

ISR Number: 6144707 Case Number: 6961467 I/F Code: I Report Date: 20090406
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011385128
 Mfg. Date: 20090327
 Mfg. Number: B0568489A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: OTHER
 Dose:
 Event Date: 20090326
 FDA Date: 20090406
 Follow Number:
 Image ID: 6144707-7
 Age: 0 Gender: F Weight:
 Occupation: CN
 Country: TURKEY
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start: 20090326
 Therapy End: 20090326
 Duration: 1 DAY
 Adverse Reactions:
 INCORRECT ROUTE OF DRUG ADMINISTRATION

ISR Number: 6160208 Case Number: 6972689 I/F Code: I Report Date: 20090420

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011449883

Mfg. Date: 20090409

Mfg. Number: B0557131A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: UNKNOWN

Dose:

Event Date: 20090125

FDA Date: 20090420

Follow Number:

Image ID: 6160208-4

Age: 12 Gender: F Weight: 54 KG

Occupation: MD

Country: UNITED KINGDOM

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

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

Therapy Start:

Therapy End: 20090125

Duration:

Adverse Reactions:

- ACCIDENTAL EXPOSURE
- ERYTHEMA
- INCORRECT ROUTE OF DRUG ADMINISTRATION
- THERMAL BURN

ISR Number: 6173476 Case Number: 6926992 I/F Code: I Report Date: 20090430

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011501734

Mfg. Date: 20090422

Mfg. Number: A0771322A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP3624

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20090301

FDA Date: 20090430

Follow Number:

Image ID: 6173476-X

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

ASTHMA

DRUG INEFFECTIVE

PRODUCT QUALITY ISSUE

ISR Number: 6173477 Case Number: 6981972 I/F Code: I Report Date: 20090430

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011501735

Mfg. Date: 20090423

Mfg. Number: A0772617A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20090430

Follow Number:

Image ID: 6173477-1

Age: Gender: Weight:

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:

Duration:

Adverse Reactions:

- ASTHMA
- DRUG INEFFECTIVE
- DYSPNOEA
- PRODUCT QUALITY ISSUE
- QUALITY OF LIFE DECREASED
- WHEEZING

ISR Number: 6176214 Case Number: 6984330 I/F Code: I Report Date: 20090501

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011512457

Mfg. Date: 20090423

Mfg. Number: A0772427A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP3625

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20090501

Follow Number:

Image ID: 6176214-X

Age: Gender: Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

ANXIETY

ASTHMA

PRODUCT QUALITY ISSUE

ISR Number: 6176230 Case Number: 6984344 I/F Code: I Report Date: 20090501

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011512502

Mfg. Date: 20090422

Mfg. Number: A0781357A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: UNKNOWN

Dose:

Event Date: 20090227

FDA Date: 20090501

Follow Number:

Image ID: 6176230-8

Age: 50 YR Gender: F Weight: 90.5 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: 20090226

Duration:

Adverse Reactions:

- ANXIETY
- BLOOD POTASSIUM DECREASED
- CRYING
- FEELING JITTERY
- INSOMNIA
- NERVOUSNESS
- PERFORMANCE STATUS DECREASED
- SCREAMING
- THYROXINE FREE INCREASED
- TRI-IODOTHYRONINE INCREASED
- WHEEZING

ISR Number: 6178250 Case Number: 6985792 I/F Code: I Report Date: 20090504

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011522304

Mfg. Date: 20090427

Mfg. Number: A0780786A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP4050

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF AS REQUIRED

Event Date: 20090201

FDA Date: 20090504

Follow Number:

Image ID: 6178250-6

Age: 57 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090201

Duration:

Adverse Reactions:

- DIZZINESS
- DRUG INEFFECTIVE
- DYSPNOEA
- INHALATION THERAPY
- MOBILITY DECREASED
- OXYGEN SUPPLEMENTATION

ISR Number: 6185837 Case Number: 6951824 I/F Code: I Report Date: 20090511

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011554378

Mfg. Date: 20090429

Mfg. Number: A0774039A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP2575,8ZP3354

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF FOUR TIMES PER DAY

Event Date: 20090301

FDA Date: 20090511

Follow Number:

Image ID: 6185837-3

Age: 62 YR Gender: F Weight:

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: 20090301

Duration:

Adverse Reactions:

- ASTHMA
- CHEST DISCOMFORT
- CHEST PAIN
- COUGH
- DRUG INEFFECTIVE
- DYSPNOEA
- PRODUCT QUALITY ISSUE
- WHEEZING

ISR Number: 6190298 Case Number: 6994551 I/F Code: I Report Date: 20090514

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011573040

Mfg. Date: 20090506

Mfg. Number: A0782781A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP4049

Expiration Date:

Indication: BRONCHITIS

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20090401

FDA Date: 20090514

Follow Number:

Image ID: 6190298-4

Age: 52 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090428

Duration:

Adverse Reactions:

- CHOKING
- DYSPNOEA
- RESPIRATORY TRACT CONGESTION

ISR Number: 6191999 Case Number: 6977589 I/F Code: I Report Date: 20090515
Drug Name: **SALBUTAMOL**
NDA Number: 20983
Role Code: PS VAL/VBM: 2
Seq Number: 1011580279
Mfg. Date: 20090501
Mfg. Number: B0571467A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: ADU84A
Expiration Date:
Indication: DEPRESSION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090515
Follow Number:
Image ID: 6191999-4
Age: Gender: F Weight:
Occupation: CN
Country: UNITED KINGDOM
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date: 20080507
Therapy Start: 20080322
Therapy End:
Duration:
Adverse Reactions:
ASTHMA

ISR Number: 6196564 Case Number: 7003165 I/F Code: I Report Date: 20090515

Drug Name: **VENTOLIN HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011600759

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 8ZP3624

Expiration Date: 20091001

Indication: DYSпноEA

Route: ORAL

Dose: 90 MCG PER ACTUATION AS NEEDED PO

Event Date: 20081231

FDA Date: 20090518

Follow Number:

Image ID: 6196564-0

Age: 32 Gender: F Weight: 160 LBS

Occupation: CN

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: 20090515

Therapy End: 20090301

Duration: 2 MON

Adverse Reactions:

- DRUG INEFFECTIVE
- DYSпноEA
- EXERCISE TOLERANCE DECREASED
- MIDDLE INSOMNIA
- PRODUCT SUBSTITUTION ISSUE
- THROAT IRRITATION
- WEIGHT INCREASED

ISR Number: 6197969 Case Number: 6999735 I/F Code: I Report Date: 20090521

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011606824

Mfg. Date: 20090513

Mfg. Number: B0575000A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ATOPY

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20090316

FDA Date: 20090521

Follow Number:

Image ID: 6197969-4

Age: 11 Gender: F Weight: 53 KG

Occupation: CN

Country: SWITZERLAND

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DEPRESSION
- DEVICE INEFFECTIVE

ISR Number: 6201555 Case Number: 7007666 I/F Code: I Report Date: 20090515
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011623771
Mfg. Date: 20090505
Mfg. Number: B0574004A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: INHALED
Event Date:
FDA Date: 20090519
Follow Number:
Image ID: 6201555-7
Age: 41 YR Gender: F Weight:
Occupation:
Country: ITALY
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ACUTE MYOCARDIAL INFARCTION
ARTERIOSPASM CORONARY
HYPOKALAEMIA

ISR Number: 6201985 Case Number: 7002157 I/F Code: I Report Date: 20090526
Drug Name: **VENTOLIN HFA**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011625086
Mfg. Date: 20090512
Mfg. Number: A0785363A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: 5446
Expiration Date:
Indication: ASTHMA
Route: UNKNOWN
Dose:
Event Date:
FDA Date: 20090526
Follow Number:
Image ID: 6201985-3
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE
PRODUCT QUALITY ISSUE

ISR Number: 6204125 Case Number: 7010072 I/F Code: I Report Date: 20090525

Drug Name: **VENTOLIN HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011632897

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 8ZP4362

Expiration Date: 20091031

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS EVERY 4 TO 6 HOURS AS NEEDED INHAL

Event Date: 20090523

FDA Date: 20090526

Follow Number:

Image ID: 6204125-X

Age: 18 Gender: M Weight: 205 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: 20090521

Therapy End: 20090518

Duration:

Adverse Reactions:

OROPHARYNGEAL PAIN

PHARYNGITIS

PRODUCT QUALITY ISSUE

ISR Number: 6207930 Case Number: 7006188 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648764

Mfg. Date: 20080603

Mfg. Number: A0721631A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 7ZP9747

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF FOUR TIMES PER DAY

Event Date: 20080101

FDA Date: 20090529

Follow Number:

Image ID: 6207930-9

Age: 49 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20070314

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PRODUCT QUALITY ISSUE

ISR Number: 6207931 Case Number: 7006189 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648769

Mfg. Date: 20080619

Mfg. Number: A0724099A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207931-0

Age: Gender: Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PRODUCT QUALITY ISSUE

ISR Number: 6207932 Case Number: 7006190 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648771
 Mfg. Date: 20080626
 Mfg. Number: A0724866A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: 7ZP1124
 Expiration Date:
 Indication: ASTHMA
 Route:
 Dose: 2PUFF SIX TIMES PER DAY
 Event Date: 20080413
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207932-2
 Age: 65 YR Gender: F Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End: 20060101
 Duration:
 Adverse Reactions:
 DYSпноEA
 PRODUCT QUALITY ISSUE

ISR Number: 6207933 Case Number: 7006191 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648785
Mfg. Date: 20080429
Mfg. Number: A0725623A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6207933-4
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
THERAPEUTIC RESPONSE DECREASED

ISR Number: 6207934 Case Number: 7006192 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648786

Mfg. Date: 20080626

Mfg. Number: A0726186A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 7ZP5502

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20080401

FDA Date: 20090529

Follow Number:

Image ID: 6207934-6

Age: 41 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20080501

Therapy End: 20080421

Duration: 2 WK

Adverse Reactions:

- DRUG INEFFECTIVE
- PRODUCT QUALITY ISSUE

ISR Number: 6207935 Case Number: 7006193 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648791
 Mfg. Date: 20080512
 Mfg. Number: A0727700A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: UNKNOWN
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date: 20080511
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207935-8
 Age: 58 YR Gender: F Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End: 20080505
 Duration:
 Adverse Reactions:
 RASH
 URTICARIA

ISR Number: 6207936 Case Number: 7006194 I/F Code: I Report Date: 20090529
Drug Name: **ALBUTEROL**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648793
Mfg. Date: 20080514
Mfg. Number: A0728110A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: UNKNOWN
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: RESPIRATORY (INHALATION)
Dose:
Event Date: 20000101
FDA Date: 20090529
Follow Number:
Image ID: 6207936-X
Age: 73 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End: 20000101
Duration: 8 YR
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 6207937 Case Number: 7006195 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648795

Mfg. Date: 20080626

Mfg. Number: A0728114A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 7ZP5679

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 18G AS REQUIRED

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207937-1

Age: 38 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration: 1 MON

Adverse Reactions:

- DRUG INEFFECTIVE
- PRODUCT QUALITY ISSUE

ISR Number: 6207938 Case Number: 7006196 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648797
Mfg. Date: 20080702
Mfg. Number: A0729441A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: UNKNOWN
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date: 20080513
FDA Date: 20090529
Follow Number:
Image ID: 6207938-3
Age: 46 YR Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End: 20070913
Duration:
Adverse Reactions:
URINE AMPHETAMINE POSITIVE

ISR Number: 6207939 Case Number: 7006197 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648806
 Mfg. Date: 20080715
 Mfg. Number: A0729944A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: 7ZP5677
 Expiration Date:
 Indication:
 Route: RESPIRATORY (INHALATION)
 Dose: 2PUFF THREE TIMES PER DAY
 Event Date: 20080514
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207939-5
 Age: 35 YR Gender: M Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End: 20080514
 Duration:
 Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6207940 Case Number: 7006198 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648809

Mfg. Date: 20080617

Mfg. Number: A0730184A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: ADT99C

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF SIX TIMES PER DAY

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207940-1

Age: Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20080401

Duration:

Adverse Reactions:

- ABDOMINAL PAIN UPPER
- ANOREXIA
- DISABILITY
- DRUG INEFFECTIVE
- DYSGEUSIA
- HEADACHE
- ILL-DEFINED DISORDER
- NAUSEA
- PRODUCT QUALITY ISSUE

ISR Number: 6207941 Case Number: 7006199 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648813
Mfg. Date: 20080611
Mfg. Number: A0732686A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: 8ZP5288
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2PUFF PER DAY
Event Date: 20080610
FDA Date: 20090529
Follow Number:
Image ID: 6207941-3
Age: 18 MON Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End: 20080610
Duration:
Adverse Reactions:
ERYTHEMA

ISR Number: 6207942 Case Number: 7006200 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648815
Mfg. Date: 20080905
Mfg. Number: A0739209A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: UNKNOWN
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2PUFF AS REQUIRED
Event Date: 20080101
FDA Date: 20090529
Follow Number:
Image ID: 6207942-5
Age: 52 YR Gender: F Weight: 59.1 KG
Occupation: OT
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End: 20080626
Duration:
Adverse Reactions:
CHEST PAIN

ISR Number: 6207943 Case Number: 7006201 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648821
 Mfg. Date: 20080916
 Mfg. Number: A0740289A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: 72P5678
 Expiration Date:
 Indication: ASTHMA
 Route: RESPIRATORY (INHALATION)
 Dose: 1PUFF FOUR TIMES PER DAY
 Event Date: 20080601
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207943-7
 Age: Gender: M Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6207944 Case Number: 7006202 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648824
Mfg. Date: 20080804
Mfg. Number: A0741122A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6207944-9
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
MALAISE

ISR Number: 6207945 Case Number: 7006203 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648825

Mfg. Date: 20080806

Mfg. Number: A0741567A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: ADP21A

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20050101

FDA Date: 20090529

Follow Number:

Image ID: 6207945-0

Age: 72 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20050101

Duration: 3 YR

Adverse Reactions:

DRUG INEFFECTIVE

EXPIRED DRUG ADMINISTERED

ISR Number: 6207946 Case Number: 7006204 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648831

Mfg. Date: 20080819

Mfg. Number: A0743547A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF FOUR TIMES PER DAY

Event Date: 20080819

FDA Date: 20090529

Follow Number:

Image ID: 6207946-2

Age: 44 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20080722

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

ISR Number: 6207947 Case Number: 7006205 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648833
 Mfg. Date: 20080819
 Mfg. Number: A0743723A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: UNKNOWN
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: UNKNOWN
 Dose:
 Event Date:
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207947-4
 Age: Gender: Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 DRUG INEFFECTIVE

ISR Number: 6207948 Case Number: 7006206 I/F Code: I Report Date: 20090529
Drug Name: **ALBUTEROL**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648834
Mfg. Date: 20080922
Mfg. Number: A0749656A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6207948-6
Age: Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 6207949 Case Number: 7006207 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648835

Mfg. Date: 20081009

Mfg. Number: A0751340A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP2963

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF FOUR TIMES PER DAY

Event Date: 20081007

FDA Date: 20090529

Follow Number:

Image ID: 6207949-8

Age: 70 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

 DIZZINESS

ISR Number: 6207950 Case Number: 7006208 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648839

Mfg. Date: 20081009

Mfg. Number: A0751355A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20081006

FDA Date: 20090529

Follow Number:

Image ID: 6207950-4

Age: 78 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

OVERDOSE

PALPITATIONS

TREMOR

ISR Number: 6207951 Case Number: 7006209 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648857

Mfg. Date: 20081002

Mfg. Number: A0751610A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP5300

Expiration Date:

Indication: EMPHYSEMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF TWICE PER DAY

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207951-6

Age: 73 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20080101

Duration:

Adverse Reactions:

- DYSпноEA
- INHALATION THERAPY
- MEMORY IMPAIRMENT
- MENTAL IMPAIRMENT

ISR Number: 6207952 Case Number: 7006210 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648862
 Mfg. Date: 20081030
 Mfg. Number: A0754417A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207952-8
 Age: Gender: M Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 DRUG INEFFECTIVE

ISR Number: 6207953 Case Number: 7006211 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648863
 Mfg. Date: 20081108
 Mfg. Number: A0756074A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207953-X
 Age: Gender: F Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 LACERATION
 PRODUCT QUALITY ISSUE

ISR Number: 6207954 Case Number: 7006212 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648864
Mfg. Date: 20081109
Mfg. Number: A0756243A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6207954-1
Age: Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 PRODUCT QUALITY ISSUE
 SKIN DISORDER

ISR Number: 6207955 Case Number: 7006213 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648865
Mfg. Date: 20081112
Mfg. Number: A0757225A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6207955-3
Age: Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE

ISR Number: 6207956 Case Number: 7006214 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648866
Mfg. Date: 20081110
Mfg. Number: A0757294A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6207956-5
Age: Gender: Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6207957 Case Number: 7006215 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648867
Mfg. Date: 20081119
Mfg. Number: A0757436A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: PP2472
Expiration Date:
Indication: BRONCHOSPASM
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6207957-7
Age: 15 YR Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start: 20080101
Therapy End: 20080101
Duration: 1 DAY
Adverse Reactions:
ANAPHYLACTIC REACTION
ASTHMA
RASH

ISR Number: 6207958 Case Number: 7006216 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648869

Mfg. Date: 20090209

Mfg. Number: A0759319A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP0827

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF TWICE PER DAY

Event Date: 20081101

FDA Date: 20090529

Follow Number:

Image ID: 6207958-9

Age: 33 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20070101

Duration:

Adverse Reactions:

- FEELING JITTERY
- HEART RATE INCREASED
- PRODUCT QUALITY ISSUE

ISR Number: 6207959 Case Number: 7006217 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648872
Mfg. Date: 20081205
Mfg. Number: A0759478A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: N/A
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1PUFF AS REQUIRED
Event Date: 20081204
FDA Date: 20090529
Follow Number:
Image ID: 6207959-0
Age: 56 YR Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start: 20081205
Therapy End: 20081204
Duration: 2 DAY
Adverse Reactions:
CHEST DISCOMFORT
DRUG INEFFECTIVE

ISR Number: 6207960 Case Number: 7006218 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648875

Mfg. Date: 20081208

Mfg. Number: A0759612A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP1545

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF FOUR TIMES PER DAY

Event Date: 20080601

FDA Date: 20090529

Follow Number:

Image ID: 6207960-7

Age: 46 YR Gender: M Weight:

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: 20080601

Duration:

Adverse Reactions:

- ASTHMA
- CHEST DISCOMFORT
- DRUG INEFFECTIVE
- DRY MOUTH
- DYSPNOEA
- WHEEZING

ISR Number: 6207961 Case Number: 7006219 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648881

Mfg. Date: 20081209

Mfg. Number: A0759725A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 7ZP5727

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF AS REQUIRED

Event Date: 20081209

FDA Date: 20090529

Follow Number:

Image ID: 6207961-9

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PRODUCT QUALITY ISSUE

ISR Number: 6207962 Case Number: 7006220 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648882

Mfg. Date: 20081211

Mfg. Number: A0760204A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP1544

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20081207

FDA Date: 20090529

Follow Number:

Image ID: 6207962-0

Age: 41 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration: 10 YR

Adverse Reactions:

- ASTHMA
- DRUG INEFFECTIVE
- PRODUCT QUALITY ISSUE

ISR Number: 6207963 Case Number: 7006221 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648885
 Mfg. Date: 20081209
 Mfg. Number: A0760251A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: ASTHMA
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207963-2
 Age: Gender: M Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 ASTHMA
 THERAPEUTIC RESPONSE DECREASED

ISR Number: 6207964 Case Number: 7006222 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648887
Mfg. Date: 20081215
Mfg. Number: A0761350A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route:
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6207964-4
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG EFFECT DECREASED

ISR Number: 6207965 Case Number: 7006223 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648888

Mfg. Date: 20090122

Mfg. Number: A0761951A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: RESPIRATORY TRACT IRRITATION

Route: UNKNOWN

Dose: 1PUFF SEE DOSAGE TEXT

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207965-6

Age: Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

ADVERSE DRUG REACTION

ANXIETY

CONDITION AGGRAVATED

DRY MOUTH

DYSPHONIA

RESPIRATORY TRACT IRRITATION

THROAT IRRITATION

ISR Number: 6207966 Case Number: 7006224 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648889
Mfg. Date: 20090105
Mfg. Number: A0762331A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose:
Event Date: 20081201
FDA Date: 20090529
Follow Number:
Image ID: 6207966-8
Age: 51 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration: 5 YR
Adverse Reactions:
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6207967 Case Number: 7006225 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648893

Mfg. Date: 20090105

Mfg. Number: A0762344A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20090101

FDA Date: 20090529

Follow Number:

Image ID: 6207967-X

Age: 94 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20090101

Therapy End: 20080601

Duration: 31 WK

Adverse Reactions:

DRUG INEFFECTIVE

HEADACHE

ISR Number: 6207968 Case Number: 7006226 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648897

Mfg. Date: 20090501

Mfg. Number: A0762527A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP4696

Expiration Date:

Indication: BRONCHIECTASIS

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20090101

FDA Date: 20090529

Follow Number:

Image ID: 6207968-1

Age: 70 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090101

Duration:

Adverse Reactions:

DYSPNOEA

WHEEZING

ISR Number: 6207969 Case Number: 7006227 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648901
 Mfg. Date: 20090113
 Mfg. Number: A0763433A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: UNKNOWN
 Expiration Date:
 Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
 Route: RESPIRATORY (INHALATION)
 Dose: 2PUFF AS REQUIRED
 Event Date: 20081201
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207969-3
 Age: 70 YR Gender: F Weight:
 Occupation: OT
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End: 20081201
 Duration:
 Adverse Reactions:
 DRUG INEFFECTIVE

ISR Number: 6207970 Case Number: 7006228 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648905

Mfg. Date: 20090113

Mfg. Number: A0763434A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20081101

FDA Date: 20090529

Follow Number:

Image ID: 6207970-X

Age: 65 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20081101

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

ISR Number: 6207971 Case Number: 7006229 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648908

Mfg. Date: 20090121

Mfg. Number: A0764519A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20090101

FDA Date: 20090529

Follow Number:

Image ID: 6207971-1

Age: 45 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20060101

Duration: 3 YR

Adverse Reactions:

CHEST DISCOMFORT

PRODUCT QUALITY ISSUE

ISR Number: 6207972 Case Number: 7006230 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648909
 Mfg. Date: 20090218
 Mfg. Number: A0764541A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: UNKNOWN
 Expiration Date:
 Indication:
 Route: UNKNOWN
 Dose:
 Event Date: 20090120
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207972-3
 Age: 48 YR Gender: F Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start: 20090121
 Therapy End: 20090119
 Duration: 3 DAY
 Adverse Reactions:
 HYPERVENTILATION

ISR Number: 6207973 Case Number: 7006231 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648912

Mfg. Date: 20090427

Mfg. Number: A0765279A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP0329

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF THREE TIMES PER DAY

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207973-5

Age: Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20090101

Therapy End: 20090101

Duration: 5 DAY

Adverse Reactions:

ASTHMA

DRUG INEFFECTIVE

PRODUCT QUALITY ISSUE

ISR Number: 6207974 Case Number: 7006232 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648916
 Mfg. Date: 20090122
 Mfg. Number: A0765533A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207974-7
 Age: Gender: M Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 DYSPHONIA

ISR Number: 6207975 Case Number: 7006233 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648917

Mfg. Date: 20090327

Mfg. Number: A0765911A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP6426

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20090103

FDA Date: 20090529

Follow Number:

Image ID: 6207975-9

Age: 58 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090103

Duration:

Adverse Reactions:

- INTENTIONAL DRUG MISUSE
- PRODUCT QUALITY ISSUE
- THERAPEUTIC RESPONSE DECREASED

ISR Number: 6207976 Case Number: 7006234 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648919

Mfg. Date: 20090306

Mfg. Number: A0765916A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP4695

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF PER DAY

Event Date: 20081201

FDA Date: 20090529

Follow Number:

Image ID: 6207976-0

Age: 41 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 19730301

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

ISR Number: 6207977 Case Number: 7006235 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648924
 Mfg. Date: 20090130
 Mfg. Number: A0766143A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose: 1SPR UNKNOWN
 Event Date: 20090129
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207977-2
 Age: Gender: F Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End: 20080129
 Duration: 1 DAY
 Adverse Reactions:
 ORAL PRURITUS
 SWOLLEN TONGUE

ISR Number: 6207978 Case Number: 7006236 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648925

Mfg. Date: 20090327

Mfg. Number: A0766329A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP0492

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF FOUR TIMES PER DAY

Event Date: 20090131

FDA Date: 20090529

Follow Number:

Image ID: 6207978-4

Age: 52 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090130

Duration:

Adverse Reactions:

DYSпноEA

PRODUCT QUALITY ISSUE

ISR Number: 6207979 Case Number: 7006237 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648927

Mfg. Date: 20090505

Mfg. Number: A0766354A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP0493

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207979-6

Age: 69 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090101

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PRODUCT QUALITY ISSUE

ISR Number: 6207980 Case Number: 7006238 I/F Code: I Report Date: 20090529

Drug Name: **ALBUTEROL**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648930

Mfg. Date: 20090202

Mfg. Number: A0767201A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207980-2

Age: Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- INHALATION THERAPY
- OVERDOSE
- PRODUCT QUALITY ISSUE
- THERAPEUTIC RESPONSE DELAYED

ISR Number: 6207981 Case Number: 7006239 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648932

Mfg. Date: 20090211

Mfg. Number: A0768219A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP9991

Expiration Date:

Indication: BRONCHITIS

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20090101

FDA Date: 20090529

Follow Number:

Image ID: 6207981-4

Age: 42 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090101

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

DYSPNOEA EXERTIONAL

ISR Number: 6207982 Case Number: 7006240 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648934

Mfg. Date: 20090211

Mfg. Number: A0768232A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP8508

Expiration Date:

Indication: BRONCHOSPASM

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF SIX TIMES PER DAY

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207982-6

Age: 58 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ABNORMAL DREAMS
- BLOOD PRESSURE INCREASED
- HEADACHE
- HEART RATE INCREASED
- RASH
- SWELLING
- THROAT TIGHTNESS
- TREMOR
- URTICARIA

ISR Number: 6207983 Case Number: 7006241 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648952
 Mfg. Date: 20090211
 Mfg. Number: A0768236A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: UNKNOWN
 Expiration Date:
 Indication: ASTHMA
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date: 20090123
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207983-8
 Age: 25 YR Gender: M Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 DRUG SCREEN FALSE POSITIVE

ISR Number: 6207984 Case Number: 7006242 I/F Code: I Report Date: 20090529
Drug Name: **ALBUTEROL**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648956
Mfg. Date: 20090202
Mfg. Number: A0768311A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6207984-X
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ADVERSE DRUG REACTION

ISR Number: 6207985 Case Number: 7006243 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648957
Mfg. Date: 20090212
Mfg. Number: A0768463A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6207985-1
Age: Gender: Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 6207986 Case Number: 7006244 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648958

Mfg. Date: 20090324

Mfg. Number: A0768487A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20090101

FDA Date: 20090529

Follow Number:

Image ID: 6207986-3

Age: 88 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20090101

Therapy End: 20090101

Duration: 1 DAY

Adverse Reactions:

- CHEST DISCOMFORT
- DRUG ADMINISTRATION ERROR
- DRUG INEFFECTIVE
- DYSPNOEA

ISR Number: 6207987 Case Number: 7006245 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648961

Mfg. Date: 20090212

Mfg. Number: A0768490A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP9892

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF VARIABLE DOSE

Event Date: 20090209

FDA Date: 20090529

Follow Number:

Image ID: 6207987-5

Age: 5 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090209

Duration:

Adverse Reactions:

COUGH

PYREXIA

THROAT IRRITATION

VOMITING

ISR Number: 6207988 Case Number: 7006246 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648963
Mfg. Date: 20090219
Mfg. Number: A0769521A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: BRONCHOSPASM
Route: RESPIRATORY (INHALATION)
Dose:
Event Date: 20090218
FDA Date: 20090529
Follow Number:
Image ID: 6207988-7
Age: 79 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start: 20090219
Therapy End: 20090216
Duration: 4 DAY
Adverse Reactions:
OVERDOSE

ISR Number: 6207989 Case Number: 7006247 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648965

Mfg. Date: 20090220

Mfg. Number: A0769782A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20090219

FDA Date: 20090529

Follow Number:

Image ID: 6207989-9

Age: 39 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20090219

Therapy End: 20090219

Duration: 1 DAY

Adverse Reactions:

ACCIDENTAL EXPOSURE

 DIZZINESS

ISR Number: 6207990 Case Number: 7006248 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648967

Mfg. Date: 20090302

Mfg. Number: A0770026A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP0328

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20090207

FDA Date: 20090529

Follow Number:

Image ID: 6207990-5

Age: Gender: M Weight:

Occupation: LW

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- EMOTIONAL DISORDER
- PRODUCT QUALITY ISSUE
- RETCHING
- VOMITING

ISR Number: 6207991 Case Number: 7006249 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648971

Mfg. Date: 20090424

Mfg. Number: A0770702A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP8972

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20090101

FDA Date: 20090529

Follow Number:

Image ID: 6207991-7

Age: Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20081101

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PRODUCT QUALITY ISSUE

ISR Number: 6207992 Case Number: 7006250 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011648973
 Mfg. Date: 20090226
 Mfg. Number: A0770713A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: 8ZP2574
 Expiration Date:
 Indication: ASTHMA
 Route: RESPIRATORY (INHALATION)
 Dose: 3PUFF SIX TIMES PER DAY
 Event Date: 20090101
 FDA Date: 20090529
 Follow Number:
 Image ID: 6207992-9
 Age: 73 YR Gender: F Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End: 20090101
 Duration:
 Adverse Reactions:
 EPISTAXIS
 OVERDOSE

ISR Number: 6207993 Case Number: 7006251 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648979

Mfg. Date: 20090227

Mfg. Number: A0770930A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP8118

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF AS REQUIRED

Event Date: 20090226

FDA Date: 20090529

Follow Number:

Image ID: 6207993-0

Age: 50 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20090226

Therapy End: 20090226

Duration: 1 DAY

Adverse Reactions:

FEELING JITTERY

PHARYNGEAL OEDEMA

ISR Number: 6207994 Case Number: 7006252 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648984

Mfg. Date: 20090303

Mfg. Number: A0771331A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP8976

Expiration Date:

Indication: COUGH

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF SINGLE DOSE

Event Date: 20090302

FDA Date: 20090529

Follow Number:

Image ID: 6207994-2

Age: 60 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090302

Duration: 1 DAY

Adverse Reactions:

BLOOD PRESSURE DECREASED

DIZZINESS

ISR Number: 6207995 Case Number: 7006253 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648988

Mfg. Date: 20090303

Mfg. Number: A0771341A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF THREE TIMES PER DAY

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207995-4

Age: 82 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20080901

Therapy End: 20080501

Duration: 3 MON

Adverse Reactions:

- DRUG ADMINISTRATION ERROR
- DRUG INEFFECTIVE
- DYSPNOEA
- VISION BLURRED

ISR Number: 6207996 Case Number: 7006254 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648991

Mfg. Date: 20090226

Mfg. Number: A0771375A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF VARIABLE DOSE

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207996-6

Age: 70 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ACTIVITIES OF DAILY LIVING IMPAIRED
- ADVERSE DRUG REACTION
- ADVERSE EVENT
- DIZZINESS
- FEELING ABNORMAL
- HEART RATE INCREASED
- PAINFUL RESPIRATION
- PANIC REACTION
- THERAPEUTIC RESPONSE DECREASED
- WHEEZING

ISR Number: 6207997 Case Number: 7006255 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648993

Mfg. Date: 20090428

Mfg. Number: A0772404A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20090529

Follow Number:

Image ID: 6207997-8

Age: Gender: Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DIZZINESS

DRUG INEFFECTIVE

PRODUCT QUALITY ISSUE

RASH

ISR Number: 6207998 Case Number: 7006256 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011648994

Mfg. Date: 20090311

Mfg. Number: A0772808A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP2576

Expiration Date:

Indication: WHEEZING

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF VARIABLE DOSE

Event Date: 20090311

FDA Date: 20090529

Follow Number:

Image ID: 6207998-X

Age: 82 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090311

Duration:

Adverse Reactions:

TONGUE DRY

ISR Number: 6207999 Case Number: 7006257 I/F Code: I Report Date: 20090529
Drug Name: **ALBUTEROL**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011648995
Mfg. Date: 20090311
Mfg. Number: A0772815A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: 080508W
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose: 2PUFF THREE TIMES PER DAY
Event Date: 20090308
FDA Date: 20090529
Follow Number:
Image ID: 6207999-1
Age: 89 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End: 20090304
Duration:
Adverse Reactions:
DYSпноEA

ISR Number: 6208000 Case Number: 7006258 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011649001
Mfg. Date: 20090312
Mfg. Number: A0773057A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: 8ZP5531
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2PUFF AS REQUIRED
Event Date: 20081101
FDA Date: 20090529
Follow Number:
Image ID: 6208000-6
Age: 51 YR Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start: 20090201
Therapy End: 20081101
Duration: 13 WK
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 6208001 Case Number: 7006259 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011649004

Mfg. Date: 20090313

Mfg. Number: A0773230A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF PER DAY

Event Date: 20090313

FDA Date: 20090529

Follow Number:

Image ID: 6208001-8

Age: 94 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090312

Duration:

Adverse Reactions:

CONSTIPATION

HEADACHE

NAUSEA

NERVOUSNESS

ISR Number: 6208002 Case Number: 7006260 I/F Code: I Report Date: 20090529
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011649006
 Mfg. Date: 20090406
 Mfg. Number: A0773272A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: 8ZP1198
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20090529
 Follow Number:
 Image ID: 6208002-X
 Age: Gender: Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 BRONCHOSPASM
 PRODUCT QUALITY ISSUE

ISR Number: 6208003 Case Number: 7006261 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011649007
Mfg. Date: 20090403
Mfg. Number: A0773594A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6208003-1
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 6208004 Case Number: 7006262 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011649008
Mfg. Date: 20090310
Mfg. Number: A0773635A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6208004-3
Age: Gender: Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 INJURY
 PRODUCT QUALITY ISSUE

ISR Number: 6208005 Case Number: 7006263 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011649009

Mfg. Date: 20090320

Mfg. Number: A0774613A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF TWICE PER DAY

Event Date: 20090101

FDA Date: 20090529

Follow Number:

Image ID: 6208005-5

Age: 67 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090101

Duration: 1 MON

Adverse Reactions:

DRUG INEFFECTIVE

PALPITATIONS

ISR Number: 6208006 Case Number: 7006264 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011649012

Mfg. Date: 20090323

Mfg. Number: A0774833A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: BRONCHITIS

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20090323

FDA Date: 20090529

Follow Number:

Image ID: 6208006-7

Age: 78 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20090301

Duration: 2 DAY

Adverse Reactions:

- ASTHENIA
- DISCOMFORT
- FEELING ABNORMAL
- FEELING OF DESPAIR
- HYPERHIDROSIS
- NERVOUSNESS
- PALPITATIONS

ISR Number: 6208007 Case Number: 7006265 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011649018
Mfg. Date: 20090323
Mfg. Number: A0774839A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: UNKNOWN
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date: 20090223
FDA Date: 20090529
Follow Number:
Image ID: 6208007-9
Age: 25 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG SCREEN FALSE POSITIVE

ISR Number: 6208008 Case Number: 7006266 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011649022
Mfg. Date: 20090327
Mfg. Number: A0775901A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20090529
Follow Number:
Image ID: 6208008-0
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 NAUSEA

ISR Number: 6208878 Case Number: 6982029 I/F Code: I Report Date: 20090529

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011652404

Mfg. Date: 20090525

Mfg. Number: B0571802A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: F3112

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 8PUFF PER DAY

Event Date: 20090401

FDA Date: 20090529

Follow Number:

Image ID: 6208878-6

Age: 31 Gender: F Weight:

Occupation: OT

Country: FRANCE

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMATIC CRISIS
- DRUG INEFFECTIVE
- PRODUCT QUALITY ISSUE

ISR Number: 6208897 Case Number: 7006867 I/F Code: I Report Date: 20090529
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011652449
Mfg. Date: 20090519
Mfg. Number: B0576131A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20080706
FDA Date: 20090529
Follow Number:
Image ID: 6208897-X
Age: 33 YR Gender: M Weight: 125 KG
Occupation: CN
Country: UNITED KINGDOM
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: Rechallenge Code: Death Date: 20080706
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
CARDIOMYOPATHY

ISR Number: 6210517 Case Number: 7008172 I/F Code: I Report Date: 20090601
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011659219
 Mfg. Date: 20090522
 Mfg. Number: A0787233A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route:
 Dose:
 Event Date:
 FDA Date: 20090601
 Follow Number:
 Image ID: 6210517-5
 Age: Gender: F Weight:
 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:
 Duration:
 Adverse Reactions:
 DYSпноEA

ISR Number: 6216233 Case Number: 7012362 I/F Code: I Report Date: 20090605
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011680120
Mfg. Date: 20090528
Mfg. Number: A0788672A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication:
Route: ORAL
Dose:
Event Date: 20090525
FDA Date: 20090605
Follow Number:
Image ID: 6216233-8
Age: 9 MON Gender: Weight:
Occupation: CN
Country: ARGENTINA
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start: 20090525
Therapy End: 20090525
Duration: 1 DAY
Adverse Reactions:
ACCIDENTAL EXPOSURE

ISR Number: 6219789 Case Number: 7015034 I/F Code: I Report Date: 20090609

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011694311

Mfg. Date: 20090603

Mfg. Number: B0577137A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: TOPICAL

Dose:

Event Date: 20090323

FDA Date: 20090609

Follow Number:

Image ID: 6219789-4

Age: 14 Gender: F Weight:

Occupation: CN

Country: FRANCE

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

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

Therapy Start: 20090323

Therapy End: 20090323

Duration: 1 DAY

Adverse Reactions:

- CHEMICAL BURN OF SKIN
- DRUG TOXICITY
- INCORRECT ROUTE OF DRUG ADMINISTRATION
- INTENTIONAL DRUG MISUSE

ISR Number: 6227399 Case Number: 7025394 I/F Code: I Report Date: 20090609

Drug Name: **VENTOLIN HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011722074

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: BZP9993

Expiration Date: 20100131

Indication: ASTHMA

Route: ORAL

Dose: 1 - 2 PUFFS AS NEEDED PO

Event Date: 20090602

FDA Date: 20090610

Follow Number:

Image ID: 6227399-8

Age: 67 YR Gender: M Weight: 200 LBS

Occupation:

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: 20090602

Therapy End: 20090601

Duration:

Adverse Reactions:

- DRY MOUTH
- DYSPHAGIA
- DYSPHONIA
- ERYTHEMA
- INCREASED UPPER AIRWAY SECRETION
- LYMPHADENOPATHY
- SWELLING
- THROAT IRRITATION

ISR Number: 6231515 Case Number: 7024815 I/F Code: I Report Date: 20090616

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011738658

Mfg. Date: 20090608

Mfg. Number: B0577873A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose: 100MCG AS REQUIRED

Event Date: 20090501

FDA Date: 20090616

Follow Number:

Image ID: 6231515-1

Age: 74 Gender: F Weight: 70 KG

Occupation: CN

Country: FRANCE

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

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

Therapy Start: 20090521

Therapy End: 20090511

Duration: 11 DAY

Adverse Reactions:

- APATHY
- DYSPHAGIA
- HYPOKALAEMIA
- MUSCULAR WEAKNESS

ISR Number: 6233030 Case Number: 7025817 I/F Code: I Report Date: 20090617

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011743962

Mfg. Date: 20090610

Mfg. Number: B0578274A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: PAIN

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20080824

FDA Date: 20090617

Follow Number:

Image ID: 6233030-8

Age: 74 Gender: M Weight:

Occupation: CN

Country: FRANCE

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

CONFUSIONAL STATE

OVERDOSE

TREMOR

ISR Number: 6234916 Case Number: 7026974 I/F Code: I Report Date: 20090618

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011750685

Mfg. Date: 20090611

Mfg. Number: A0790410A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: F0458

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF FOUR TIMES PER DAY

Event Date: 20090601

FDA Date: 20090618

Follow Number:

Image ID: 6234916-0

Age: 70 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20090101

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- DRY MOUTH
- ORAL DISCOMFORT
- STOMATITIS
- TONGUE DISCOLOURATION
- TONGUE DISORDER

ISR Number: 6234957 Case Number: 7027004 I/F Code: I Report Date: 20090618

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011750861

Mfg. Date: 20090610

Mfg. Number: B0579370A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20090618

Follow Number:

Image ID: 6234957-3

Age: 57 YR Gender: F Weight:

Occupation: PH

Country: NEW ZEALAND

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG HYPERSENSITIVITY

TERMINAL STATE

WHEEZING

ISR Number: 6247290 Case Number: 7034569 I/F Code: I Report Date: 20090626
Drug Name: **ALBUTEROL**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1011799318
Mfg. Date: 20090619
Mfg. Number: A0792511A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1PUFF AS REQUIRED
Event Date: 20090605
FDA Date: 20090626
Follow Number:
Image ID: 6247290-0
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration: 10 YR
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE

ISR Number: 6247291 Case Number: 7034570 I/F Code: I Report Date: 20090626

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011799319

Mfg. Date: 20090619

Mfg. Number: A0792515A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNAVAILABLE

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF FOUR TIMES PER DAY

Event Date: 20090501

FDA Date: 20090626

Follow Number:

Image ID: 6247291-2

Age: 32 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- CHEST DISCOMFORT
- COUGH
- DRUG INEFFECTIVE
- RESPIRATORY TRACT CONGESTION

ISR Number: 6248220 Case Number: 7035484 I/F Code: I Report Date: 20090609
 Drug Name: **VENTOLIN HFA**
 NDA Number: 18473
 Role Code: PS VAL/VBM: 1
 Seq Number: 1011803930
 Mfg. Date: 20090415
 Mfg. Number: A0779771A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route:
 Dose:
 Event Date:
 FDA Date: 20090629
 Follow Number:
 Image ID: 6248220-8
 Age: Gender: F Weight:
 Occupation: CN
 Country: UNITED STATES
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End:
 Duration:
 Adverse Reactions:
 DRUG INEFFECTIVE

ISR Number: 6249508 Case Number: 7027004 I/F Code: I Report Date: 20090629

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011808088

Mfg. Date: 20090610

Mfg. Number: B0579370A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20090629

Follow Number:

Image ID: 6249508-7

Age: 57 YR Gender: F Weight:

Occupation: PH

Country: NEW ZEALAND

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

APPARENT LIFE THREATENING EVENT

DRUG HYPERSENSITIVITY

WHEEZING

ISR Number: 6252758 Case Number: 7045258 I/F Code: I Report Date: 20090628
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011822971
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: DYSPNOEA EXERTIONAL
Route: ORAL
Dose: 2 PUFFS Q6H PRN PO
Event Date: 20090514
FDA Date: 20090629
Follow Number:
Image ID: 6252758-7
Age: 92 YR 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: 20090514
Therapy End: 20090401
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 HEART RATE INCREASED