

ISR Number: 6157705 Case Number: 6981585 I/F Code: I Report Date: 20090413

Drug Name: **XOPENEX**

NDA Number: 21730

Role Code: PS VAL/VBM: 1

Seq Number: 1011439138

Mfg. Date: 20090330

Mfg. Number: 2009SP000867

Mfg. Sender: SEPRACOR INC.

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 90 UG; PRN; INHALATION

Event Date: 20090301

FDA Date: 20090414

Follow Number:

Image ID: 6157705-4

Age: 33 YR Gender: F Weight:

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start: 20090301

Therapy End: 20090301

Duration:

Adverse Reactions:

- ANXIETY
- ASTHMA
- CHEST PAIN
- CONDITION AGGRAVATED
- MULTIPLE ALLERGIES
- NAUSEA
- PHARYNGEAL OEDEMA
- PNEUMONIA
- PRESYNCOPE

ISR Number: 6190738 Case Number: 6999244 I/F Code: I Report Date: 20090512  
Drug Name: **XOPENEX HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011574611  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date: 20090130  
FDA Date: 20090513  
Follow Number:  
Image ID: 6190738-0  
Age: 52 YR Gender: F Weight: 125 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y  
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PRODUCT QUALITY ISSUE

ISR Number: 6192880 Case Number: 7002470 I/F Code: I Report Date: 20090513

Drug Name: **XOPENEX HFA**

NDA Number: 21730

Role Code: PS VAL/VBM: 1

Seq Number: 1011585065

Mfg. Date: 20090501

Mfg. Number: 2009SP001144

Mfg. Sender: SEPRACOR INC.

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route:

Dose: 45 UG; QID; INHALATION; PRN; INHALATION; 90 UG; BID; INHALATION

Event Date: 20080101

FDA Date: 20090514

Follow Number:

Image ID: 6192880-7

Age: Gender: F Weight: 33.6 KG

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: 20070101

Therapy End:

Duration:

Adverse Reactions:

- ALOPECIA
- BLOOD PRESSURE INCREASED
- DECREASED APPETITE
- DYSURIA
- FATIGUE
- NAUSEA
- PNEUMONIA
- PRURITUS
- PULMONARY CONGESTION
- SCRATCH
- URTICARIA
- WEIGHT DECREASED

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ISR Number: 6223515 Case Number: 7027889 I/F Code: I Report Date: 20090609  
Drug Name: **XOPENEX HFA**  
NDA Number: 21730  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011709515  
Mfg. Date: 20090528  
Mfg. Number: 2009SP001379  
Mfg. Sender: SEPRACOR INC.  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 45 UG; PRN; INHALATION, 45 UG; PRN; INHALATION  
Event Date: 20090409  
FDA Date: 20090610  
Follow Number:  
Image ID: 6223515-2  
Age: 70 YR Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: HO Dechallenge Code: Y Rechallenge Code: Y Death Date:  
Therapy Start: 20090409  
Therapy End: 20081201  
Duration:  
Adverse Reactions:  
ANXIETY  
DRUG EFFECT DECREASED  
DYSPNOEA