfg. Number: 2006SP003435

Mfg. Sender: SEPRACOR INC

Lot Number: 50790

Expiration Date: 20070701

Indication:

Route: RESPIRATORY (INHALATION)

Dose: INHALATION

Event Date: 20060928

FDA Date: 20061213

Follow Number:

Image ID: 5186527-6

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20060101

Duration:

Adverse Reactions:

- DYSпноEA
- HYPERVENTILATION
- MUSCULOSKELETAL STIFFNESS
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5200008 Case Number: 6161416 I/F Code: I Report Date: 20070102

Drug Name: **XOPENEX**

NDA Number: 21730

Role Code: PS VAL/VBM: 1

Seq Number: 1008015149

Mfg. Date: 20061003

Mfg. Number: 2006SP003640

Mfg. Sender: SEPRACOR INC.

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 45 UG; PRN; INHALATION

Event Date: 20061001

FDA Date: 20070103

Follow Number:

Image ID: 5200008-2

Age: 54 YR Gender: F Weight: 86 KG

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20060301

Duration:

Adverse Reactions:

- BLOOD CHOLESTEROL INCREASED
- BLOOD CREATINE PHOSPHOKINASE INCREASED
- BLOOD THYROID STIMULATING HORMONE DECREASED
- BLOOD TRIGLYCERIDES INCREASED
- BRONCHITIS
- CARDIAC FAILURE CONGESTIVE
- HIGH DENSITY LIPOPROTEIN INCREASED
- HYPERTENSION
- PLEURITIC PAIN
- PULMONARY CONGESTION

ISR Number: 5224566 Case Number: 6233760 I/F Code: I Report Date: 20070125
Drug Name: **XOPENEX**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1008098104
Mfg. Date: 20070112
Mfg. Number: 2007SP000142
Mfg. Sender: SEPRACOR INC.
Lot Number: 60142
Expiration Date: 20080101
Indication: EMPHYSEMA
Route: RESPIRATORY (INHALATION)
Dose: 90 UG; QID; INHALATION
Event Date: 20061217
FDA Date: 20070126
Follow Number:
Image ID: 5224566-7
Age: 71 YR Gender: M Weight: 175 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End: 20060101
Duration:
Adverse Reactions:
MYOCARDIAL INFARCTION
PERIPHERAL EMBOLISM

ISR Number: 5246479 Case Number: 6254635 I/F Code: I Report Date: 20070215
Drug Name: **XOPENEX**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1008181004
Mfg. Date: 20070202
Mfg. Number: 2007SP000386
Mfg. Sender: SEPRACOR INC.
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1X; INHALATION
Event Date: 20070125
FDA Date: 20070216
Follow Number:
Image ID: 5246479-7
Age: 33 YR Gender: F Weight: 180 LBS
Occupation: PH
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date: 20070201
Therapy Start: 20070125
Therapy End: 20070125
Duration:
Adverse Reactions:
EPISTAXIS
HAEMOPTYSIS
PULMONARY HAEMORRHAGE
PULMONARY THROMBOSIS

ISR Number: 5251920 Case Number: 6257062 I/F Code: I Report Date: 20070222

Drug Name: **XOPENEX**

NDA Number: 21730

Role Code: PS VAL/VBM: 1

Seq Number: 1008198698

Mfg. Date: 20070208

Mfg. Number: 2007SP000459

Mfg. Sender: SEPRACOR INC.

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: PRN;INHALATION

Event Date: 20061023

FDA Date: 20070223

Follow Number:

Image ID: 5251920-X

Age: 70 YR Gender: F Weight: 188 LBS

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

BACK PAIN

BLADDER PROLAPSE

POST PROCEDURAL COMPLICATION

PROCEDURAL PAIN

STRESS URINARY INCONTINENCE

ISR Number: 5257034 Case Number: 6261894 I/F Code: I Report Date: 20070301
Drug Name: **XOPENEX**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1008219839
Mfg. Date: 20070216
Mfg. Number: 2007SP000534
Mfg. Sender: SEPRACOR INC.
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: INHALATION
Event Date:
FDA Date: 20070302
Follow Number:
Image ID: 5257034-7
Age: 13 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
PALPITATIONS

ISR Number: 5277886 Case Number: 6279707 I/F Code: I Report Date: 20070320
 Drug Name: **XOPENEX HFA**
 NDA Number: 21730
 Role Code: PS VAL/VBM: 1
 Seq Number: 1008299851
 Mfg. Date: 20070306
 Mfg. Number: 2007SP000797
 Mfg. Sender: SEPRACOR, INC.
 Lot Number:
 Expiration Date:
 Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
 Route: RESPIRATORY (INHALATION)
 Dose: INHALATION
 Event Date: 20070219
 FDA Date: 20070321
 Follow Number:
 Image ID: 5277886-4
 Age: 72 YR Gender: M Weight: 172 LBS
 Occupation: MD
 Country: UNITED STATES
 Report Source: Electronic Submit: N Mfg. Notified: Confidential:
 Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 ARTHRALGIA

ISR Number: 5341305 Case Number: 6330138 I/F Code: I Report Date: 20070529

Drug Name: **XOPENEX**

NDA Number: 21730

Role Code: PS VAL/VBM: 1

Seq Number: 1008537703

Mfg. Date: 20070515

Mfg. Number: 2007SP001819

Mfg. Sender: SEPRACOR INC.

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: INHALATION

Event Date: 20070410

FDA Date: 20070530

Follow Number:

Image ID: 5341305-X

Age: 61 YR Gender: F Weight: 118 LBS

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- CANDIDIASIS
- CHRONIC OBSTRUCTIVE PULMONARY DISEASE
- CLUBBING
- CONDITION AGGRAVATED
- CYANOSIS
- DEEP VEIN THROMBOSIS
- NAUSEA
- PLEURAL EFFUSION
- PNEUMONIA ASPIRATION
- RESPIRATORY DISTRESS
- SINUS TACHYCARDIA
- VENOUS THROMBOSIS LIMB

ISR Number: 5353233 Case Number: 6335520 I/F Code: I Report Date: 20070607
Drug Name: **XOPENEX HFA**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1008573965
Mfg. Date: 20070605
Mfg. Number: 2007SP002120
Mfg. Sender: SEPRACOR, INC.
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose:
Event Date:
FDA Date: 20070608
Follow Number:
Image ID: 5353233-4
Age: 36 YR Gender: F Weight:
Occupation: MD
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 DYSPTNOEA
 MYOCARDIAL INFARCTION

ISR Number: 5363126 Case Number: 6342133 I/F Code: I Report Date: 20070615

Drug Name: **XOPENEX HFA**

NDA Number: 20837

Role Code: PS VAL/VBM: 1

Seq Number: 1008606731

Mfg. Date: 20070605

Mfg. Number: 2007SP002213

Mfg. Sender: SEPRACOR INC.

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 90 UG; PRN; INHALATION

Event Date: 20070407

FDA Date: 20070618

Follow Number:

Image ID: 5363126-4

Age: 48 YR Gender: M Weight: 103. KG

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20070301

Duration:

Adverse Reactions:

- ANION GAP INCREASED
- BLOOD GLUCOSE INCREASED
- NEUTROPHIL PERCENTAGE INCREASED
- SMALL INTESTINAL OBSTRUCTION
- WHITE BLOOD CELL COUNT INCREASED

ISR Number: 5363479 Case Number: 6342207 I/F Code: I Report Date: 20070615
Drug Name: **XOPENEX**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1008608231
Mfg. Date: 20070605
Mfg. Number: 2007SP002018
Mfg. Sender: SEPRACOR INC.
Lot Number:
Expiration Date:
Indication: DYSPNOEA
Route: RESPIRATORY (INHALATION)
Dose: Q4H; INHALATION
Event Date: 20061201
FDA Date: 20070618
Follow Number:
Image ID: 5363479-7
Age: 86 YR Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End: 20060101
Duration:
Adverse Reactions:
HOSPITALISATION
MEDICATION ERROR

ISR Number: 5409593 Case Number: 6382507 I/F Code: I Report Date: 20070806
Drug Name: **XOPENEX**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1008790382
Mfg. Date: 20070725
Mfg. Number: 2007SP002708
Mfg. Sender: SEPRACOR INC.
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: RESPIRATORY (INHALATION)
Dose: BID; INHALATION
Event Date: 20070527
FDA Date: 20070807
Follow Number:
Image ID: 5409593-9
Age: 76 YR Gender: M Weight: 177 LBS
Occupation: MD
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
CALCINOSIS
DYSPHAGIA
FOREIGN BODY TRAUMA
HAEMATOCRIT DECREASED
HAEMOGLOBIN DECREASED
OESOPHAGEAL DISCOMFORT
OESOPHAGEAL FOOD IMPACTION
RENAL FAILURE
SPINAL OSTEOARTHRITIS

ISR Number: 5490422 Case Number: 6487668 I/F Code: I Report Date: 20071003
Drug Name: **XOPENEX HFA**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1009057376
Mfg. Date: 20070831
Mfg. Number: 2007SP003080
Mfg. Sender: SEPRACOR INC.
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 90 UG; PRN; INHALATION
Event Date: 20070608
FDA Date: 20071011
Follow Number:
Image ID: 5490422-2
Age: 62 YR Gender: F Weight: 235 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End: 20070608
Duration:
Adverse Reactions:
CHEST PAIN
DIZZINESS
HEART RATE INCREASED
HYPERHIDROSIS
NERVOUSNESS

ISR Number: 5490423 Case Number: 6487671 I/F Code: I Report Date: 20071003
Drug Name: **XOPENEX HFA**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1009057377
Mfg. Date: 20070905
Mfg. Number: 2007SP002978
Mfg. Sender: SEPRACOR INC.
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: INHALATION
Event Date: 20070818
FDA Date: 20071011
Follow Number:
Image ID: 5490423-4
Age: Gender: F Weight:
Occupation: MD
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End: 20070818
Duration:
Adverse Reactions:
DYSпноEA
HYPERSENSITIVITY

ISR Number: 5619517 Case Number: 6617458 I/F Code: I Report Date: 20071221
Drug Name: **XOPENEX HFA**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1009492417
Mfg. Date: 20071115
Mfg. Number: 2007SP003873
Mfg. Sender: SEPRACOR INC.
Lot Number:
Expiration Date:
Indication: PNEUMONIA
Route: RESPIRATORY (INHALATION)
Dose: 90 UG;1X;INHALATION
Event Date: 20071113
FDA Date: 20080111
Follow Number:
Image ID: 5619517-7
Age: 47 YR Gender: F Weight: 240 LBS
Occupation: OT
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20071113
Therapy End: 20071113
Duration:
Adverse Reactions:
CHEST PAIN
CHOLELITHIASIS
TYPE I HYPERSENSITIVITY

ISR Number: 5662780 Case Number: 6589243 I/F Code: I Report Date: 20080310
Drug Name: **XOPENEX HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009641546
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 70482
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: 2 METERED DOSES PRN PO
Event Date: 20080309
FDA Date: 20080311
Follow Number:
Image ID: 5662780-7
Age: Gender: F Weight: 180 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: Death Date:
Therapy Start: 20080308
Therapy End: 20080201
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 HEADACHE

ISR Number: 5674047 Case Number: 6601221 I/F Code: I Report Date: 20080318
Drug Name: **XOPENEX HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009679707
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: URTICARIA
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS Q4-6HR INHALATION
Event Date: 20080208
FDA Date: 20080319
Follow Number:
Image ID: 5674047-1
Age: 3 YR Gender: F Weight:
Occupation: MD
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: 20080208
Duration:
Adverse Reactions:
URTICARIA