

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: 3 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: 20070719

Therapy End: 20070719

Duration: 1 DAY

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: 20070915

Therapy End: 20070901

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

ISR Number: 5712738 Case Number: 6628917 I/F Code: I Report Date: 20080420
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1009815719
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: MDI PRN INHAL
Event Date: 20080419
FDA Date: 20080421
Follow Number:
Image ID: 5712738-4
Age: 26 YR Gender: M Weight: 197 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: RI Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
DYSпноEA
WHEEZING

ISR Number: 5725228 Case Number: 6630500 I/F Code: I Report Date: 20080501
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009861896
Mfg. Date: 20080428
Mfg. Number: B0518832A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20080501
Follow Number:
Image ID: 5725228-X
Age: Gender: Weight:
Occupation: PH
Country: AUSTRALIA
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
HOSPITALISATION
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5736446 Case Number: 6639115 I/F Code: I Report Date: 20080513

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009902462

Mfg. Date: 20080512

Mfg. Number: B0519809A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: PROPHYLAXIS

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20080101

FDA Date: 20080513

Follow Number:

Image ID: 5736446-9

Age: 79 YR Gender: M 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: 19950306

Duration:

Adverse Reactions:

IDIOPATHIC PULMONARY FIBROSIS

ISR Number: 5744871 Case Number: 6647860 I/F Code: I Report Date: 20080515

Drug Name: **ALBUTEROL SULFATE**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009933920

Mfg. Date: 20080509

Mfg. Number: B0519678A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 5 MG / INHALED

Event Date:

FDA Date: 20080516

Follow Number:

Image ID: 5744871-5

Age: 39 YR Gender: M Weight:

Occupation:

Country: UNITED KINGDOM

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- BLOOD GASES ABNORMAL
- LACTIC ACIDOSIS

ISR Number: 5753227 Case Number: 6652842 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969587

Mfg. Date: 20070406

Mfg. Number: A0646175A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 271

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF TWICE PER DAY

Event Date: 20061215

FDA Date: 20080530

Follow Number:

Image ID: 5753227-0

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: 20070327

Therapy End: 20061205

Duration: 16 WK

Adverse Reactions:

- BURNING SENSATION
- CHEST PAIN
- DYSGEUSIA
- DYSPHAGIA
- DYSPHONIA
- HYPOAESTHESIA
- MUSCULAR WEAKNESS
- PARAESTHESIA
- PHARYNGOLARYNGEAL PAIN
- POLLAKIURIA
- TREMOR
- VISUAL DISTURBANCE
- WEIGHT INCREASED

ISR Number: 5753228 Case Number: 6652843 I/F Code: I Report Date: 20080530

Drug Name: **ALBUTEROL**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969590

Mfg. Date: 20070406

Mfg. Number: A0646692A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20080530

Follow Number:

Image ID: 5753228-2

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

ISR Number: 5753229 Case Number: 6652844 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969592
 Mfg. Date: 20070405
 Mfg. Number: A0646886A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: WHEEZING
 Route:
 Dose:
 Event Date: 20061001
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753229-4
 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: 20061001
 Duration:
 Adverse Reactions:
 DRUG INEFFECTIVE

ISR Number: 5753230 Case Number: 6652845 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969594

Mfg. Date: 20070417

Mfg. Number: A0648057A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070101

FDA Date: 20080530

Follow Number:

Image ID: 5753230-0

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: 20070101

Duration:

Adverse Reactions:

 HYPERSENSITIVITY

 PRURITUS

ISR Number: 5753235 Case Number: 6652851 I/F Code: I Report Date: 20080530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969608
Mfg. Date: 20070508
Mfg. Number: A0650432A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: UNKNOWN
Dose:
Event Date: 20070501
FDA Date: 20080530
Follow Number:
Image ID: 5753235-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:
ASTHENIA
TREMOR

ISR Number: 5753237 Case Number: 6652853 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN HFA**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969610
 Mfg. Date: 20070509
 Mfg. Number: A0650650A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: BRONCHOSPASM
 Route: UNKNOWN
 Dose:
 Event Date:
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753237-3
 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:
 DRUG INEFFECTIVE

ISR Number: 5753238 Case Number: 6652854 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN HFA**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969611

Mfg. Date: 20070522

Mfg. Number: A0652393A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 6ZP8537

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF FOUR TIMES PER DAY

Event Date: 20070522

FDA Date: 20080530

Follow Number:

Image ID: 5753238-5

Age: 10 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: 20070522

Duration: 1 DAY

Adverse Reactions:

NAUSEA

ISR Number: 5753239 Case Number: 6652855 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969615
 Mfg. Date: 20070523
 Mfg. Number: A0652678A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753239-7
 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: 5753240 Case Number: 6652856 I/F Code: I Report Date: 20080530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969616
Mfg. Date: 20070523
Mfg. Number: A0652679A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20080530
Follow Number:
Image ID: 5753240-3
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:
DRUG INEFFECTIVE

ISR Number: 5753241 Case Number: 6652857 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969617
 Mfg. Date: 20070523
 Mfg. Number: A0652680A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753241-5
 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

ISR Number: 5753242 Case Number: 6652858 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969618

Mfg. Date: 20070525

Mfg. Number: A0653015A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 4ZP7542

Expiration Date:

Indication: RESPIRATORY SYNCYTIAL VIRUS INFECTION

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF FOUR TIMES PER DAY

Event Date:

FDA Date: 20080530

Follow Number:

Image ID: 5753242-7

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: 20060521

Duration:

Adverse Reactions:

- COUGH
- DYSPNOEA
- EXPIRED DRUG ADMINISTERED

ISR Number: 5753243 Case Number: 6652859 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969621

Mfg. Date: 20070525

Mfg. Number: A0653027A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070524

FDA Date: 20080530

Follow Number:

Image ID: 5753243-9

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: 20070524

Therapy End: 20070524

Duration: 1 DAY

Adverse Reactions:

DYSпноEA

THROAT TIGHTNESS

ISR Number: 5753244 Case Number: 6652860 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969623
 Mfg. Date: 20070530
 Mfg. Number: A0653515A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: ASTHMA
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date: 20070101
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753244-0
 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: 19970101
 Duration:
 Adverse Reactions:
 ALCOHOL POISONING

ISR Number: 5753245 Case Number: 6652861 I/F Code: I Report Date: 20080530
Drug Name: **ALBUTEROL**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969624
Mfg. Date: 20070608
Mfg. Number: A0654852A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: UNKNOWN
Dose:
Event Date:
FDA Date: 20080530
Follow Number:
Image ID: 5753245-2
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:
TREMOR

ISR Number: 5753246 Case Number: 6652862 I/F Code: I Report Date: 20080530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969625
Mfg. Date: 20070611
Mfg. Number: A0655068A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20080530
Follow Number:
Image ID: 5753246-4
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: 1 MON
Adverse Reactions:
URTICARIA

ISR Number: 5753247 Case Number: 6652863 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN HFA**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969626
 Mfg. Date: 20070611
 Mfg. Number: A0655724A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication:
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753247-6
 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: 5753248 Case Number: 6652864 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN HFA**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969627
 Mfg. Date: 20070611
 Mfg. Number: A0656107A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: UNKNOWN
 Dose:
 Event Date:
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753248-8
 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
 DYSPTNOEA

ISR Number: 5753249 Case Number: 6652865 I/F Code: I Report Date: 20080530
Drug Name: **VENTOLIN HFA**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969628
Mfg. Date: 20070613
Mfg. Number: A0657262A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route:
Dose:
Event Date:
FDA Date: 20080530
Follow Number:
Image ID: 5753249-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: 1 DAY
Adverse Reactions:
COUGH

ISR Number: 5753250 Case Number: 6652866 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969629
 Mfg. Date: 20070615
 Mfg. Number: A0658740A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: UNKNOWN
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753250-6
 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: 5753251 Case Number: 6652867 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969630

Mfg. Date: 20070625

Mfg. Number: A0659989A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: 4PUFF AS REQUIRED

Event Date:

FDA Date: 20080530

Follow Number:

Image ID: 5753251-8

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: 20061201

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5753252 Case Number: 6652868 I/F Code: I Report Date: 20080530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969633
Mfg. Date: 20070620
Mfg. Number: A0660031A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date: 20070101
FDA Date: 20080530
Follow Number:
Image ID: 5753252-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 EFFECT DECREASED

ISR Number: 5753253 Case Number: 6652869 I/F Code: I Report Date: 20080530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969634
Mfg. Date: 20070620
Mfg. Number: A0660032A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date: 20070101
FDA Date: 20080530
Follow Number:
Image ID: 5753253-1
Age: 18 YR 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 EFFECT DECREASED

ISR Number: 5753254 Case Number: 6652870 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969635
 Mfg. Date: 20070628
 Mfg. Number: A0661350A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: UNKNOWN
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753254-3
 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 ADMINISTRATION ERROR

ISR Number: 5753256 Case Number: 6652872 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969638
 Mfg. Date: 20070710
 Mfg. Number: A0663478A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: UNKNOWN
 Dose:
 Event Date:
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753256-7
 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: 5753257 Case Number: 6652873 I/F Code: I Report Date: 20080530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969639
Mfg. Date: 20070713
Mfg. Number: A0664643A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: UNKNOWN
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: UNKNOWN
Dose:
Event Date:
FDA Date: 20080530
Follow Number:
Image ID: 5753257-9
Age: Gender: M 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:
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 5753260 Case Number: 6652876 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969642

Mfg. Date: 20070801

Mfg. Number: A0667674A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20080530

Follow Number:

Image ID: 5753260-9

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:

MALAISE

ISR Number: 5753261 Case Number: 6652877 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969644

Mfg. Date: 20070813

Mfg. Number: A0670699A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20080530

Follow Number:

Image ID: 5753261-0

Age: 43 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: 5753262 Case Number: 6652878 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969645

Mfg. Date: 20070824

Mfg. Number: A0676133A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 7ZP3418

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2SPR AS REQUIRED

Event Date: 20070815

FDA Date: 20080530

Follow Number:

Image ID: 5753262-2

Age: 66 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: 20070823

Therapy End: 20070814

Duration: 1 WK

Adverse Reactions:

- ANXIETY
- CHEST DISCOMFORT
- CHEST PAIN
- DRUG INEFFECTIVE
- DYSPNOEA
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5753263 Case Number: 6652879 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN HFA**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969649

Mfg. Date: 20070829

Mfg. Number: A0677474A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20080530

Follow Number:

Image ID: 5753263-4

Age: 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:

Duration:

Adverse Reactions:

APHONIA

DYSPNOEA

THROAT TIGHTNESS

ISR Number: 5753264 Case Number: 6652880 I/F Code: I Report Date: 20080530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969650
Mfg. Date: 20070906
Mfg. Number: A0679191A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20080530
Follow Number:
Image ID: 5753264-6
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: 5753265 Case Number: 6652881 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969651
 Mfg. Date: 20070921
 Mfg. Number: A0683536A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number: 7ZP5481
 Expiration Date:
 Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE
 Route: RESPIRATORY (INHALATION)
 Dose: 2PUFF THREE TIMES PER DAY
 Event Date: 20070918
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753265-8
 Age: 87 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: 20070912
 Duration:
 Adverse Reactions:
 PRURITUS
 RASH

ISR Number: 5753271 Case Number: 6654637 I/F Code: I Report Date: 20080530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969673
Mfg. Date: 20071019
Mfg. Number: A0689274A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20080530
Follow Number:
Image ID: 5753271-3
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: 5753272 Case Number: 6652888 I/F Code: I Report Date: 20080530
Drug Name: **ALBUTEROL**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969677
Mfg. Date: 20071018
Mfg. Number: A0689360A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: RESPIRATORY (INHALATION)
Dose:
Event Date:
FDA Date: 20080530
Follow Number:
Image ID: 5753272-5
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:
Duration:
Adverse Reactions:
 BLOOD GLUCOSE FLUCTUATION
 BLOOD PRESSURE INCREASED

ISR Number: 5753273 Case Number: 6652889 I/F Code: I Report Date: 20080530
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1009969685
Mfg. Date: 20071018
Mfg. Number: A0689406A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route:
Dose:
Event Date:
FDA Date: 20080530
Follow Number:
Image ID: 5753273-7
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

ISR Number: 5753274 Case Number: 6652890 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969686

Mfg. Date: 20071029

Mfg. Number: A0691304A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20080530

Follow Number:

Image ID: 5753274-9

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:

- ADVERSE DRUG REACTION
- ADVERSE EVENT
- DRY THROAT
- DYSPNOEA

ISR Number: 5753301 Case Number: 6654638 I/F Code: I Report Date: 20080530

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1009969742

Mfg. Date: 20071127

Mfg. Number: A0697985A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20080530

Follow Number:

Image ID: 5753301-9

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 ADMINISTRATION ERROR

DRUG INEFFECTIVE

FEELING JITTERY

ISR Number: 5753304 Case Number: 6652920 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969749
 Mfg. Date: 20071210
 Mfg. Number: A0698881A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: UNKNOWN
 Dose:
 Event Date:
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753304-4
 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:
 ANGIOEDEMA

ISR Number: 5753305 Case Number: 6652921 I/F Code: I Report Date: 20080530
 Drug Name: **VENTOLIN**
 NDA Number: 20983
 Role Code: PS VAL/VBM: 1
 Seq Number: 1009969750
 Mfg. Date: 20071217
 Mfg. Number: A0699837A
 Mfg. Sender: GLAXOSMITHKLINE
 Lot Number:
 Expiration Date:
 Indication: DRUG USE FOR UNKNOWN INDICATION
 Route: RESPIRATORY (INHALATION)
 Dose:
 Event Date:
 FDA Date: 20080530
 Follow Number:
 Image ID: 5753305-6
 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 EFFECT DECREASED

ISR Number: 5765504 Case Number: 6662365 I/F Code: I Report Date: 20080611

Drug Name: **ALBUTEROL**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1010015585

Mfg. Date: 20080609

Mfg. Number: D0057623A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20080117

FDA Date: 20080611

Follow Number:

Image ID: 5765504-8

Age: 15 MON Gender: M Weight:

Occupation: CN

Country: GERMANY

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

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

Therapy Start: 20080501

Therapy End: 20070601

Duration: 11 MON

Adverse Reactions:

AGITATION

COUGH

CYANOSIS

DYSPNOEA

PNEUMONIA VIRAL

ISR Number: 5765664 Case Number: 6673656 I/F Code: I Report Date: 20080607
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010016120
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: TWO PUFFS WHEN NEEDED PO
Event Date: 20080606
FDA Date: 20080609
Follow Number:
Image ID: 5765664-9
Age: 20 YR Gender: F Weight: 155 LBS
Occupation:
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: 20080607
Therapy End: 20071101
Duration:
Adverse Reactions:
ANXIETY
DRUG INEFFECTIVE
FEAR
PHARMACEUTICAL PRODUCT COMPLAINT
WHEEZING

ISR Number: 5800227 Case Number: 6698520 I/F Code: I Report Date: 20080701
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010130366
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20080601
Indication: ASTHMA
Route: ORAL
Dose: 200 METERED DOSE AS NEEDED PO
Event Date: 20071101
FDA Date: 20080702
Follow Number:
Image ID: 5800227-8
Age: 34 YR Gender: F Weight: 170 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: N Rechallenge Code: Y Death Date:
Therapy Start: 20080216
Therapy End: 20071001
Duration:
Adverse Reactions:
DRUG INEFFECTIVE

ISR Number: 5800505 Case Number: 6690696 I/F Code: I Report Date: 20080703

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1010131367

Mfg. Date: 20080625

Mfg. Number: B0527087A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNSPECIFIED

Expiration Date:

Indication: BRONCHIOLITIS

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF THREE TIMES PER DAY

Event Date: 20080623

FDA Date: 20080703

Follow Number:

Image ID: 5800505-2

Age: 10 MON Gender: M Weight:

Occupation: MD

Country: FRANCE

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

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

Therapy Start: 20080623

Therapy End: 20080623

Duration: 1 DAY

Adverse Reactions:

- CONVULSION
- EYE DISORDER
- HYPERTONIA

ISR Number: 5807209 Case Number: 6696920 I/F Code: I Report Date: 20080711

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1010159747

Mfg. Date: 20080704

Mfg. Number: B0528088A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20071201

FDA Date: 20080711

Follow Number:

Image ID: 5807209-0

Age: 75 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: 20071213

Therapy End: 20071211

Duration: 3 DAY

Adverse Reactions:

ALLERGY TEST POSITIVE

EOSINOPHILIA

ERYTHEMA

FEELING HOT

RASH MACULO-PAPULAR

ISR Number: 5843673 Case Number: 6728353 I/F Code: I Report Date: 20080811
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010299901
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose: 2 PUFFS AS NEEDED
Event Date: 20080501
FDA Date: 20080812
Follow Number:
Image ID: 5843673-9
Age: 64 YR Gender: M Weight: 160 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Y Death Date:
Therapy Start: 20080811
Therapy End: 20080501
Duration:
Adverse Reactions:
ASTHMA

ISR Number: 5879441 Case Number: 6755058 I/F Code: I Report Date: 20080912

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1010435395

Mfg. Date: 20080904

Mfg. Number: B0536476A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20080912

Follow Number:

Image ID: 5879441-1

Age: 88 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:

Duration:

Adverse Reactions:

- ANGER
- ANXIETY
- DRUG DEPENDENCE