
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

DYSPNOEA

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

ISR Number: 5694101 Case Number: 6614915 I/F Code: I Report Date: 20080401
Drug Name: **XOPENEX HFA**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1009744962
Mfg. Date: 20080323
Mfg. Number: 2008SP000696
Mfg. Sender: SEPRACOR INC.
Lot Number: 70290
Expiration Date: 20090101
Indication:
Route: RESPIRATORY (INHALATION)
Dose: 90 UG;BID;INHALATION
Event Date: 20080101
FDA Date: 20080402
Follow Number:
Image ID: 5694101-8
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End: 20070509
Duration:
Adverse Reactions:
BRONCHITIS
PALPITATIONS

ISR Number: 5743448 Case Number: 6657656 I/F Code: I Report Date: 20080509
Drug Name: **XOPENEX HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009928924
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 70542
Expiration Date: 20090317
Indication: ASTHMA
Route:
Dose: USE 2 PUFFS TWICE DAILY
Event Date: 20080506
FDA Date: 20080519
Follow Number:
Image ID: 5743448-5
Age: 15 YR Gender: M Weight:
Occupation: PH
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: D Rechallenge Code: Y Death Date:
Therapy Start: 20080501
Therapy End: 20080101
Duration:
Adverse Reactions:
 DEVICE FAILURE
 INCORRECT DOSE ADMINISTERED
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5766613 Case Number: 6678381 I/F Code: I Report Date: 20080609

Drug Name: **XOPENEX HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010019269

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose:

Event Date:

FDA Date: 20080610

Follow Number:

Image ID: 5766613-X

Age: 25 YR Gender: F Weight: 135 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

DYSPNOEA

PAIN

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5772962 Case Number: 6679769 I/F Code: I Report Date: 20080610

Drug Name: **XOPENEX HFA**

NDA Number: 21730

Role Code: PS VAL/VBM: 1

Seq Number: 1010040417

Mfg. Date: 20080602

Mfg. Number: 2008SP001278

Mfg. Sender: SEPRACOR INC .

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 90 UG;Q 4H; INHALATION

Event Date: 20060201

FDA Date: 20080611

Follow Number:

Image ID: 5772962-1

Age: 49 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20060201

Duration:

Adverse Reactions:

BREATH ALCOHOL TEST POSITIVE
IMPRISONMENT

ISR Number: 5827084 Case Number: 6720407 I/F Code: I Report Date: 20080728
Drug Name: **XOPENEX HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010237183
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 70326
Expiration Date: 20090131
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS ORALLY EVERY 6 HOURS AS NEEDED INHAL
Event Date: 20080725
FDA Date: 20080729
Follow Number:
Image ID: 5827084-8
Age: Gender: F Weight: 181 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: Dechallenge Code: Y Rechallenge Code: Death Date:
Therapy Start: 20080725
Therapy End: 20080404
Duration:
Adverse Reactions:
BLOOD PRESSURE INCREASED
DRUG HYPERSENSITIVITY
FLUID RETENTION
HEART RATE INCREASED
MALAISE
MUSCULAR WEAKNESS
RASH
TINNITUS
TREMOR

ISR Number: 5892757 Case Number: 6773975 I/F Code: I Report Date: 20080918
Drug Name: **XOPENEX HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010485517
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20100202
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 90 MCG 2 PUFF 4 TIMES DAY INHAL
Event Date: 20080706
FDA Date: 20080919
Follow Number:
Image ID: 5892757-8
Age: 26 YR Gender: M Weight: 247 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: HO Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration: 1 DAY
Adverse Reactions:
DRUG EFFECT DECREASED
FEAR

ISR Number: 5902758 Case Number: 6779149 I/F Code: I Report Date: 20080926
Drug Name: **XOPENEX HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010518321
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 70706
Expiration Date: 20090630
Indication: MULTIPLE ALLERGIES
Route: ORAL
Dose: 2 PUFFS BY MOUTH EVERY 4 HOURS PO
Event Date: 20070101
FDA Date: 20080929
Follow Number:
Image ID: 5902758-9
Age: Gender: Weight:
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: 20080926
Therapy End: 20070101
Duration:
Adverse Reactions:
DRUG EFFECT DECREASED