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ISR Number: 4641099 Case Number: 5786024 I/F Code: I Report Date: 20040212  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1005898939  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 19990101  
FDA Date: 20050419  
Follow Number:  
Image ID: 4641099-7  
Age: 44 YR Gender: M Weight: 185 LBS  
Occupation: CN  
Country:  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: DS Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
CEREBROSCLEROSIS  
SLEEP DISORDER

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ISR Number: 4646734 Case Number: 5783646 I/F Code: I Report Date: 20050427

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1005920078

Mfg. Date: 20050422

Mfg. Number: FR-GLAXOSMITHKLINE-B0378917A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: PSYCHOTIC DISORDER

Route:

Dose:

Event Date: 20050409

FDA Date: 20050427

Follow Number:

Image ID: 4646734-5

Age: 28 YR Gender: M Weight:

Occupation: CN

Country:

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

Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date: 20050409

Therapy Start: 20050409

Therapy End: 20050408

Duration: 2 DAY

Adverse Reactions:

SOMNOLENCE

VOMITING

ISR Number: 4648534 Case Number: 5789452 I/F Code: I Report Date: 20050421

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1005928190

Mfg. Date: 20050413

Mfg. Number: B0377715A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose: PER DAY/INHALED

Event Date:

FDA Date: 20050427

Follow Number:

Image ID: 4648534-9

Age: 18 YR Gender: F Weight:

Occupation:

Country:

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:

- ASTHMA
- CONDITION AGGRAVATED
- FATIGUE
- HEART RATE INCREASED
- HYPERGLYCAEMIA
- HYPOKALAEMIA
- LACTIC ACIDOSIS
- METABOLIC ACIDOSIS
- RESPIRATORY ACIDOSIS
- RESPIRATORY FAILURE
- SOMNOLENCE

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ISR Number: 4679501 Case Number: 5815214 I/F Code: I Report Date: 20050527  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006068162  
Mfg. Date: 20050519  
Mfg. Number: A0560258A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose: 1UNIT AS REQUIRED  
Event Date:  
FDA Date: 20050531  
Follow Number:  
Image ID: 4679501-7  
Age: 25 YR Gender: F Weight:  
Occupation:  
Country:  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
HEADACHE  
SUICIDE ATTEMPT  
SYNCOPE  
TACHYCARDIA  
VOMITING

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ISR Number: 4690298 Case Number: 5818876 I/F Code: I Report Date: 20050614

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006109945

Mfg. Date: 20050603

Mfg. Number: GB-GLAXOSMITHKLINE-B0383427A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20050615

Follow Number:

Image ID: 4690298-7

Age: Gender: F 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:

- CHOKING
- FOREIGN BODY ASPIRATION
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4690645 Case Number: 5819175 I/F Code: I Report Date: 20050615

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006111917

Mfg. Date: 20050614

Mfg. Number: US-GLAXOSMITHKLINE-A0562615A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20040601

FDA Date: 20050615

Follow Number:

Image ID: 4690645-6

Age: Gender: F Weight:

Occupation: CN

Country:

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

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

Therapy Start: 20040101

Therapy End: 20040601

Duration: 0 DAY

Adverse Reactions:

APHASIA

HYPERHIDROSIS

PALPITATIONS

---

ISR Number: 4696036 Case Number: 5822963 I/F Code: I Report Date: 20050621

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006131769

Mfg. Date: 20050620

Mfg. Number: FR-GLAXOSMITHKLINE-B0384932A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: GROWTH RETARDATION

Route: UNKNOWN

Dose:

Event Date: 20050512

FDA Date: 20050621

Follow Number:

Image ID: 4696036-6

Age: 4 YR Gender: M 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: 20010101

Duration:

Adverse Reactions:

LUNG DISORDER

THROMBOCYTOPENIA

---

ISR Number: 4700064 Case Number: 5826097 I/F Code: I Report Date: 20050627

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006147272

Mfg. Date: 20050614

Mfg. Number: NZ-GLAXOSMITHKLINE-B0384393A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: UNKNOWN

Dose:

Event Date:

FDA Date: 20050627

Follow Number:

Image ID: 4700064-1

Age: 57 YR 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:

- ANAPHYLACTIC REACTION
- ERYTHEMA
- FIBRINOLYSIS
- HYPOTENSION
- PLATELET COUNT INCREASED
- TACHYCARDIA

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ISR Number: 4702349 Case Number: 5827572 I/F Code: I Report Date: 20050629  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155891  
Mfg. Date: 20040504  
Mfg. Number: S2004US05302  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ILL-DEFINED DISORDER  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702349-1  
Age: Gender: F Weight:  
Occupation: CN  
Country:  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
HEADACHE

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ISR Number: 4702350 Case Number: 5827573 I/F Code: I Report Date: 20050629

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006155892

Mfg. Date: 20040506

Mfg. Number: US-GLAXOSMITHKLINE-A0509984A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20050629

Follow Number:

Image ID: 4702350-8

Age: Gender: F Weight:

Occupation: CN

Country:

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- EYE PAIN
- MUSCLE TWITCHING
- VISION BLURRED

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ISR Number: 4702351 Case Number: 5827574 I/F Code: I Report Date: 20050629  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155895  
Mfg. Date: 20040518  
Mfg. Number: US-GLAXOSMITHKLINE-A0511287A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702351-X  
Age: Gender: M Weight:  
Occupation: CN  
Country:  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
COUGH

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ISR Number: 4702352 Case Number: 5827575 I/F Code: I Report Date: 20050629  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155896  
Mfg. Date: 20040607  
Mfg. Number: US-GLAXOSMITHKLINE-A0513613A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702352-1  
Age: Gender: F Weight:  
Occupation: CN  
Country:  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
NERVOUSNESS

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ISR Number: 4702353 Case Number: 5827576 I/F Code: I Report Date: 20050629  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155901  
Mfg. Date: 20040706  
Mfg. Number: US-GLAXOSMITHKLINE-A0517777A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ILL-DEFINED DISORDER  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702353-3  
Age: Gender: Weight:  
Occupation: OT  
Country:  
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

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ISR Number: 4702354 Case Number: 5827577 I/F Code: I Report Date: 20050629

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006155902

Mfg. Date: 20040719

Mfg. Number: US-GLAXOSMITHKLINE-A0519006A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20050629

Follow Number:

Image ID: 4702354-5

Age: 3 YR Gender: M Weight:

Occupation: CN

Country:

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

COUGH

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ISR Number: 4702355 Case Number: 5827578 I/F Code: I Report Date: 20050629  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155904  
Mfg. Date: 20040817  
Mfg. Number: US-GLAXOSMITHKLINE-A0522611A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702355-7  
Age: Gender: F Weight:  
Occupation: CN  
Country:  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
HEADACHE

ISR Number: 4702356 Case Number: 5827579 I/F Code: I Report Date: 20050629

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006155906

Mfg. Date: 20040824

Mfg. Number: US-GLAXOSMITHKLINE-A0523325A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ILL-DEFINED DISORDER

Route: UNKNOWN

Dose:

Event Date:

FDA Date: 20050629

Follow Number:

Image ID: 4702356-9

Age: Gender: F Weight:

Occupation: CN

Country:

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

BLOOD PRESSURE INCREASED

DRUG INEFFECTIVE

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ISR Number: 4702357 Case Number: 5827580 I/F Code: I Report Date: 20050629

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006155907

Mfg. Date: 20040914

Mfg. Number: US-GLAXOSMITHKLINE-A0525623A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF SIX TIMES PER DAY

Event Date:

FDA Date: 20050629

Follow Number:

Image ID: 4702357-0

Age: Gender: F Weight:

Occupation: CN

Country:

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

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

Therapy Start:

Therapy End: 19800101

Duration: 20 YR

Adverse Reactions:

TREMOR

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ISR Number: 4702358 Case Number: 5827581 I/F Code: I Report Date: 20050629  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155924  
Mfg. Date: 20040915  
Mfg. Number: US-GLAXOSMITHKLINE-A0526108A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702358-2  
Age: 10 YR Gender: M Weight:  
Occupation: CN  
Country:  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End: 20040910  
Duration: 5 DAY  
Adverse Reactions:  
DRUG INEFFECTIVE  
HYPERSENSITIVITY

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ISR Number: 4702360 Case Number: 5827583 I/F Code: I Report Date: 20050629  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155936  
Mfg. Date: 20041005  
Mfg. Number: US-GLAXOSMITHKLINE-A0529311A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702360-0  
Age: Gender: M Weight:  
Occupation: CN  
Country:  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
PALPITATIONS

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ISR Number: 4702361 Case Number: 5827584 I/F Code: I Report Date: 20050629  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155937  
Mfg. Date: 20041018  
Mfg. Number: US-GLAXOSMITHKLINE-A0530335A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702361-2  
Age: 70 YR Gender: F Weight:  
Occupation: CN  
Country:  
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

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ISR Number: 4702362 Case Number: 5827585 I/F Code: I Report Date: 20050629  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155938  
Mfg. Date: 20041122  
Mfg. Number: US-GLAXOSMITHKLINE-A0534709A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702362-4  
Age: Gender: M Weight:  
Occupation: CN  
Country:  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration: 1 MON  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 4702363 Case Number: 5827586 I/F Code: I Report Date: 20050629  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155940  
Mfg. Date: 20041129  
Mfg. Number: 2004-11-1107  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702363-6  
Age: Gender: M Weight:  
Occupation: CN  
Country:  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
BREATH ODOUR

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ISR Number: 4702364 Case Number: 5827587 I/F Code: I Report Date: 20050629

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006155945

Mfg. Date: 20050106

Mfg. Number: US-GLAXOSMITHKLINE-A0539727A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20050629

Follow Number:

Image ID: 4702364-8

Age: Gender: F Weight:

Occupation: CN

Country:

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

WHEEZING

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ISR Number: 4702365 Case Number: 5827588 I/F Code: I Report Date: 20050629  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155946  
Mfg. Date: 20050112  
Mfg. Number: US-GLAXOSMITHKLINE-A0540455A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702365-X  
Age: Gender: F Weight:  
Occupation: CN  
Country:  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
TACHYCARDIA

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ISR Number: 4702366 Case Number: 5827589 I/F Code: I Report Date: 20050629  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006155948  
Mfg. Date: 20050114  
Mfg. Number: US-GLAXOSMITHKLINE-A0540810A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ILL-DEFINED DISORDER  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20050629  
Follow Number:  
Image ID: 4702366-1  
Age: Gender: Weight:  
Occupation: CN  
Country:  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG SCREEN POSITIVE

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ISR Number: 4702368 Case Number: 5827591 I/F Code: I Report Date: 20050629

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006155950

Mfg. Date: 20050203

Mfg. Number: US-GLAXOSMITHKLINE-A0543718A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20050629

Follow Number:

Image ID: 4702368-5

Age: Gender: F Weight:

Occupation: CN

Country:

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

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

Therapy Start:

Therapy End:

Duration: 2 MON

Adverse Reactions:

DRUG INEFFECTIVE

HYPERSENSITIVITY

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ISR Number: 4702369 Case Number: 5827592 I/F Code: I Report Date: 20050629

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006155954

Mfg. Date: 20050310

Mfg. Number: US-GLAXOSMITHKLINE-A0549224A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20050629

Follow Number:

Image ID: 4702369-7

Age: 15 YR Gender: F Weight:

Occupation: OT

Country:

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- FEELING JITTERY
- PALPITATIONS
- TREMOR

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ISR Number: 4752308 Case Number: 5866732 I/F Code: I Report Date: 20050825

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006354523

Mfg. Date: 20050823

Mfg. Number: US-GLAXOSMITHKLINE-A0571466A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date:

FDA Date: 20050825

Follow Number:

Image ID: 4752308-8

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:

- ASTHMA
- DIZZINESS
- DRUG INEFFECTIVE
- FEELING ABNORMAL
- PHARMACEUTICAL PRODUCT COMPLAINT
- WHEEZING

---

ISR Number: 4763690 Case Number: 5874467 I/F Code: I Report Date: 20050908

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006398809

Mfg. Date: 20050906

Mfg. Number: US-GLAXOSMITHKLINE-A0573132A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20050908

Follow Number:

Image ID: 4763690-X

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

ASTHMA

CONDITION AGGRAVATED

---

ISR Number: 4767322 Case Number: 5876748 I/F Code: I Report Date: 20050913

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006413147

Mfg. Date: 20050905

Mfg. Number: CN-GLAXOSMITHKLINE-B0393199A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route:

Dose:

Event Date: 20050904

FDA Date: 20050913

Follow Number:

Image ID: 4767322-6

Age: 30 YR Gender: M Weight:

Occupation: MD

Country: CHINA

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

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

Therapy Start:

Therapy End: 20050904

Duration:

Adverse Reactions:

- CONVULSION
- CYANOSIS
- HYPERSENSITIVITY
- TACHYCARDIA
- WHEEZING

---

ISR Number: 4819187 Case Number: 5916845 I/F Code: I Report Date: 20051103  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006589299  
Mfg. Date: 20051031  
Mfg. Number: 2005-10-1360  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date: 20050101  
FDA Date: 20051103  
Follow Number:  
Image ID: 4819187-1  
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: 20 YR  
Adverse Reactions:  
SURGERY

---

ISR Number: 4831408 Case Number: 5925196 I/F Code: I Report Date: 20051118

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006637855

Mfg. Date: 20051110

Mfg. Number: FR-GLAXOSMITHKLINE-B0400755A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: PROPHYLAXIS

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF TWICE PER DAY

Event Date: 20051020

FDA Date: 20051118

Follow Number:

Image ID: 4831408-8

Age: 7 YR Gender: M Weight: 32 KG

Occupation: CN

Country: FRANCE

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

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

Therapy Start: 20050903

Therapy End: 20050903

Duration: 1 DAY

Adverse Reactions:

- ASTHENIA
- BRONCHITIS
- COUGH
- DERMATITIS BULLOUS
- PYREXIA
- RESPIRATORY DISORDER
- STEVENS-JOHNSON SYNDROME

---

ISR Number: 4912895 Case Number: 5995134 I/F Code: I Report Date: 20060208

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1006939811

Mfg. Date: 20060202

Mfg. Number: A0592342A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 5875

Expiration Date: 20070531

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: TWICE PER DAY / INHALED

Event Date: 20050126

FDA Date: 20060210

Follow Number:

Image ID: 4912895-3

Age: 22 YR Gender: F Weight: 154 LBS

Occupation: CN

Country: BRAZIL

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- DYSPNOEA EXACERBATED
- MEDICAL DEVICE COMPLICATION
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 4930372 Case Number: 5996809 I/F Code: I Report Date: 20060302

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007003042

Mfg. Date: 20060215

Mfg. Number: US-GLAXOSMITHKLINE-B0411693A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060302

Follow Number:

Image ID: 4930372-0

Age: 80 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:

- BREATH SOUNDS ABNORMAL
- BRONCHOSPASM PARADOXICAL
- DYSPNOEA EXACERBATED
- OXYGEN SATURATION DECREASED
- TACHYPNOEA

---

ISR Number: 4937762 Case Number: 6007787 I/F Code: I Report Date: 20060228

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007030848

Mfg. Date: 20060215

Mfg. Number: B0411693A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: INHALED

Event Date:

FDA Date: 20060306

Follow Number:

Image ID: 4937762-0

Age: 80 YR Gender: M Weight:

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

BRONCHOSPASM PARADOXICAL

---

ISR Number: 4943625 Case Number: 6011023 I/F Code: I Report Date: 20060308

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007050993

Mfg. Date: 20060228

Mfg. Number: B0414730A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: NINE TIMES PER DAY/ INHALE

Event Date:

FDA Date: 20060310

Follow Number:

Image ID: 4943625-7

Age: 47 YR Gender: M Weight:

Occupation:

Country: NETHERLANDS

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:

- ABNORMAL BEHAVIOUR
- AGGRESSION
- ATTENTION DEFICIT/HYPERACTIVITY DISORDER
- DRUG ABUSER
- INAPPROPRIATE SCHEDULE OF DRUG ADMINISTRATION

---

ISR Number: 4961832 Case Number: 6018300 I/F Code: I Report Date: 20060404

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007126427

Mfg. Date: 20060330

Mfg. Number: FR-GLAXOSMITHKLINE-B0418469A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: SLEEP DISORDER

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20060204

FDA Date: 20060404

Follow Number:

Image ID: 4961832-4

Age: 49 YR Gender: F Weight: 130 KG

Occupation: CN

Country: FRANCE

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

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

Therapy Start: 20060204

Therapy End: 20050901

Duration: 5 MON

Adverse Reactions:

- BLOOD CREATINE PHOSPHOKINASE INCREASED
- MYALGIA
- RENAL FAILURE

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ISR Number: 5001852 Case Number: 6045487 I/F Code: I Report Date: 20060515

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007284674

Mfg. Date: 20060508

Mfg. Number: GB-GLAXOSMITHKLINE-B0422916A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060515

Follow Number:

Image ID: 5001852-7

Age: Gender: M Weight:

Occupation: OT

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:

ASTHMA

TREMOR

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ISR Number: 5033692 Case Number: 6071462 I/F Code: I Report Date: 20060623

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007410600

Mfg. Date: 20060619

Mfg. Number: SE-GLAXOSMITHKLINE-B0428518A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: HYPERTONIA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20060301

FDA Date: 20060623

Follow Number:

Image ID: 5033692-7

Age: 77 YR Gender: F Weight:

Occupation: OT

Country: SWEDEN

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

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

Therapy Start:

Therapy End: 20060301

Duration:

Adverse Reactions:

- ATRIAL FIBRILLATION
- HYPOTENSION
- TRANSAMINASES INCREASED

---

ISR Number: 5037459 Case Number: 6073851 I/F Code: I Report Date: 20060628

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007422120

Mfg. Date: 20050615

Mfg. Number: US-GLAXOSMITHKLINE-A0562806A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 19940101

FDA Date: 20060628

Follow Number:

Image ID: 5037459-5

Age: 46 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20040101

Duration:

Adverse Reactions:

- BLOOD PRESSURE DECREASED
- DIZZINESS
- DRUG INEFFECTIVE
- DRY EYE
- DYSPHONIA
- EYE PAIN
- HEADACHE
- HYPERTENSION
- NECK PAIN
- OCULAR HYPERAEMIA
- PALPITATIONS
- PHARYNGEAL ULCERATION
- POSTNASAL DRIP
- RHINORRHOEA
- SHOULDER PAIN
- TINNITUS
- WHEEZING

---

ISR Number: 5037460 Case Number: 6073852 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422124  
Mfg. Date: 20050707  
Mfg. Number: US-GLAXOSMITHKLINE-A0565318A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 5PUFF AS REQUIRED  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037460-1  
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: 1 YR  
Adverse Reactions:  
DRUG INEFFECTIVE  
OVERDOSE

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ISR Number: 5037461 Case Number: 6073853 I/F Code: I Report Date: 20060628

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007422130

Mfg. Date: 20050711

Mfg. Number: US-GLAXOSMITHKLINE-A0565635A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060628

Follow Number:

Image ID: 5037461-3

Age: Gender: Weight:

Occupation: PH

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:

HYPERSENSITIVITY

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ISR Number: 5037462 Case Number: 6073854 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422131  
Mfg. Date: 20050722  
Mfg. Number: US-GLAXOSMITHKLINE-A0567414A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037462-5  
Age: 69 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: 19990101  
Duration:  
Adverse Reactions:  
AGITATION  
DRUG INEFFECTIVE  
INSOMNIA

---

ISR Number: 5037463 Case Number: 6073855 I/F Code: I Report Date: 20060628

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007422134

Mfg. Date: 20050726

Mfg. Number: US-GLAXOSMITHKLINE-A0567720A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF AS REQUIRED

Event Date: 20030101

FDA Date: 20060628

Follow Number:

Image ID: 5037463-7

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: 20030101

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

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ISR Number: 5037467 Case Number: 6073859 I/F Code: I Report Date: 20060628

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007422150

Mfg. Date: 20050823

Mfg. Number: US-GLAXOSMITHKLINE-A0571469A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: MULTIPLE ALLERGIES

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060628

Follow Number:

Image ID: 5037467-4

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: 20 YR

Adverse Reactions:

DRUG INEFFECTIVE

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ISR Number: 5037468 Case Number: 6073860 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422151  
Mfg. Date: 20050823  
Mfg. Number: US-GLAXOSMITHKLINE-A0571694A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route:  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037468-6  
Age: Gender: M Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5037469 Case Number: 6073861 I/F Code: I Report Date: 20060628

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007422152

Mfg. Date: 20050826

Mfg. Number: US-GLAXOSMITHKLINE-A0571962A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060628

Follow Number:

Image ID: 5037469-8

Age: 4 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

ANGIONEUROTIC OEDEMA

URTICARIA

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ISR Number: 5037470 Case Number: 6073862 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422153  
Mfg. Date: 20050907  
Mfg. Number: US-GLAXOSMITHKLINE-A0573364A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037470-4  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPNOEA EXERTIONAL  
    WHEEZING

---

ISR Number: 5037471 Case Number: 6073863 I/F Code: I Report Date: 20060628

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007422154

Mfg. Date: 20050912

Mfg. Number: US-GLAXOSMITHKLINE-A0573872A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: UNKNOWN

Dose:

Event Date:

FDA Date: 20060628

Follow Number:

Image ID: 5037471-6

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: 5037472 Case Number: 6073864 I/F Code: I Report Date: 20060628

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007422156

Mfg. Date: 20050921

Mfg. Number: US-GLAXOSMITHKLINE-A0575241A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: UNKNOWN

Dose: 2PUFF AS REQUIRED

Event Date: 20020101

FDA Date: 20060628

Follow Number:

Image ID: 5037472-8

Age: 48 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration: 2 DAY

Adverse Reactions:

DYSPNOEA

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ISR Number: 5037473 Case Number: 6073865 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422160  
Mfg. Date: 20050920  
Mfg. Number: US-GLAXOSMITHKLINE-A0575253A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037473-X  
Age: 20 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

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ISR Number: 5037474 Case Number: 6073866 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422162  
Mfg. Date: 20050920  
Mfg. Number: US-GLAXOSMITHKLINE-A0575254A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037474-1  
Age: 50 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

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ISR Number: 5037476 Case Number: 6073868 I/F Code: I Report Date: 20060628  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422165  
Mfg. Date: 20051013  
Mfg. Number: US-GLAXOSMITHKLINE-A0578061A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037476-5  
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

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ISR Number: 5037478 Case Number: 6073870 I/F Code: I Report Date: 20060628  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422167  
Mfg. Date: 20051017  
Mfg. Number: US-GLAXOSMITHKLINE-A0578475A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: EMPHYSEMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037478-9  
Age: 59 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:  
COUGH  
WHEEZING

---

ISR Number: 5037479 Case Number: 6073871 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422168  
Mfg. Date: 20051018  
Mfg. Number: US-GLAXOSMITHKLINE-A0578543A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037479-0  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5037480 Case Number: 6073872 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422169  
Mfg. Date: 20051021  
Mfg. Number: US-GLAXOSMITHKLINE-A0579189A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2PUFF TWICE PER DAY  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037480-7  
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: 14 YR  
Adverse Reactions:  
COUGH

---

ISR Number: 5037485 Case Number: 6073876 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422180  
Mfg. Date: 20051221  
Mfg. Number: US-GLAXOSMITHKLINE-A0586656A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date: 20050101  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037485-6  
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: 20050101  
Duration: 3 MON  
Adverse Reactions:  
DRUG INEFFECTIVE

---

ISR Number: 5037488 Case Number: 6073879 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422183  
Mfg. Date: 20060130  
Mfg. Number: US-GLAXOSMITHKLINE-A0591465A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037488-1  
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:  
COUGH

---

ISR Number: 5037489 Case Number: 6073880 I/F Code: I Report Date: 20060628

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007422184

Mfg. Date: 20060131

Mfg. Number: US-GLAXOSMITHKLINE-A0591708A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20060628

Follow Number:

Image ID: 5037489-3

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:

RASH

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ISR Number: 5037490 Case Number: 6073881 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422185  
Mfg. Date: 20060130  
Mfg. Number: US-GLAXOSMITHKLINE-A0592007A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: UNKNOWN  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037490-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:  
MUSCLE SPASMS

---

ISR Number: 5037491 Case Number: 6073882 I/F Code: I Report Date: 20060628

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007422186

Mfg. Date: 20060329

Mfg. Number: US-GLAXOSMITHKLINE-A0599556A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF EIGHT TIMES PER DAY

Event Date:

FDA Date: 20060628

Follow Number:

Image ID: 5037491-1

Age: 70 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20051201

Duration: 3 MON

Adverse Reactions:

DRUG INEFFECTIVE

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ISR Number: 5037492 Case Number: 6073883 I/F Code: I Report Date: 20060628

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007422188

Mfg. Date: 20060329

Mfg. Number: US-GLAXOSMITHKLINE-A0599557A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF UNKNOWN

Event Date:

FDA Date: 20060628

Follow Number:

Image ID: 5037492-3

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

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ISR Number: 5037493 Case Number: 6073884 I/F Code: I Report Date: 20060628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007422189  
Mfg. Date: 20060410  
Mfg. Number: US-GLAXOSMITHKLINE-A0601907A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: UNKNOWN  
Dose:  
Event Date:  
FDA Date: 20060628  
Follow Number:  
Image ID: 5037493-5  
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: 20060401  
Duration:  
Adverse Reactions:  
BACK PAIN  
DYSPNOEA  
THROAT IRRITATION

ISR Number: 5037494 Case Number: 6073885 I/F Code: I Report Date: 20060628  
 Drug Name: **ALBUTEROL**  
 NDA Number: 18473  
 Role Code: PS VAL/VBM: 1  
 Seq Number: 1007422192  
 Mfg. Date: 20060421  
 Mfg. Number: US-GLAXOSMITHKLINE-A0603031A  
 Mfg. Sender: GLAXOSMITHKLINE  
 Lot Number:  
 Expiration Date:  
 Indication: ASTHMA  
 Route: RESPIRATORY (INHALATION)  
 Dose:  
 Event Date:  
 FDA Date: 20060628  
 Follow Number:  
 Image ID: 5037494-7  
 Age: Gender: M Weight:  
 Occupation: CN  
 Country: UNITED STATES  
 Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
 Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
 Therapy Start:  
 Therapy End:  
 Duration:  
 Adverse Reactions:  
     ASTHMA  
     DRUG EFFECT DECREASED

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ISR Number: 5040404 Case Number: 6075442 I/F Code: I Report Date: 20060630

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007431045

Mfg. Date: 20060629

Mfg. Number: CA-GLAXOSMITHKLINE-A0610820A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20060601

FDA Date: 20060630

Follow Number:

Image ID: 5040404-X

Age: 7 YR Gender: F Weight:

Occupation: PH

Country: CANADA

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

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

Therapy Start:

Therapy End:

Duration: 2 WK

Adverse Reactions:

MYDRIASIS

---

ISR Number: 5054998 Case Number: 6080981 I/F Code: I Report Date: 20060719

Drug Name: **VENTOLIN**

NDA Number: 72273

Role Code: PS VAL/VBM: 1

Seq Number: 1007480905

Mfg. Date: 20060704

Mfg. Number: FR-GLAXOSMITHKLINE-B0430569A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: INFECTION PROPHYLAXIS

Route:

Dose: 2 ACTUTIONS AS NEEDED

Event Date: 20060204

FDA Date: 20060719

Follow Number:

Image ID: 5054998-1

Age: 4 YR Gender: F Weight: 12 KG

Occupation: CN

Country: FRANCE

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

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

Therapy Start:

Therapy End: 20020501

Duration:

Adverse Reactions:

- CRYOGLOBULINAEMIA
- CUTANEOUS VASCULITIS
- ECCHYMOSIS
- OEDEMA PERIPHERAL
- PAIN IN EXTREMITY
- TOE AMPUTATION

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ISR Number: 5072656 Case Number: 6100630 I/F Code: I Report Date: 20060807

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007550570

Mfg. Date: 20060731

Mfg. Number: FI-GLAXOSMITHKLINE-B0433148A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: SPIROMETRY

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20060714

FDA Date: 20060807

Follow Number:

Image ID: 5072656-4

Age: 65 YR Gender: M Weight:

Occupation: CN

Country: FINLAND

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- BURNING SENSATION
- ERYTHEMA
- LOSS OF CONSCIOUSNESS
- NAUSEA

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ISR Number: 5074724 Case Number: 6106917 I/F Code: I Report Date: 20060802

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007557197

Mfg. Date: 20060720

Mfg. Number: B0432521A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route: RESPIRATORY (INHALATION)

Dose: INHALED

Event Date:

FDA Date: 20060803

Follow Number:

Image ID: 5074724-X

Age: 24 MON Gender: F Weight:

Occupation:

Country: NETHERLANDS

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ACUTE RESPIRATORY DISTRESS SYNDROME
- BRONCHIAL OBSTRUCTION
- DRUG INEFFECTIVE
- LOWER RESPIRATORY TRACT INFLAMMATION
- LUNG CONSOLIDATION
- PNEUMOMEDIASTINUM
- SPUTUM PURULENT
- SUBCUTANEOUS EMPHYSEMA

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ISR Number: 5121007 Case Number: 6146646 I/F Code: I Report Date: 20060928

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007732277

Mfg. Date: 20060921

Mfg. Number: B0439178A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: ORAL

Dose: ORAL

Event Date:

FDA Date: 20060929

Follow Number:

Image ID: 5121007-5

Age: 44 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:

- AGITATION
- CLONUS
- FEELING ABNORMAL
- HYPERHIDROSIS
- HYPERREFLEXIA
- INCORRECT DOSE ADMINISTERED
- IRON DEFICIENCY ANAEMIA
- OVERDOSE
- PUPILLARY REFLEX IMPAIRED
- SINUS TACHYCARDIA
- SKIN WARM
- TREATMENT NONCOMPLIANCE
- VASODILATATION

---

ISR Number: 5121337 Case Number: 6146365 I/F Code: I Report Date: 20060929

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007733635

Mfg. Date: 20060921

Mfg. Number: B0439183A

Mfg. Sender: GLAXOSMITHKLI NE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: ORAL

Event Date:

FDA Date: 20061002

Follow Number:

Image ID: 5121337-7

Age: Gender: UNK 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:

HYPOKALAEMIA

POISONING DELIBERATE

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ISR Number: 5121338 Case Number: 6146366 I/F Code: I Report Date: 20060929

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007733636

Mfg. Date: 20060921

Mfg. Number: B0439181A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose: ORAL

Event Date:

FDA Date: 20061002

Follow Number:

Image ID: 5121338-9

Age: Gender: UNK 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:

- HYPOKALAEMIA
- OVERDOSE
- POISONING DELIBERATE

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ISR Number: 5164725 Case Number: 6179632 I/F Code: I Report Date: 20061205  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007908851  
Mfg. Date: 20061130  
Mfg. Number: US-GLAXOSMITHKLINE-A0629685A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20061205  
Follow Number:  
Image ID: 5164725-5  
Age: Gender: M Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: DE Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DEATH  
FALL  
LOSS OF CONSCIOUSNESS

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ISR Number: 5171059 Case Number: 6184113 I/F Code: I Report Date: 20061213

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007932454

Mfg. Date: 20061207

Mfg. Number: US-GLAXOSMITHKLINE-A0630784A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: UNKNOWN

Dose:

Event Date:

FDA Date: 20061213

Follow Number:

Image ID: 5171059-1

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 EVENT
- DEPENDENCE
- DRUG DEPENDENCE

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ISR Number: 5177051 Case Number: 6190004 I/F Code: I Report Date: 20061218

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007949846

Mfg. Date: 20061211

Mfg. Number: GB-GLAXOSMITHKLINE-B0450025A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20061208

FDA Date: 20061218

Follow Number:

Image ID: 5177051-5

Age: Gender: F 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
- PHARMACEUTICAL PRODUCT COMPLAINT
- RETCHING

ISR Number: 5183845 Case Number: 6195946 I/F Code: I Report Date: 20061220

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007963891

Mfg. Date: 20061212

Mfg. Number: NL-GLAXOSMITHKLINE-B0450943A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20061220

Follow Number:

Image ID: 5183845-2

Age: 13 YR Gender: F Weight:

Occupation: CN

Country: NETHERLANDS

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

ASTHMA

DRUG INEFFECTIVE

INCREASED UPPER AIRWAY SECRETION

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ISR Number: 5191749 Case Number: 6209850 I/F Code: I Report Date: 20061215

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007984139

Mfg. Date: 20061207

Mfg. Number: B0450091A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose: INHALED

Event Date:

FDA Date: 20061219

Follow Number:

Image ID: 5191749-4

Age: 27 YR Gender: F Weight:

Occupation: MD

Country: JAPAN

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

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

Therapy Start:

Therapy End: 20040209

Duration:

Adverse Reactions:

- ASTHMA
- CAESAREAN SECTION
- CONDITION AGGRAVATED
- DRUG EXPOSURE DURING PREGNANCY
- NO THERAPEUTIC RESPONSE
- PREGNANCY
- PREMATURE LABOUR

---

ISR Number: 5192541 Case Number: 6211440 I/F Code: I Report Date: 20061219

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007987276

Mfg. Date: 20061212

Mfg. Number: B0450943A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: INHALED

Event Date:

FDA Date: 20061220

Follow Number:

Image ID: 5192541-7

Age: 13 YR Gender: F Weight:

Occupation:

Country: NETHERLANDS

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:

DRUG INEFFECTIVE

MUCOUS MEMBRANE DISORDER

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ISR Number: 5193728 Case Number: 6204473 I/F Code: I Report Date: 20061228

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007991598

Mfg. Date: 20061221

Mfg. Number: US-GLAXOSMITHKLINE-A0632474A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20010101

FDA Date: 20061228

Follow Number:

Image ID: 5193728-X

Age: Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End: 20010101

Duration:

Adverse Reactions:

- ARRHYTHMIA
- HEADACHE
- HEART RATE INCREASED
- SWELLING

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ISR Number: 5198421 Case Number: 6216045 I/F Code: I Report Date: 20061228  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008009774  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ANXIETY  
Route:  
Dose: 2PUFF AS REQUIRED  
Event Date:  
FDA Date: 20061229  
Follow Number:  
Image ID: 5198421-5  
Age: 70 YR Gender: F Weight: 147 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    PHARMACEUTICAL PRODUCT COUNTERFEIT  
    POOR QUALITY DRUG ADMINISTERED

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ISR Number: 5205949 Case Number: 6213327 I/F Code: I Report Date: 20070111

Drug Name: **VENTOLIN**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008032414

Mfg. Date: 20070108

Mfg. Number: FR-GLAXOSMITHKLINE-B0453356A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASPERGILLOSIS

Route:

Dose: 2 X 4

Event Date: 20061020

FDA Date: 20070111

Follow Number:

Image ID: 5205949-8

Age: 50 YR Gender: F Weight: 38 KG

Occupation: CN

Country: FRANCE

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

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

Therapy Start:

Therapy End: 20060524

Duration:

Adverse Reactions:

- CHEST PAIN
- GENERAL PHYSICAL HEALTH DETERIORATION
- HYPOKALAEMIA

---

ISR Number: 5253640 Case Number: 6259319 I/F Code: I Report Date: 20070215

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1008204497

Mfg. Date: 20070205

Mfg. Number: B0458341A

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: 5253640-4

Age: 16 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:

- COMA
- DYSPNOEA
- LACTIC ACIDOSIS
- LUNG HYPERINFLATION
- TACHYCARDIA
- TREATMENT NONCOMPLIANCE
- UNRESPONSIVE TO STIMULI

---

ISR Number: 5256493 Case Number: 6254143 I/F Code: I Report Date: 20070306

Drug Name: **VENTOLIN**

NDA Number: 72273

Role Code: PS VAL/VBM: 1

Seq Number: 1008216638

Mfg. Date: 20070223

Mfg. Number: GR-EOF-60974

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 110107

Expiration Date: 20081201

Indication: DRUG USE FOR UNKNOWN INDICATION

Route:

Dose: 2 ACTUATIONS AS NEEDED

Event Date: 20061023

FDA Date: 20070306

Follow Number:

Image ID: 5256493-3

Age: 24 YR Gender: M Weight:

Occupation: CN

Country: GREECE

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

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

Therapy Start: 20061023

Therapy End: 20060501

Duration:

Adverse Reactions:

- BLOOD ALBUMIN INCREASED
- BLOOD CREATINE PHOSPHOKINASE INCREASED
- TRANSAMINASES INCREASED

---

ISR Number: 5259936 Case Number: 6257237 I/F Code: I Report Date: 20070309  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008231352  
Mfg. Date: 20070307  
Mfg. Number: US-GLAXOSMITHKLINE-A0642489A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: MULTIPLE ALLERGIES  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20070309  
Follow Number:  
Image ID: 5259936-4  
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:  
    CHOKING  
    COUGH  
    DRY THROAT

---

ISR Number: 5268198 Case Number: 6272032 I/F Code: I Report Date: 20070220  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008262535  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070220  
FDA Date: 20070314  
Follow Number:  
Image ID: 5268198-3  
Age: Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    ORAL MUCOSAL BLISTERING  
    PHARMACEUTICAL PRODUCT COMPLAINT  
    PHARYNGOLARYNGEAL PAIN  
    TONGUE BLISTERING

---

ISR Number: 5294626 Case Number: 6286506 I/F Code: I Report Date: 20070412

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1008360206

Mfg. Date: 20070326

Mfg. Number: FR-GLAXOSMITHKLINE-B0463536A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNSPECIFIED

Expiration Date:

Indication: RESPIRATORY DISTRESS

Route:

Dose:

Event Date: 20061219

FDA Date: 20070412

Follow Number:

Image ID: 5294626-3

Age: 30 MON Gender: F Weight:

Occupation: CN

Country: FRANCE

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

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

Therapy Start:

Therapy End: 20061218

Duration:

Adverse Reactions:

- LACTIC ACIDOSIS
- OXYGEN SATURATION DECREASED
- RESPIRATORY DISTRESS

---

ISR Number: 5304622 Case Number: 6294264 I/F Code: I Report Date: 20070423

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1008397842

Mfg. Date: 20070412

Mfg. Number: FR-GLAXOSMITHKLINE-B0466284A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: G0067

Expiration Date:

Indication: RALES

Route: RESPIRATORY (INHALATION)

Dose: 4PUFF PER DAY

Event Date: 20070319

FDA Date: 20070423

Follow Number:

Image ID: 5304622-5

Age: 69 YR Gender: M Weight:

Occupation: CN

Country: FRANCE

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

Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date: 20070321

Therapy Start: 20070321

Therapy End: 20070317

Duration: 5 DAY

Adverse Reactions:

- AKINESIA
- CEREBROVASCULAR ACCIDENT
- CONDITION AGGRAVATED
- EJECTION FRACTION DECREASED
- EPILEPSY
- PAIN
- PERICARDITIS
- PLEURAL EFFUSION
- RESPIRATORY ARREST

---

ISR Number: 5354097 Case Number: 6331224 I/F Code: I Report Date: 20070612

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1008576535

Mfg. Date: 20070606

Mfg. Number: B0474762A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication:

Route:

Dose:

Event Date:

FDA Date: 20070612

Follow Number:

Image ID: 5354097-5

Age: Gender: F Weight:

Occupation: PH

Country: AUSTRALIA

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

PHARMACEUTICAL PRODUCT COMPLAINT

---

ISR Number: 5374379 Case Number: 6345545 I/F Code: I Report Date: 20070628

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1008645727

Mfg. Date: 20060508

Mfg. Number: A0604666A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20000101

FDA Date: 20070629

Follow Number:

Image ID: 5374379-0

Age: 73 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20000101

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- DRUG INEFFECTIVE
- SUFFOCATION FEELING

---

ISR Number: 5374380 Case Number: 6345546 I/F Code: I Report Date: 20070628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645731  
Mfg. Date: 20060516  
Mfg. Number: A0605824A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: RESTRICTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374380-7  
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:  
FEELING JITTERY  
NERVOUSNESS

---

ISR Number: 5374381 Case Number: 6345547 I/F Code: I Report Date: 20070628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645740  
Mfg. Date: 20060522  
Mfg. Number: A0607382A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374381-9  
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: 5374382 Case Number: 6345548 I/F Code: I Report Date: 20070628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645741  
Mfg. Date: 20060607  
Mfg. Number: A0608215A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: UNKNOWN  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374382-0  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

---

ISR Number: 5374383 Case Number: 6345549 I/F Code: I Report Date: 20070628  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645743  
Mfg. Date: 20060629  
Mfg. Number: A0610790A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number: UNKNOWN  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: UNKNOWN  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374383-2  
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: 5374387 Case Number: 6345553 I/F Code: I Report Date: 20070628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645754  
Mfg. Date: 20060807  
Mfg. Number: A0615599A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374387-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: 5374388 Case Number: 6294919 I/F Code: I Report Date: 20070628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645757  
Mfg. Date: 20060808  
Mfg. Number: A0616080A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: UNKNOWN  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374388-1  
Age: Gender: M Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
FEELING JITTERY

---

ISR Number: 5374389 Case Number: 6345554 I/F Code: I Report Date: 20070628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645758  
Mfg. Date: 20060811  
Mfg. Number: A0616310A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: BRONCHITIS  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374389-3  
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  
    OBSTRUCTIVE AIRWAYS DISORDER

---

ISR Number: 5374390 Case Number: 6345555 I/F Code: I Report Date: 20070628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645759  
Mfg. Date: 20060817  
Mfg. Number: A0617352A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date: 20060721  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374390-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: 5374392 Case Number: 6345557 I/F Code: I Report Date: 20070628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645765  
Mfg. Date: 20070103  
Mfg. Number: A0633754A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374392-3  
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:  
    BLOOD PRESSURE INCREASED  
    FLUSHING

---

ISR Number: 5374393 Case Number: 6345558 I/F Code: I Report Date: 20070628

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1008645767

Mfg. Date: 20070109

Mfg. Number: A0634922A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 6ZP9776

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF TWICE PER DAY

Event Date: 20070108

FDA Date: 20070629

Follow Number:

Image ID: 5374393-5

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: 20070108

Duration:

Adverse Reactions:

MIGRAINE

RASH

---

ISR Number: 5374396 Case Number: 6345560 I/F Code: I Report Date: 20070628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645771  
Mfg. Date: 20070212  
Mfg. Number: A0639274A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374396-0  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    INHALATION THERAPY  
    OVERDOSE

---

ISR Number: 5374397 Case Number: 6345561 I/F Code: I Report Date: 20070628

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1008645772

Mfg. Date: 20070222

Mfg. Number: A0640859A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20070629

Follow Number:

Image ID: 5374397-2

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:

BRONCHIAL HYPERREACTIVITY

FORCED EXPIRATORY VOLUME DECREASED

---

ISR Number: 5374398 Case Number: 6345562 I/F Code: I Report Date: 20070628

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1008645773

Mfg. Date: 20070402

Mfg. Number: A0645581A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070402

FDA Date: 20070629

Follow Number:

Image ID: 5374398-4

Age: 22 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: 20070402

Duration:

Adverse Reactions:

- DIZZINESS
- DRUG ADMINISTRATION ERROR
- EXPIRED DRUG ADMINISTERED
- EYE SWELLING
- SWELLING FACE
- VISION BLURRED

---

ISR Number: 5374399 Case Number: 6345563 I/F Code: I Report Date: 20070628  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008645774  
Mfg. Date: 20070419  
Mfg. Number: A0648054A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374399-6  
Age: 74 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: 20070412  
Duration:  
Adverse Reactions:  
INHALATION THERAPY

---

ISR Number: 5374524 Case Number: 6345671 I/F Code: I Report Date: 20070629  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008646302  
Mfg. Date: 20060621  
Mfg. Number: A0609897A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication:  
Route: UNKNOWN  
Dose:  
Event Date:  
FDA Date: 20070629  
Follow Number:  
Image ID: 5374524-7  
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: 5397881 Case Number: 6371176 I/F Code: I Report Date: 20070720

Drug Name: **VENTOLIN**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008741004

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 7ZP4356

Expiration Date: 20080531

Indication: BRONCHITIS CHRONIC

Route: ORAL

Dose: 2 INHALATIONS EVERY 4-6 HOURS PO

Event Date: 20070710

FDA Date: 20070723

Follow Number:

Image ID: 5397881-4

Age: 25 YR Gender: F Weight: 235 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20070719

Therapy End: 20070710

Duration:

Adverse Reactions:

- CHEST PAIN
- DRUG EFFECT DECREASED
- DYSPNOEA
- PALPITATIONS
- THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

---

ISR Number: 5403998 Case Number: 6373716 I/F Code: I Report Date: 20070802

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1008766452

Mfg. Date: 20070725

Mfg. Number: B0481507A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: BF6353

Expiration Date:

Indication: ASTHMA

Route:

Dose:

Event Date:

FDA Date: 20070802

Follow Number:

Image ID: 5403998-8

Age: Gender: M Weight:

Occupation: PH

Country: NEW ZEALAND

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

ASTHMA

DRUG INEFFECTIVE

---

ISR Number: 5451436 Case Number: 6412898 I/F Code: I Report Date: 20070913  
Drug Name: **VENTOLIN**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008919641  
Mfg. Date: 20070907  
Mfg. Number: B0486885A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose:  
Event Date: 20070801  
FDA Date: 20070913  
Follow Number:  
Image ID: 5451436-1  
Age: Gender: F Weight:  
Occupation: CN  
Country: RUSSIAN FEDERATION  
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:  
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End: 20040101  
Duration:  
Adverse Reactions:  
POLYCYSTIC OVARIES

---

ISR Number: 5453893 Case Number: 6415094 I/F Code: I Report Date: 20070917

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1008929402

Mfg. Date: 20070905

Mfg. Number: B0487250A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20070917

Follow Number:

Image ID: 5453893-3

Age: 43 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ASTHMA
- CHEST DISCOMFORT
- CHOKING SENSATION
- COUGH
- DYSPNOEA
- FOREIGN BODY ASPIRATION
- OBSTRUCTIVE AIRWAYS DISORDER
- PHARYNGEAL OEDEMA
- PNEUMOMEDIASTINUM
- PNEUMOTHORAX
- THROAT IRRITATION
- WHEEZING

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ISR Number: 5494458 Case Number: 6455689 I/F Code: I Report Date: 20071019

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1009072526

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: KN6680

Expiration Date:

Indication:

Route:

Dose:

Event Date: 20071016

FDA Date: 20071022

Follow Number:

Image ID: 5494458-7

Age: 33 YR Gender: F Weight: 55 KG

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- DRUG INEFFECTIVE
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5494705 Case Number: 6455756 I/F Code: I Report Date: 20071021

Drug Name: **VENTOLIN**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009073683

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 4594

Expiration Date: 20090331

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS 2-4 TIMES DAILY INHAL

Event Date: 20071021

FDA Date: 20071023

Follow Number:

Image ID: 5494705-1

Age: 51 YR Gender: M Weight: 220 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start: 20071021

Therapy End: 20071002

Duration:

Adverse Reactions:

EAR PAIN

HEADACHE

ILL-DEFINED DISORDER

INNER EAR DISORDER

PHARYNGOLARYNGEAL PAIN

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ISR Number: 5519559 Case Number: 6469939 I/F Code: I Report Date: 20071116

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1009167638

Mfg. Date: 20071105

Mfg. Number: B0495530A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20070213

FDA Date: 20071116

Follow Number:

Image ID: 5519559-6

Age: 86 YR Gender: F Weight:

Occupation: MD

Country: NORWAY

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

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

Therapy Start:

Therapy End: 20070213

Duration:

Adverse Reactions:

- CARDIAC FAILURE
- DIARRHOEA
- DYSPNOEA
- FEELING ABNORMAL
- GENERAL PHYSICAL HEALTH DETERIORATION
- HYDROTHORAX
- NAUSEA

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ISR Number: 5522203 Case Number: 6472232 I/F Code: I Report Date: 20071120  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009178945  
Mfg. Date: 20071116  
Mfg. Number: B0495669A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date:  
FDA Date: 20071120  
Follow Number:  
Image ID: 5522203-5  
Age: Gender: F Weight: 2.23 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: 20051001  
Duration:  
Adverse Reactions:  
SEPSIS

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ISR Number: 5552894 Case Number: 6517616 I/F Code: I Report Date: 20071210

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1009269561

Mfg. Date: 20071127

Mfg. Number: B0498765A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: INHALED

Event Date:

FDA Date: 20071211

Follow Number:

Image ID: 5552894-4

Age: Gender: UNK Weight:

Occupation: MD

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:

- BASE EXCESS
- HYPERGLYCAEMIA
- HYPERVENTILATION
- LACTIC ACIDOSIS

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ISR Number: 5552895 Case Number: 6517617 I/F Code: I Report Date: 20071210  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009269563  
Mfg. Date: 20071127  
Mfg. Number: B0498763A  
Mfg. Sender: GLAXOSMITHKLINE  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: INHALED  
Event Date:  
FDA Date: 20071211  
Follow Number:  
Image ID: 5552895-6  
Age: Gender: UNK Weight:  
Occupation: MD  
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:  
    HYPERGLYCAEMIA  
    HYPERVENTILATION  
    METABOLIC ACIDOSIS

---

ISR Number: 5552896 Case Number: 6517618 I/F Code: I Report Date: 20071210

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1009269564

Mfg. Date: 20071127

Mfg. Number: B0498760A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: SEE DOSAGE TEXT / INHALED

Event Date:

FDA Date: 20071211

Follow Number:

Image ID: 5552896-8

Age: 6 YR Gender: M Weight: 48.4 LBS

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- BLOOD GLUCOSE INCREASED
- CHEST DISCOMFORT
- COUGH
- GLUCOSE URINE PRESENT
- HEART RATE INCREASED
- METABOLIC ACIDOSIS
- OXYGEN SATURATION DECREASED
- RESPIRATORY DISTRESS
- TACHYPNOEA
- WHEEZING

ISR Number: 5569649 Case Number: 6511495 I/F Code: I Report Date: 20071220

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1009320290

Mfg. Date: 20071217

Mfg. Number: A0699835A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: RESPIRATORY DISORDER

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20071211

FDA Date: 20071220

Follow Number:

Image ID: 5569649-7

Age: 2 YR Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- DYSпноEA
- INHALATION THERAPY
- RESPIRATORY ARREST
- STATUS EPILEPTICUS

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ISR Number: 5569669 Case Number: 6511508 I/F Code: I Report Date: 20071220

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1009320383

Mfg. Date: 20071210

Mfg. Number: B0499674A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNSPECIFIED

Expiration Date:

Indication: INSOMNIA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20060101

FDA Date: 20071220

Follow Number:

Image ID: 5569669-2

Age: 83 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: 20070129

Therapy End:

Duration:

Adverse Reactions:

- ALKALOSIS
- BLOOD PH INCREASED
- CHEST X-RAY ABNORMAL
- COGNITIVE DISORDER
- DRUG ABUSE
- DYSPNOEA
- FALL
- HAEMOCONCENTRATION
- HEART RATE INCREASED
- HYPOKALAEMIA
- LUNG DISORDER
- MOBILITY DECREASED
- NEUROPATHIC ARTHROPATHY

ISR Number: 5574989 Case Number: 6515205 I/F Code: I Report Date: 20071227

Drug Name: **VENTOLIN**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1009339532

Mfg. Date: 20071218

Mfg. Number: B0500895A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNSPECIFIED

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20061101

FDA Date: 20071227

Follow Number:

Image ID: 5574989-1

Age: 18 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:

Therapy End:

Duration:

Adverse Reactions:

- AMNESIA
- ANGIOEDEMA
- DRUG HYPERSENSITIVITY
- DYSAESTHESIA
- DYSKINESIA
- DYSPNOEA
- LARYNGEAL OEDEMA
- LIP OEDEMA
- LOSS OF CONSCIOUSNESS
- MALAISE
- OVERDOSE
- PRURITUS
- RALES
- TONGUE OEDEMA
- URTICARIA CHRONIC

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ISR Number: 5581574 Case Number: 6521871 I/F Code: I Report Date: 20071231

Drug Name: **VENTOLIN**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1009362002

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 6ZP8536

Expiration Date: 20110228

Indication: ASTHMA

Route: ORAL

Dose: 2PUFFS ORALLY EVERY 4 TO 6 HOURS PO

Event Date: 20071215

FDA Date: 20080102

Follow Number:

Image ID: 5581574-4

Age: Gender: F Weight: 138 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20071220

Therapy End: 20071215

Duration:

Adverse Reactions:

- CHEST PAIN
- EAR PAIN
- HEADACHE
- HYPERSENSITIVITY
- INFLUENZA LIKE ILLNESS
- PHARYNGOLARYNGEAL PAIN

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ISR Number: 5652753 Case Number: 6585244 I/F Code: I Report Date: 20080304  
Drug Name: **VENTOLIN**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009606042  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFF AS NEEDED INHAL  
Event Date: 20080225  
FDA Date: 20080305  
Follow Number:  
Image ID: 5652753-2  
Age: 25 YR Gender: M Weight: 200 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration: 2 WK  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5672231 Case Number: 6597024 I/F Code: I Report Date: 20080315  
Drug Name: **VENTOLIN**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009673422  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date:  
FDA Date: 20080317  
Follow Number:  
Image ID: 5672231-4  
Age: 56 YR Gender: F Weight: 185 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
PHARMACEUTICAL PRODUCT COMPLAINT