
ISR Number: 5913748 Case Number: 6791454 I/F Code: I Report Date: 20081006
Drug Name: **XOPENEX HFA**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1010557961
Mfg. Date: 20080923
Mfg. Number: 2008SP002293
Mfg. Sender: SEPRACOR INC.
Lot Number: 70621
Expiration Date: 20090601
Indication: EMPHYSEMA
Route: RESPIRATORY (INHALATION)
Dose: INHALATION
Event Date: 20080101
FDA Date: 20081007
Follow Number:
Image ID: 5913748-4
Age: 58 YR Gender: M Weight:
Occupation: MD
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: D Death Date:
Therapy Start:
Therapy End: 20080101
Duration:
Adverse Reactions:
ANXIETY
BLOOD PRESSURE INCREASED
BRONCHITIS
CHRONIC OBSTRUCTIVE PULMONARY DISEASE
CONDITION AGGRAVATED
DRUG INEFFECTIVE
GASTROESOPHAGEAL REFLUX DISEASE
HYPERLIPIDAEMIA
INSOMNIA
OROPHARYNGEAL PAIN
RHINITIS ALLERGIC

ISR Number: 5954316 Case Number: 6817179 I/F Code: I Report Date: 20081112
Drug Name: **XOPENEX HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010708713
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 80265
Expiration Date: 20090930
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 45 MCG 2X2 INHAL
Event Date: 20081014
FDA Date: 20081113
Follow Number:
Image ID: 5954316-8
Age: 62 YR Gender: F Weight: 180 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: 20081112
Therapy End: 20081001
Duration:
Adverse Reactions:
CONDITION AGGRAVATED
DRUG INEFFECTIVE
OBSTRUCTIVE AIRWAYS DISORDER
PRODUCT QUALITY ISSUE

ISR Number: 5985901 Case Number: 6853426 I/F Code: I Report Date: 20081124
Drug Name: **XOPENEX HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010815236
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 70837
Expiration Date:
Indication:
Route:
Dose: INHALE 2 PUFFS EVERY 4 HOURS AS NEEDED
Event Date: 20081124
FDA Date: 20081203
Follow Number:
Image ID: 5985901-5
Age: Gender: F Weight:
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:
Therapy End:
Duration:
Adverse Reactions:
RASH

ISR Number: 5991126 Case Number: 6860942 I/F Code: I Report Date: 20081208
Drug Name: **XOPENEX HFA**
NDA Number: 21730
Role Code: PS VAL/VBM: 1
Seq Number: 1010831659
Mfg. Date: 20081125
Mfg. Number: 2008SP002985
Mfg. Sender: SEPRACOR INC.
Lot Number:
Expiration Date:
Indication: EMPHYSEMA
Route: RESPIRATORY (INHALATION)
Dose: 90 UG; PRN; INHALATION
Event Date: 20080101
FDA Date: 20081209
Follow Number:
Image ID: 5991126-X
Age: 67 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
CONSTIPATION
HYPOTENSION
ILEUS
LUNG INFECTION
NO THERAPEUTIC RESPONSE
TACHYCARDIA