
ISR Number: 4633114 Case Number: 5774164 I/F Code: I Report Date: 20050412

Drug Name: **VENTOLIN HFA**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1005869924

Mfg. Date: 20050408

Mfg. Number: US-GLAXOSMITHKLINE-A0553392A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20050101

FDA Date: 20050412

Follow Number:

Image ID: 4633114-1

Age: 35 YR Gender: F Weight:

Occupation: CN

Country:

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

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

Therapy Start:

Therapy End: 20050101

Duration:

Adverse Reactions:

DRUG ABUSER

LOSS OF CONSCIOUSNESS

ISR Number: 4661423 Case Number: 5794912 I/F Code: I Report Date: 20050513

Drug Name: **VENTOLIN HFA**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1005978262

Mfg. Date: 20050505

Mfg. Number: CA-GLAXOSMITHKLINE-A0558007A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose: 2.5MG SINGLE DOSE

Event Date: 20040303

FDA Date: 20050513

Follow Number:

Image ID: 4661423-9

Age: 54 YR Gender: F Weight:

Occupation: MD

Country:

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

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

Therapy Start:

Therapy End:

Duration: 1 DAY

Adverse Reactions:

- HYPOAESTHESIA
- TONGUE OEDEMA
- URTICARIA

ISR Number: 4661424 Case Number: 5794913 I/F Code: I Report Date: 20050513
Drug Name: **VENTOLIN HFA**
NDA Number: 18473
Role Code: PS VAL/VBM: 1
Seq Number: 1005978265
Mfg. Date: 20050505
Mfg. Number: CA-GLAXOSMITHKLINE-A0558028A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20050513
Follow Number:
Image ID: 4661424-0
Age: Gender: M Weight:
Occupation: CN
Country:
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 OEDEMA

ISR Number: 4661425 Case Number: 5794914 I/F Code: I Report Date: 20050513
Drug Name: **VENTOLIN HFA**
NDA Number: 18473
Role Code: PS VAL/VBM: 1
Seq Number: 1005978267
Mfg. Date: 20050505
Mfg. Number: CA-GLAXOSMITHKLINE-A0558031A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: UNKNOWN
Dose:
Event Date:
FDA Date: 20050513
Follow Number:
Image ID: 4661425-2
Age: Gender: M Weight:
Occupation: PH
Country:
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ACCIDENTAL OVERDOSE
ASTHMA
CONDITION AGGRAVATED

ISR Number: 4738402 Case Number: 5855068 I/F Code: I Report Date: 20050809

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1006296872

Mfg. Date: 20050802

Mfg. Number: GB-GLAXOSMITHKLINE-B0389431A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8768

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20050809

Follow Number:

Image ID: 4738402-6

Age: 73 YR Gender: F Weight:

Occupation: PH

Country: UNITED KINGDOM

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

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

Therapy Start:

Therapy End:

Duration: 2 YR

Adverse Reactions:

CHOKING

DYSPNOEA EXACERBATED

ISR Number: 4804411 Case Number: 5905114 I/F Code: I Report Date: 20051020
Drug Name: **VENTOLIN HFA**
NDA Number: 18473
Role Code: PS VAL/VBM: 1
Seq Number: 1006534749
Mfg. Date: 20051018
Mfg. Number: US-GLAXOSMITHKLINE-A0578631A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20051020
Follow Number:
Image ID: 4804411-1
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: 20 YR
Adverse Reactions:
ASTHMA
CIRCULATORY COLLAPSE
DRUG EXPOSURE DURING PREGNANCY
EPISTAXIS

ISR Number: 4805997 Case Number: 5906130 I/F Code: I Report Date: 20051021

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1006539631

Mfg. Date: 20051019

Mfg. Number: US-GLAXOSMITHKLINE-A0578780A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20051021

Follow Number:

Image ID: 4805997-3

Age: 67 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:

Duration: 1 YR

Adverse Reactions:

DYSPNOEA

ISR Number: 4888296 Case Number: 5966485 I/F Code: I Report Date: 20060123
Drug Name: **VENTOLIN HFA**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1006852164
Mfg. Date: 20060117
Mfg. Number: US-GLAXOSMITHKLINE-A0589718A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20060123
Follow Number:
Image ID: 4888296-3
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
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4893729 Case Number: 5970508 I/F Code: I Report Date: 20060127

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1006873640

Mfg. Date: 20060123

Mfg. Number: GB-GLAXOSMITHKLINE-B0407533A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: [NOT ENTERED]

Expiration Date:

Indication: REVERSIBLE AIRWAYS OBSTRUCTION

Route: RESPIRATORY (INHALATION)

Dose: 100MCG UNKNOWN

Event Date: 20051224

FDA Date: 20060127

Follow Number:

Image ID: 4893729-2

Age: 10 YR Gender: M Weight:

Occupation: CN

Country: UNITED KINGDOM

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

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

Therapy Start: 20051226

Therapy End: 20051223

Duration: 4 DAY

Adverse Reactions:

- ANOREXIA
- BLISTER
- MOUTH ULCERATION
- PALLOR
- STEVENS-JOHNSON SYNDROME

ISR Number: 4986555 Case Number: 6034775 I/F Code: I Report Date: 20060428
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1007224879
Mfg. Date: 20050406
Mfg. Number: US-GLAXOSMITHKLINE-A0552986A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20060428
Follow Number:
Image ID: 4986555-7
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: 4986556 Case Number: 6034776 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224881

Mfg. Date: 20050426

Mfg. Number: US-GLAXOSMITHKLINE-A0555826A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 4ZP7542

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF PER DAY

Event Date: 20050419

FDA Date: 20060428

Follow Number:

Image ID: 4986556-9

Age: 71 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: 20050419

Duration: 13 YR

Adverse Reactions:

 DIZZINESS

ISR Number: 4986558 Case Number: 6034778 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224893

Mfg. Date: 20050601

Mfg. Number: US-GLAXOSMITHKLINE-A0560783A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 5ZP3482

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986558-2

Age: 49 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: 20050516

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4986559 Case Number: 6034779 I/F Code: I Report Date: 20060428
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1007224895
Mfg. Date: 20050610
Mfg. Number: US-GLAXOSMITHKLINE-A0562135A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose:
Event Date:
FDA Date: 20060428
Follow Number:
Image ID: 4986559-4
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: 4986560 Case Number: 6034780 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224896

Mfg. Date: 20050720

Mfg. Number: US-GLAXOSMITHKLINE-A0567029A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 4ZP1143

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF AS REQUIRED

Event Date: 20050626

FDA Date: 20060428

Follow Number:

Image ID: 4986560-0

Age: 17 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: 9 YR

Adverse Reactions:

- DRUG INEFFECTIVE
- DYSPNOEA
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4986561 Case Number: 6034781 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224898

Mfg. Date: 20050823

Mfg. Number: US-GLAXOSMITHKLINE-A0571437A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 4ZP1142

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20050801

FDA Date: 20060428

Follow Number:

Image ID: 4986561-2

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: 20050819

Duration:

Adverse Reactions:

DRUG ADMINISTRATION ERROR

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4986562 Case Number: 6034782 I/F Code: I Report Date: 20060428
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1007224901
Mfg. Date: 20050901
Mfg. Number: US-GLAXOSMITHKLINE-A0572729A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date: 20010101
FDA Date: 20060428
Follow Number:
Image ID: 4986562-4
Age: 68 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: 4986563 Case Number: 6034783 I/F Code: I Report Date: 20060428
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1007224904
Mfg. Date: 20050909
Mfg. Number: US-GLAXOSMITHKLINE-A0573609A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: UNKNOWN
Dose:
Event Date:
FDA Date: 20060428
Follow Number:
Image ID: 4986563-6
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: 4986564 Case Number: 6034784 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224905

Mfg. Date: 20050912

Mfg. Number: US-GLAXOSMITHKLINE-A0573881A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 5ZP3484

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF FOUR TIMES PER DAY

Event Date: 20050901

FDA Date: 20060428

Follow Number:

Image ID: 4986564-8

Age: 2 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: 20050906

Therapy End: 20050901

Duration: 6 DAY

Adverse Reactions:

- BLISTER
- DIARRHOEA
- RASH
- SKIN ULCER

ISR Number: 4986565 Case Number: 6034785 I/F Code: I Report Date: 20060428
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1007224909
 Mfg. Date: 20050913
 Mfg. Number: US-GLAXOSMITHKLINE-A0574046A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: NAV
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose: 1PUFF TWICE PER DAY
 Event Date:
 FDA Date: 20060428
 Follow Number:
 Image ID: 4986565-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: 20050913
 Duration: 10 YR
 Adverse Reactions:
 THERAPEUTIC RESPONSE DECREASED

ISR Number: 4986566 Case Number: 6034786 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224911

Mfg. Date: 20050923

Mfg. Number: US-GLAXOSMITHKLINE-A0575696A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: [NOT ENTERED]

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF AS REQUIRED

Event Date: 20050917

FDA Date: 20060428

Follow Number:

Image ID: 4986566-1

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: 20050101

Duration: 9 MON

Adverse Reactions:

- DRUG INEFFECTIVE
- PHARMACEUTICAL PRODUCT COMPLAINT
- PHARYNGOLARYNGEAL PAIN

ISR Number: 4986567 Case Number: 6034787 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224915

Mfg. Date: 20051026

Mfg. Number: US-GLAXOSMITHKLINE-A0579785A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986567-3

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:

Duration: 10 YR

Adverse Reactions:

- DRUG ADMINISTRATION ERROR
- DRUG INEFFECTIVE
- DRY SKIN
- DYSPHAGIA
- GENERAL PHYSICAL HEALTH DETERIORATION
- PHARYNGEAL OEDEMA

ISR Number: 4986569 Case Number: 6034788 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224928

Mfg. Date: 20051116

Mfg. Number: US-GLAXOSMITHKLINE-A0582561A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: SKIN DISORDER

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986569-7

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:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

ISR Number: 4986570 Case Number: 6034789 I/F Code: I Report Date: 20060428
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1007224933
Mfg. Date: 20051116
Mfg. Number: US-GLAXOSMITHKLINE-A0582638A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20060428
Follow Number:
Image ID: 4986570-3
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:
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 4986571 Case Number: 6034790 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224934

Mfg. Date: 20051116

Mfg. Number: US-GLAXOSMITHKLINE-A0582640A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986571-5

Age: 19 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 INEFFECTIVE

ISR Number: 4986573 Case Number: 6034792 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224944

Mfg. Date: 20051128

Mfg. Number: US-GLAXOSMITHKLINE-A0583689A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986573-9

Age: 74 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:

DRUG INEFFECTIVE

ISR Number: 4986574 Case Number: 6034793 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224946

Mfg. Date: 20051129

Mfg. Number: US-GLAXOSMITHKLINE-A0583858A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20040101

FDA Date: 20060428

Follow Number:

Image ID: 4986574-0

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: 20040101

Duration: 1 YR

Adverse Reactions:

DRUG INEFFECTIVE

ISR Number: 4986575 Case Number: 6034794 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224948

Mfg. Date: 20051130

Mfg. Number: US-GLAXOSMITHKLINE-A0584109A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986575-2

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:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4986576 Case Number: 6034795 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224950

Mfg. Date: 20051215

Mfg. Number: US-GLAXOSMITHKLINE-A0585976A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20020101

FDA Date: 20060428

Follow Number:

Image ID: 4986576-4

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: 20020101

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

ISR Number: 4986577 Case Number: 6034796 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224961

Mfg. Date: 20051216

Mfg. Number: US-GLAXOSMITHKLINE-A0586115A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 5ZP3484

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986577-6

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: 30 YR

Adverse Reactions:

- DRUG INEFFECTIVE
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4986578 Case Number: 6034797 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224967

Mfg. Date: 20051222

Mfg. Number: US-GLAXOSMITHKLINE-A0586824A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 1SPR AS REQUIRED

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986578-8

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: 4986579 Case Number: 6034798 I/F Code: I Report Date: 20060428
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1007224969
Mfg. Date: 20051222
Mfg. Number: US-GLAXOSMITHKLINE-A0586835A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20060428
Follow Number:
Image ID: 4986579-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:
DRUG INEFFECTIVE

ISR Number: 4986580 Case Number: 6034799 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224973

Mfg. Date: 20060105

Mfg. Number: US-GLAXOSMITHKLINE-A0587925A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20051201

FDA Date: 20060428

Follow Number:

Image ID: 4986580-6

Age: 94 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:

DYSPNOEA

ISR Number: 4986581 Case Number: 6034800 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224974

Mfg. Date: 20060123

Mfg. Number: US-GLAXOSMITHKLINE-A0590506A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNAVAILABLE

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986581-8

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: 4986582 Case Number: 6034801 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224975

Mfg. Date: 20060125

Mfg. Number: US-GLAXOSMITHKLINE-A0590927A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986582-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:

DYSGEUSIA

ISR Number: 4986583 Case Number: 6034803 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224976

Mfg. Date: 20060215

Mfg. Number: US-GLAXOSMITHKLINE-A0593887A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986583-1

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

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4986584 Case Number: 6034804 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224977

Mfg. Date: 20060217

Mfg. Number: US-GLAXOSMITHKLINE-A0594165A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 5ZP3482

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20060101

FDA Date: 20060428

Follow Number:

Image ID: 4986584-3

Age: 62 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:

- MUSCULOSKELETAL CHEST PAIN
- PAIN
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4986585 Case Number: 6034805 I/F Code: I Report Date: 20060428

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007224979

Mfg. Date: 20060308

Mfg. Number: US-GLAXOSMITHKLINE-A0596745A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date:

FDA Date: 20060428

Follow Number:

Image ID: 4986585-5

Age: 62 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:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4988555 Case Number: 6036031 I/F Code: I Report Date: 20060502
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1007233508
Mfg. Date: 20060426
Mfg. Number: FR-GLAXOSMITHKLINE-B0421412A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20060502
Follow Number:
Image ID: 4988555-X
Age: 39 YR Gender: F Weight: 80 KG
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:
DRUG ABUSER

ISR Number: 5008674 Case Number: 6050461 I/F Code: I Report Date: 20060523

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007313159

Mfg. Date: 20060516

Mfg. Number: FR-GLAXOSMITHKLINE-B0423991A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: NASOPHARYNGITIS

Route: RESPIRATORY (INHALATION)

Dose: 3PUFF SIX TIMES PER DAY

Event Date: 20060418

FDA Date: 20060523

Follow Number:

Image ID: 5008674-1

Age: 2 YR Gender: F Weight: 11 KG

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: 20060418

Duration:

Adverse Reactions:

- BLOOD GLUCOSE DECREASED
- BLOOD SODIUM DECREASED
- CONVULSION
- HYPERKALAEMIA
- OVERDOSE

ISR Number: 5028438 Case Number: 6066973 I/F Code: I Report Date: 20060616

Drug Name: **VENTOLIN HFA**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007388907

Mfg. Date: 20060612

Mfg. Number: US-GLAXOSMITHKLINE-A0608636A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date:

FDA Date: 20060617

Follow Number:

Image ID: 5028438-2

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:

- DRUG HYPERSENSITIVITY
- OESOPHAGEAL INJURY
- PNEUMONIA
- VOMITING

ISR Number: 5037466 Case Number: 6073858 I/F Code: I Report Date: 20060628
Drug Name: **VENTOLIN HFA**
NDA Number: 18473
Role Code: PS VAL/VBM: 1
Seq Number: 1007422149
Mfg. Date: 20050808
Mfg. Number: US-GLAXOSMITHKLINE-A0570668A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date:
FDA Date: 20060628
Follow Number:
Image ID: 5037466-2
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:
DRUG INEFFECTIVE

ISR Number: 5072879 Case Number: 6106221 I/F Code: I Report Date: 20060801
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1007551391
Mfg. Date: 20060728
Mfg. Number: B0432527A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: INHALED
Event Date: 20060725
FDA Date: 20060802
Follow Number:
Image ID: 5072879-4
Age: 20 YR Gender: M Weight:
Occupation: PH
Country: FRANCE
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20060725
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DRUG DISPENSING ERROR

ISR Number: 5079552 Case Number: 6110414 I/F Code: I Report Date: 20060810
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1007575880
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 5ZP3453
Expiration Date: 20061130
Indication: EMPHYSEMA
Route: ORAL
Dose: 2 PUFFS 4 TIMES DAILY PO
Event Date:
FDA Date: 20060811
Follow Number:
Image ID: 5079552-7
Age: 73 YR Gender: F Weight: 110 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20060805
Therapy End: 20060724
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5082366 Case Number: 6115308 I/F Code: I Report Date: 20060811
Drug Name: **VENTOLIN HFA**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1007586854
Mfg. Date: 20060803
Mfg. Number: B0433745A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 90 MCG / THREE TIMES PER DAY / INHAL
Event Date:
FDA Date: 20060814
Follow Number:
Image ID: 5082366-5
Age: Gender: UNK Weight:
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ELECTROCARDIOGRAM QT PROLONGED
ELECTROCARDIOGRAM T WAVE ABNORMAL

ISR Number: 5097748 Case Number: 6128255 I/F Code: I Report Date: 20060831

Drug Name: **VENTOLIN HFA**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007645085

Mfg. Date: 20060821

Mfg. Number: B0435667A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: TRANSPLACENTAL

Dose: TRANSPLACENTARY

Event Date:

FDA Date: 20060905

Follow Number:

Image ID: 5097748-5

Age: Gender: F Weight:

Occupation:

Country: JAPAN

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:

- APGAR SCORE ABNORMAL
- BREECH DELIVERY
- CEREBRAL PALSY
- DIPLEGIA
- DRUG EXPOSURE DURING PREGNANCY
- FOETAL DISTRESS SYNDROME
- MATERNAL CONDITION AFFECTING FOETUS
- NEONATAL ASPIRATION
- PERIVENTRICULAR LEUKOMALACIA

ISR Number: 5141407 Case Number: 6159698 I/F Code: I Report Date: 20061101

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007813292

Mfg. Date: 20061027

Mfg. Number: FR-GLAXOSMITHKLINE-B0444614A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20061101

Follow Number:

Image ID: 5141407-7

Age: 37 YR Gender: F Weight:

Occupation: OT

Country: FRANCE

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

ERYTHEMA MULTIFORME

ISR Number: 5177054 Case Number: 6190007 I/F Code: I Report Date: 20061218

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1007949850

Mfg. Date: 20061212

Mfg. Number: FR-GLAXOSMITHKLINE-B0450151A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: LUNG DISORDER

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF AS REQUIRED

Event Date: 20060101

FDA Date: 20061218

Follow Number:

Image ID: 5177054-0

Age: 35 YR 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: 20061102

Therapy End: 20061029

Duration: 5 DAY

Adverse Reactions:

- ANOREXIA
- CHEILITIS
- CONJUNCTIVITIS
- DEHYDRATION
- ORAL SOFT TISSUE DISORDER
- STEVENS-JOHNSON SYNDROME
- STOMATITIS
- URETHRAL DISORDER
- VAGINAL DISORDER

ISR Number: 5248097 Case Number: 6246412 I/F Code: I Report Date: 20070227

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008187412

Mfg. Date: 20070223

Mfg. Number: US-GLAXOSMITHKLINE-A0641015A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20070227

Follow Number:

Image ID: 5248097-3

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:

- ADVERSE DRUG REACTION
- ASTHMA
- HEADACHE
- HYPERTENSION
- PAIN
- REACTION TO DRUG EXCIPIENTS
- SWELLING

ISR Number: 5253516 Case Number: 6259317 I/F Code: I Report Date: 20070215

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008204114

Mfg. Date: 20070205

Mfg. Number: B0458319A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 7.5 MG/HR SEE DOSAGE TEXT INHALED

Event Date:

FDA Date: 20070220

Follow Number:

Image ID: 5253516-2

Age: 11 YR Gender: F Weight:

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration: 5 HR

Adverse Reactions:

LACTIC ACIDOSIS

ISR Number: 5253642 Case Number: 6259323 I/F Code: I Report Date: 20070216

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008204501

Mfg. Date: 20070205

Mfg. Number: B0458342A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: SEE DOSAGE TEXT INHALED

Event Date:

FDA Date: 20070220

Follow Number:

Image ID: 5253642-8

Age: 17 YR Gender: M Weight:

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ATELECTASIS
- LACTIC ACIDOSIS
- LUNG HYPERINFLATION
- METABOLIC ACIDOSIS

ISR Number: 5253645 Case Number: 6259324 I/F Code: I Report Date: 20070216

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008204504

Mfg. Date: 20070205

Mfg. Number: B0458343A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: SEE DOSAGE TEXT INHALED

Event Date:

FDA Date: 20070220

Follow Number:

Image ID: 5253645-3

Age: 16 YR Gender: F Weight:

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- LACTIC ACIDOSIS
- LUNG HYPERINFLATION
- METABOLIC ACIDOSIS
- OXYGEN SATURATION DECREASED

ISR Number: 5254289 Case Number: 6252257 I/F Code: I Report Date: 20070302

Drug Name: **VENTILAN**

NDA Number: 20983

Role Code: PS VAL/VBM: 2

Seq Number: 1008207263

Mfg. Date: 20070222

Mfg. Number: PT-GLAXOSMITHKLINE-B0460161A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070126

FDA Date: 20070302

Follow Number:

Image ID: 5254289-X

Age: 5 MON Gender: F Weight: 18 KG

Occupation: CN

Country: PORTUGAL

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

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

Therapy Start:

Therapy End: 20070122

Duration:

Adverse Reactions:

- ERYTHEMA
- OEDEMA PERIPHERAL
- PRURITUS

ISR Number: 5270797 Case Number: 6274338 I/F Code: I Report Date: 20070318
Drug Name: **PRO-AIR HFA, VENTOLIN HFA ALBUTEROL HFA INHALER**
NDA Number:
Role Code: PS VAL/VBM: 2
Seq Number: 1008272818
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20070318
FDA Date: 20070319
Follow Number:
Image ID: 5270797-X
Age: Gender: M Weight: 185 LBS
Occupation:
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 EFFECT DECREASED
 MEDICAL DEVICE COMPLICATION
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5301446 Case Number: 6297899 I/F Code: I Report Date: 20070410

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008385149

Mfg. Date: 20070402

Mfg. Number: B0465291A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: AS REQUIRED / INHALED

Event Date:

FDA Date: 20070412

Follow Number:

Image ID: 5301446-X

Age: 59 YR Gender: M Weight:

Occupation:

Country: GERMANY

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- APNOEA
- BRONCHOSPASM
- CHEST DISCOMFORT
- INFLUENZA LIKE ILLNESS
- LOSS OF CONSCIOUSNESS
- OBSTRUCTIVE AIRWAYS DISORDER

ISR Number: 5302103 Case Number: 6291942 I/F Code: I Report Date: 20070419

Drug Name: **ALBUTEROL**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008387466

Mfg. Date: 20070402

Mfg. Number: US-GLAXOSMITHKLINE-B0465291A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20070419

Follow Number:

Image ID: 5302103-6

Age: 59 YR Gender: M 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:

Duration:

Adverse Reactions:

- APNOEA
- BRONCHOSPASM PARADOXICAL
- CHEST DISCOMFORT
- DYSPNOEA
- INFLUENZA LIKE ILLNESS
- LOSS OF CONSCIOUSNESS
- WHEEZING

ISR Number: 5310064 Case Number: 6298367 I/F Code: I Report Date: 20070427

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008417978

Mfg. Date: 20070419

Mfg. Number: FR-GLAXOSMITHKLINE-B0467419A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNSPECIFIED

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 100MCG UNKNOWN

Event Date: 20070326

FDA Date: 20070427

Follow Number:

Image ID: 5310064-9

Age: 6 MON 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: 20070301

Therapy End: 20070301

Duration: 1 DAY

Adverse Reactions:

- AGRANULOCYTOSIS
- HAEMOGLOBIN DECREASED
- NEUTROPENIA

ISR Number: 5313833 Case Number: 6301705 I/F Code: I Report Date: 20070501

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008432668

Mfg. Date: 20070427

Mfg. Number: US-GLAXOSMITHKLINE-A0649099A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 6ZP7455

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070101

FDA Date: 20070501

Follow Number:

Image ID: 5313833-4

Age: 33 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: 20070101

Duration: 3 MON

Adverse Reactions:

- ABDOMINAL PAIN UPPER
- ASTHMA
- PHARYNGOLARYNGEAL PAIN

ISR Number: 5338661 Case Number: 6322690 I/F Code: I Report Date: 20070530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008530229

Mfg. Date: 20060419

Mfg. Number: A0602467A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date:

FDA Date: 20070530

Follow Number:

Image ID: 5338661-5

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: 5 YR

Adverse Reactions:

DRUG SCREEN POSITIVE

ISR Number: 5338662 Case Number: 6322691 I/F Code: I Report Date: 20070530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008530235

Mfg. Date: 20060426

Mfg. Number: A0603390A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF SINGLE DOSE

Event Date:

FDA Date: 20070530

Follow Number:

Image ID: 5338662-7

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: 1 DAY

Adverse Reactions:

- DRUG HYPERSENSITIVITY
- DYSPNOEA
- PHARYNGEAL OEDEMA
- SENSATION OF FOREIGN BODY

ISR Number: 5338663 Case Number: 6322692 I/F Code: I Report Date: 20070530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008530239

Mfg. Date: 20060524

Mfg. Number: A0606813A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF AS REQUIRED

Event Date: 20060524

FDA Date: 20070530

Follow Number:

Image ID: 5338663-9

Age: 62 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: 20060524

Therapy End: 20060524

Duration:

Adverse Reactions:

- ANXIETY
- BURNING SENSATION
- CHEST DISCOMFORT
- FLUSHING
- WHEEZING

ISR Number: 5338664 Case Number: 6322693 I/F Code: I Report Date: 20070530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1008530243
 Mfg. Date: 20060530
 Mfg. Number: A0607260A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: UNKNOWN
 Expiration Date:
 Indication: ASTHMA
 Route: RESPIRATORY (INHALATION)
 Dose: 1PUFF AS REQUIRED
 Event Date: 20040101
 FDA Date: 20070530
 Follow Number:
 Image ID: 5338664-0
 Age: 49 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: 20040101
 Therapy End: 20040101
 Duration: 1 DAY
 Adverse Reactions:
 DRUG INEFFECTIVE

ISR Number: 5338665 Case Number: 6322694 I/F Code: I Report Date: 20070530
Drug Name: **VENTOLIN HFA**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1008530245
Mfg. Date: 20060721
Mfg. Number: A0613593A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20070530
Follow Number:
Image ID: 5338665-2
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:
Duration:
Adverse Reactions:
DYSпноEA

ISR Number: 5338666 Case Number: 6322695 I/F Code: I Report Date: 20070530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1008530246
Mfg. Date: 20061016
Mfg. Number: A0623700A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20070530
Follow Number:
Image ID: 5338666-4
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: 5338667 Case Number: 6322696 I/F Code: I Report Date: 20070530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1008530247
Mfg. Date: 20061114
Mfg. Number: A0627485A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication:
Route: RESPIRATORY (INHALATION)
Dose:
Event Date: 20061113
FDA Date: 20070530
Follow Number:
Image ID: 5338667-6
Age: 14 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: 20061113
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 5338668 Case Number: 6322697 I/F Code: I Report Date: 20070530
Drug Name: **ALBUTEROL**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1008530248
Mfg. Date: 20070312
Mfg. Number: A0643130A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: UNKNOWN
Dose:
Event Date:
FDA Date: 20070530
Follow Number:
Image ID: 5338668-8
Age: 84 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:
DRUG INEFFECTIVE

ISR Number: 5338669 Case Number: 6322698 I/F Code: I Report Date: 20070530
Drug Name: **VENTOLIN HFA**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1008530252
Mfg. Date: 20070312
Mfg. Number: A0643138A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: UNKNOWN
Dose:
Event Date:
FDA Date: 20070530
Follow Number:
Image ID: 5338669-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:
OEDEMA MOUTH

ISR Number: 5338670 Case Number: 6322699 I/F Code: I Report Date: 20070530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1008530253
Mfg. Date: 20070314
Mfg. Number: A0643397A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20070530
Follow Number:
Image ID: 5338670-6
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: 5338671 Case Number: 6322700 I/F Code: I Report Date: 20070530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1008530254
Mfg. Date: 20070327
Mfg. Number: A0644811A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20070530
Follow Number:
Image ID: 5338671-8
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

ISR Number: 5338672 Case Number: 6322701 I/F Code: I Report Date: 20070530
Drug Name: **VENTOLIN HFA**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1008530255
Mfg. Date: 20070326
Mfg. Number: A0645081A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: UNKNOWN
Dose:
Event Date:
FDA Date: 20070530
Follow Number:
Image ID: 5338672-X
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 EVENT

ISR Number: 5338720 Case Number: 6322735 I/F Code: I Report Date: 20070530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1008530424
Mfg. Date: 20070522
Mfg. Number: B0471870A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1PUFF AS REQUIRED
Event Date: 20070522
FDA Date: 20070530
Follow Number:
Image ID: 5338720-7
Age: 53 YR Gender: M Weight:
Occupation: PH
Country: UNITED KINGDOM
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start: 20070522
Therapy End: 20070522
Duration: 1 DAY
Adverse Reactions:
FLUSHING
MALAISE
PALPITATIONS

ISR Number: 5339831 Case Number: 6329790 I/F Code: I Report Date: 20070525

Drug Name: **ALBUTEROL SULFATE**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008533606

Mfg. Date: 20070516

Mfg. Number: B0472242A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route:

Dose: 200 MCG/ SEE DOSAGE TEXT

Event Date:

FDA Date: 20070529

Follow Number:

Image ID: 5339831-2

Age: 77 YR Gender: F Weight:

Occupation: MD

Country: HUNGARY

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ACUTE MYOCARDIAL INFARCTION
- CARDIAC FAILURE
- CORONARY ARTERY STENOSIS
- MITRAL VALVE INCOMPETENCE

ISR Number: 5374394 Case Number: 6337087 I/F Code: I Report Date: 20070628
Drug Name: **VENTOLIN HFA**
NDA Number: 18473
Role Code: PS VAL/VBM: 1
Seq Number: 1008645769
Mfg. Date: 20070118
Mfg. Number: A0636392A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date:
FDA Date: 20070629
Follow Number:
Image ID: 5374394-7
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:
DYSGEUSIA
NAUSEA

ISR Number: 5382989 Case Number: 6353383 I/F Code: I Report Date: 20070710

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008681239

Mfg. Date: 20070703

Mfg. Number: B0477669A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20070710

Follow Number:

Image ID: 5382989-X

Age: Gender: M Weight:

Occupation: CN

Country: UNITED KINGDOM

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- CHOKING
- FOREIGN BODY TRAUMA
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5386098 Case Number: 6359668 I/F Code: I Report Date: 20070709

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008693537

Mfg. Date: 20070625

Mfg. Number: B0476750A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 5 MG/ INHALED

Event Date:

FDA Date: 20070710

Follow Number:

Image ID: 5386098-5

Age: 28 YR Gender: F Weight:

Occupation:

Country: UNITED KINGDOM

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:

- ABDOMINAL PAIN
- ASTHMA
- BASE EXCESS
- HYPERLACTACIDAEMIA

ISR Number: 5397905 Case Number: 6372345 I/F Code: I Report Date: 20070721

Drug Name: **VENTOLIN HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008741081

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS THREE X DAY INHAL

Event Date: 20070612

FDA Date: 20070723

Follow Number:

Image ID: 5397905-4

Age: 34 YR Gender: F Weight: 160 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20070615

Therapy End: 20070515

Duration:

Adverse Reactions:

- DRUG INEFFECTIVE
- DYSPNOEA

ISR Number: 5402366 Case Number: 6373938 I/F Code: I Report Date: 20070727
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008761213
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: FHK03**
Expiration Date: 20081101
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 90 MCG PER INHALATION AS NEEDED INHAL
Event Date: 20070725
FDA Date: 20070730
Follow Number:
Image ID: 5402366-2
Age: 27 YR Gender: M Weight: 220 LBS
Occupation: CN
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: 20070727
Therapy End: 20070401
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
DRUG INEFFECTIVE

ISR Number: 5444440 Case Number: 6413123 I/F Code: I Report Date: 20070828

Drug Name: **ALBUTEROL SULFATE**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008893191

Mfg. Date: 20070816

Mfg. Number: B0484499A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: INHALED

Event Date:

FDA Date: 20070830

Follow Number:

Image ID: 5444440-0

Age: 8 YR Gender: F Weight: 64.2 LBS

Occupation:

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:

Duration:

Adverse Reactions:

BLOOD PRESSURE DIASTOLIC DECREASED
GENERAL PHYSICAL HEALTH DETERIORATION
HYPERGLYCAEMIA
METABOLIC ACIDOSIS
POLYURIA
SOMNOLENCE

ISR Number: 5447526 Case Number: 6409668 I/F Code: I Report Date: 20070910

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008905070

Mfg. Date: 20070829

Mfg. Number: B0486158A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: BRONCHIOLITIS

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070722

FDA Date: 20070910

Follow Number:

Image ID: 5447526-X

Age: 3 MON Gender: F Weight: 5.1 KG

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: 20070722

Duration:

Adverse Reactions:

ACUTE RESPIRATORY DISTRESS SYNDROME

APNOEA

ISR Number: 5453878 Case Number: 6415079 I/F Code: I Report Date: 20070917

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1008929330

Mfg. Date: 20070904

Mfg. Number: B0486812A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNSPECIFIED

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070701

FDA Date: 20070917

Follow Number:

Image ID: 5453878-7

Age: 65 YR Gender: F Weight:

Occupation: CN

Country: FRANCE

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

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

Therapy Start:

Therapy End: 20070701

Duration:

Adverse Reactions:

ASTHMATIC CRISIS

DRUG INEFFECTIVE

ISR Number: 5464304 Case Number: 6424608 I/F Code: I Report Date: 20070921
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1008960137
 Mfg. Date: 20070914
 Mfg. Number: B0487848A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: UNSPECIFIED
 Expiration Date:
 Indication: ASTHMATIC CRISIS
 Route: RESPIRATORY (INHALATION)
 Dose: 10PUFF SEE DOSAGE TEXT
 Event Date: 20070914
 FDA Date: 20070921
 Follow Number:
 Image ID: 5464304-6
 Age: 10 YR Gender: M Weight:
 Occupation: CN
 Country: FRANCE
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
 Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
 Therapy Start:
 Therapy End: 20070913
 Duration:
 Adverse Reactions:
 AGGRESSION

ISR Number: 5465723 Case Number: 6429568 I/F Code: I Report Date: 20070918
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1008966009
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Route: RESPIRATORY (INHALATION)
Dose: 2 PUFFS TWICE A DAY INHAL
Event Date:
FDA Date: 20070919
Follow Number:
Image ID: 5465723-4
Age: Gender: Weight:
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start: 20070917
Therapy End: 20070801
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 ECONOMIC PROBLEM
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5479645 Case Number: 6437571 I/F Code: I Report Date: 20071008
Drug Name: **VENTOLIN HFA**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009016834
Mfg. Date: 20071003
Mfg. Number: A0686208A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: UNKNOWN
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date: 20070101
FDA Date: 20071008
Follow Number:
Image ID: 5479645-6
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:
PNEUMONIA

ISR Number: 5479688 Case Number: 6437605 I/F Code: I Report Date: 20071008

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009016992

Mfg. Date: 20071002

Mfg. Number: B0490120A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070727

FDA Date: 20071008

Follow Number:

Image ID: 5479688-2

Age: 10 YR Gender: F Weight: 39.5 KG

Occupation: CN

Country: UNITED KINGDOM

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

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

Therapy Start: 20070727

Therapy End: 20070727

Duration: 1 DAY

Adverse Reactions:

- APPLICATION SITE DISCOLOURATION
- BURNING SENSATION
- THERMAL BURN

ISR Number: 5481441 Case Number: 6439030 I/F Code: I Report Date: 20071010

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009024284

Mfg. Date: 20071003

Mfg. Number: B0490394A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20071010

Follow Number:

Image ID: 5481441-0

Age: Gender: F Weight:

Occupation: CN

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:

- ASTHMA
- BURNING SENSATION
- DRUG HYPERSENSITIVITY
- FEELING ABNORMAL
- HYPERSENSITIVITY
- PHARMACEUTICAL PRODUCT COMPLAINT
- UNEVALUABLE EVENT

ISR Number: 5489442 Case Number: 6453912 I/F Code: I Report Date: 20071015
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009053954
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20070930
FDA Date: 20071016
Follow Number:
Image ID: 5489442-3
Age: Gender: M Weight: 205 LBS
Occupation: OT
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: D Rechallenge Code: Death Date:
Therapy Start: 20070930
Therapy End: 20070916
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5504171 Case Number: 6457125 I/F Code: I Report Date: 20071101

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009110808

Mfg. Date: 20071026

Mfg. Number: A0691102A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20071101

Follow Number:

Image ID: 5504171-5

Age: 11 YR Gender: M Weight: 60 KG

Occupation: OT

Country: CANADA

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
- HEART RATE INCREASED
- PALPITATIONS
- PARAESTHESIA

ISR Number: 5556730 Case Number: 6517620 I/F Code: I Report Date: 20071210
Drug Name: **VENTOLIN HFA**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009278637
Mfg. Date: 20071128
Mfg. Number: B0126762A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication:
Route: TOPICAL
Dose: TOPICAL
Event Date:
FDA Date: 20071211
Follow Number:
Image ID: 5556730-1
Age: 22 YR Gender: F Weight:
Occupation: PH
Country: UNITED KINGDOM
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
BLISTER
INCORRECT ROUTE OF DRUG ADMINISTRATION
INTENTIONAL SELF-INJURY
THERMAL BURN
WOUND

ISR Number: 5569642 Case Number: 6511489 I/F Code: I Report Date: 20071220

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009320269

Mfg. Date: 20071211

Mfg. Number: A0699164A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20071220

Follow Number:

Image ID: 5569642-4

Age: Gender: F Weight:

Occupation: CN

Country: CANADA

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 INEFFECTIVE
- FRUSTRATION
- HEART RATE INCREASED
- PULMONARY OEDEMA

ISR Number: 5591853 Case Number: 6527374 I/F Code: I Report Date: 20080115

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009397976

Mfg. Date: 20080114

Mfg. Number: B0502596A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNSPECIFIED

Expiration Date:

Indication: COUGH

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20071126

FDA Date: 20080115

Follow Number:

Image ID: 5591853-2

Age: 48 YR 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: 20071130

Therapy End: 20071124

Duration: 7 DAY

Adverse Reactions:

- DERMATITIS CONTACT
- ECZEMA NUMMULAR
- ENANTHEMA
- TOXIC SKIN ERUPTION
- URTICARIA

ISR Number: 5601317 Case Number: 6533986 I/F Code: I Report Date: 20080124

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009432621

Mfg. Date: 20080123

Mfg. Number: B0504773A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: HYPERTENSION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070910

FDA Date: 20080124

Follow Number:

Image ID: 5601317-5

Age: 66 YR Gender: F Weight: 65 KG

Occupation: CN

Country: UNITED KINGDOM

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

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

Therapy Start:

Therapy End: 20050101

Duration:

Adverse Reactions:

- ANOREXIA
- CHEST PAIN
- NAUSEA
- PHARYNGOLARYNGEAL DISCOMFORT

ISR Number: 5644112 Case Number: 6578618 I/F Code: I Report Date: 20080225
Drug Name: **VENTOLIN HFA**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009579097
Mfg. Date: 20080214
Mfg. Number: B0509361A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose: INHALED
Event Date: 20080201
FDA Date: 20080226
Follow Number:
Image ID: 5644112-3
Age: 30 YR Gender: M Weight:
Occupation: MD
Country: FRANCE
Report Source: Electronic Submit: N Mfg. Notified: Confidential:
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date: 20080213
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
CARDIAC ARREST
DRUG ABUSE
OVERDOSE