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ISR Number: 4661346 Case Number: 5800026 I/F Code: I Report Date: 20050506  
Drug Name: **ALBUTEROL**  
NDA Number: 73272  
Role Code: PS VAL/VBM: 1  
Seq Number: 1005978055  
Mfg. Date: 20050506  
Mfg. Number: 05/05/65  
Mfg. Sender: IVAX PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication:  
Route: RESPIRATORY (INHALATION)  
Dose: INHALATION  
Event Date:  
FDA Date: 20050512  
Follow Number:  
Image ID: 4661346-5  
Age: Gender: F Weight:  
Occupation:  
Country:  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: DE Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
BRONCHITIS ACUTE  
CARDIAC FAILURE  
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE EXACERBATED  
INFECTION

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ISR Number: 4663682 Case Number: 5802696 I/F Code: I Report Date: 20050510  
Drug Name: **ALBUTEROL**  
NDA Number: 73272  
Role Code: PS VAL/VBM: 1  
Seq Number: 1005990427  
Mfg. Date: 20050510  
Mfg. Number: 05/05/15  
Mfg. Sender: IVAX PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: SEE IMAGE  
Event Date:  
FDA Date: 20050517  
Follow Number:  
Image ID: 4663682-5  
Age: 84 YR Gender: F Weight:  
Occupation: MD  
Country:  
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:  
ACUTE MYOCARDIAL INFARCTION  
ATRIAL FIBRILLATION  
HEART RATE INCREASED  
VENTRICULAR HYPOKINESIA

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ISR Number: 4702359 Case Number: 5827582 I/F Code: I Report Date: 20050629

Drug Name: **ALBUTEROL**

NDA Number: 72273

Role Code: PS VAL/VBM: 1

Seq Number: 1006155930

Mfg. Date: 20041001

Mfg. Number: US-GLAXOSMITHKLINE-A0528457A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 721

Expiration Date: 20080901

Indication: PAIN

Route:

Dose: 2 ACTUATIONS AS NEEDED

Event Date: 20040928

FDA Date: 20050629

Follow Number:

Image ID: 4702359-4

Age: 58 YR Gender: F Weight:

Occupation: CN

Country:

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- BLOOD PRESSURE INCREASED
- DYSPNOEA
- OXYGEN SATURATION DECREASED

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ISR Number: 4777769 Case Number: 5887317 I/F Code: I Report Date: 20050919  
Drug Name: **ALBUTEROL**  
NDA Number: 73272  
Role Code: PS VAL/VBM: 2  
Seq Number: 1006450108  
Mfg. Date: 20050906  
Mfg. Number: 2005-US-00086  
Mfg. Sender: IVAX PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20050101  
FDA Date: 20050922  
Follow Number:  
Image ID: 4777769-X  
Age: Gender: F Weight:  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: HO Dechallenge Code: U Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
HEPATIC FUNCTION ABNORMAL

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ISR Number: 4805856 Case Number: 5910454 I/F Code: I Report Date: 20051013  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006539236  
Mfg. Date: 20050429  
Mfg. Number: CC05-013  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 1605  
Expiration Date: 20060701  
Indication: ASTHMA EXERCISE INDUCED  
Route: RESPIRATORY (INHALATION)  
Dose: PRN, INHALATION  
Event Date:  
FDA Date: 20051018  
Follow Number:  
Image ID: 4805856-6  
Age: Gender: F Weight: 144 LBS  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 4805859 Case Number: 5910460 I/F Code: I Report Date: 20051013  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006539239  
Mfg. Date: 20050222  
Mfg. Number: CC05-003  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 1504  
Expiration Date: 20050901  
Indication:  
Route: RESPIRATORY (INHALATION)  
Dose: INHALATION; CHRONIC  
Event Date:  
FDA Date: 20051018  
Follow Number:  
Image ID: 4805859-1  
Age: Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
ASTHMA

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ISR Number: 4805862 Case Number: 5910466 I/F Code: I Report Date: 20051013  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006539251  
Mfg. Date: 20041213  
Mfg. Number: CC04-049  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 1604  
Expiration Date: 20050901  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: PRN, 180 MCG, INHALATION; CHRONIC  
Event Date:  
FDA Date: 20051018  
Follow Number:  
Image ID: 4805862-1  
Age: Gender: M Weight: 160 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSGEUSIA

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ISR Number: 4805867 Case Number: 5910480 I/F Code: I Report Date: 20051013  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006539268  
Mfg. Date: 20050805  
Mfg. Number: CC04-035  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 104  
Expiration Date: 20050701  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: INHALATION, 3X DAILY, CHRONIC  
Event Date: 20040805  
FDA Date: 20051018  
Follow Number:  
Image ID: 4805867-0  
Age: Gender: M Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 4923353 Case Number: 5995983 I/F Code: I Report Date: 20051229  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1006979486  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: 103207  
Expiration Date: 20080901  
Indication:  
Route:  
Dose: 2 ACTUACIONES AS NEEDED  
Event Date:  
FDA Date: 20060222  
Follow Number:  
Image ID: 4923353-4  
Age: Gender: Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG DISPENSING ERROR  
    MEDICATION ERROR

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ISR Number: 4932189 Case Number: 6003911 I/F Code: I Report Date: 20060224

Drug Name: **ALBUTEROL**

NDA Number: 73272

Role Code: PS VAL/VBM: 1

Seq Number: 1007009671

Mfg. Date: 20060210

Mfg. Number: 2006-US-00433

Mfg. Sender: IVAX RESEARCH, INC.

Lot Number: ACX96A

Expiration Date: 20070501

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS Q3-4H PRN, INHALATION

Event Date: 20050201

FDA Date: 20060228

Follow Number:

Image ID: 4932189-X

Age: 78 YR Gender: M Weight: 178 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

CEREBROVASCULAR ACCIDENT

HYPERTENSION

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ISR Number: 4947116 Case Number: 6011708 I/F Code: I Report Date: 20060306  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007065363  
Mfg. Date: 20060228  
Mfg. Number: CC06-014  
Mfg. Sender: AMPHASTAR PHARMACEUTICALS, INC.  
Lot Number: 12806  
Expiration Date: 20070901  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20060205  
FDA Date: 20060314  
Follow Number:  
Image ID: 4947116-9  
Age: 75 YR Gender: M Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 4959143 Case Number: 6020521 I/F Code: I Report Date: 20060329  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007115275  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: 15006  
Expiration Date: 20071101  
Indication:  
Route:  
Dose: USED AS NEEDED  
Event Date: 20060328  
FDA Date: 20060330  
Follow Number:  
Image ID: 4959143-6  
Age: 21 YR Gender: F Weight: 125 LBS  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DEVICE FAILURE

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ISR Number: 4975804 Case Number: 6034119 I/F Code: I Report Date: 20060405  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007180950  
Mfg. Date: 20060403  
Mfg. Number: 06-016  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS INC  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS PRN-ORAL  
Event Date:  
FDA Date: 20060411  
Follow Number:  
Image ID: 4975804-7  
Age: 15 YR Gender: M Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5040900 Case Number: 6080484 I/F Code: I Report Date:

Drug Name: **ALBUTEROL**

NDA Number: 72273

Role Code: PS VAL/VBM: 1

Seq Number: 1007433379

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 19006

Expiration Date: 20080201

Indication: ASTHMA

Route:

Dose: 2 ACTUATIONS AS NEEDED

Event Date: 20060531

FDA Date: 20060630

Follow Number:

Image ID: 5040900-5

Age: Gender: M Weight:

Occupation: PH

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:  
DRUG INEFFECTIVE

ISR Number: 5079188 Case Number: 6110190 I/F Code: I Report Date: 20060804

Drug Name: **ALBUTEROL INHALATION AEROSOL, 90 MGC/ACTUATION**

NDA Number: 72273

Role Code: PS VAL/VBM: 2

Seq Number: 1007574601

Mfg. Date: 20060720

Mfg. Number: CC06-035

Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.

Lot Number: 13106

Expiration Date: 20070901

Indication: ASTHMA

Route: ORAL

Dose: Q4-6H PRN, ORAL

Event Date:

FDA Date: 20060808

Follow Number:

Image ID: 5079188-8

Age: 61 YR Gender: F Weight: 120 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

PHARMACEUTICAL PRODUCT COMPLAINT  
THERAPY NON-RESPONDER

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ISR Number: 5110786 Case Number: 6140200 I/F Code: I Report Date: 20060912  
Drug Name: **ALBUTEROL**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007692399  
Mfg. Date: 20060911  
Mfg. Number: US\_ARMSTRONGPHARM\_00001  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS INC  
Lot Number: 5BBS626  
Expiration Date: 20071231  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20060911  
FDA Date: 20060919  
Follow Number:  
Image ID: 5110786-9  
Age: 75 YR Gender: M Weight: 189 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT  
    THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5142604 Case Number: 6167473 I/F Code: I Report Date: 20061024  
Drug Name: **ALBUTEROL**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007818384  
Mfg. Date: 20060825  
Mfg. Number: CC06-043  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 05506 1107  
Expiration Date: 20071101  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20060825  
FDA Date: 20061027  
Follow Number:  
Image ID: 5142604-7  
Age: Gender: F Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5142625 Case Number: 6167674 I/F Code: I Report Date: 20061023

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1007818443

Mfg. Date: 20061023

Mfg. Number: CC06-051

Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose:

Event Date: 20061002

FDA Date: 20061027

Follow Number:

Image ID: 5142625-4

Age: 48 YR Gender: M Weight: 165 LBS

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- BRONCHITIS
- DRUG INEFFECTIVE
- FEELING ABNORMAL
- RESPIRATORY DISORDER
- THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 5145025 Case Number: 6162720 I/F Code: I Report Date: 20061107

Drug Name: **ALBUTEROL**

NDA Number: 72273

Role Code: PS VAL/VBM: 1

Seq Number: 1007827948

Mfg. Date: 20061102

Mfg. Number: US-GLAXOSMITHKLINE-A0626253A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 19206

Expiration Date: 20080401

Indication: ASTHMA

Route:

Dose: 2 ACTUATIONS AS NEEDED

Event Date:

FDA Date: 20061107

Follow Number:

Image ID: 5145025-6

Age: Gender: F Weight: 3.3 KG

Occupation: MD

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

CONGENITAL HAND MALFORMATION

DRUG EXPOSURE DURING PREGNANCY

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ISR Number: 5152651 Case Number: 6175133 I/F Code: I Report Date: 20061102  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007859975  
Mfg. Date: 20061101  
Mfg. Number: CC06-061  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20061101  
FDA Date: 20061109  
Follow Number:  
Image ID: 5152651-7  
Age: 20 YR Gender: F Weight: 145 LBS  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5152654 Case Number: 6174988 I/F Code: I Report Date: 20061102  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007859992  
Mfg. Date: 20061027  
Mfg. Number: CC06-057  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS INC  
Lot Number: 14806  
Expiration Date: 20071101  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20061027  
FDA Date: 20061109  
Follow Number:  
Image ID: 5152654-2  
Age: 78 YR Gender: M Weight: 145 LBS  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT  
    THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

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ISR Number: 5156532 Case Number: 6179132 I/F Code: I Report Date: 20061026  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1007875805  
Mfg. Date: 20061026  
Mfg. Number: CC06-055  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20061025  
FDA Date: 20061115  
Follow Number:  
Image ID: 5156532-4  
Age: 72 YR Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    AGEUSIA  
    DRUG INEFFECTIVE  
    THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

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ISR Number: 5160189 Case Number: 6181593 I/F Code: I Report Date: 20061109

Drug Name: **ALBUTEROL**

NDA Number: 73272

Role Code: PS VAL/VBM: 1

Seq Number: 1007890806

Mfg. Date: 20061109

Mfg. Number: 149637USA

Mfg. Sender: TEVA PHARMACEUTICALS

Lot Number:

Expiration Date:

Indication: OEDEMA PERIPHERAL

Route: RESPIRATORY (INHALATION)

Dose: AT LEAST 8 TIMES IN 2 HOURS PRIORR, RESPIRATORY (INHALATION)

Event Date:

FDA Date: 20061120

Follow Number:

Image ID: 5160189-6

Age: 68 YR Gender: F Weight:

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- CONDUCTION DISORDER
- HYPOKALAEMIA
- MYOCARDIAL ISCHAEMIA
- OEDEMA PERIPHERAL
- RESPIRATORY ALKALOSIS
- RESPIRATORY DISTRESS
- RESPIRATORY RATE INCREASED
- VENTRICULAR EXTRASYSTOLES
- VENTRICULAR TACHYCARDIA

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ISR Number: 5196608 Case Number: 6214643 I/F Code: I Report Date: 20061228  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008003719  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20061225  
FDA Date: 20061229  
Follow Number:  
Image ID: 5196608-9  
Age: 63 YR Gender: M Weight: 210 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start: 20061225  
Therapy End: 20061225  
Duration:  
Adverse Reactions:  
ADVERSE DRUG REACTION  
DYSPNOEA  
REACTION TO DRUG EXCIPIENTS

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ISR Number: 5203797 Case Number: 6222841 I/F Code: I Report Date: 20061221

Drug Name: **ALBUTEROL**

NDA Number: 72859

Role Code: PS VAL/VBM: 1

Seq Number: 1008026951

Mfg. Date: 20061221

Mfg. Number: DAV-AE-ALB-06-001

Mfg. Sender: STADA PHARMACEUTICALS, INC.

Lot Number:

Expiration Date:

Indication: OEDEMA PERIPHERAL

Route: RESPIRATORY (INHALATION)

Dose: INHALATION

Event Date:

FDA Date: 20070105

Follow Number:

Image ID: 5203797-6

Age: 68 YR Gender: F Weight:

Occupation:

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- HYPERHIDROSIS
- HYPOKALAEMIA
- OEDEMA PERIPHERAL
- PALLOR
- RESPIRATORY DISTRESS
- VENTRICULAR EXTRASYSTOLES
- VENTRICULAR TACHYCARDIA

ISR Number: 5209659 Case Number: 6223227 I/F Code: I Report Date: 20070103

Drug Name: **ALBUTEROL**

NDA Number: 72273

Role Code: PS VAL/VBM: 1

Seq Number: 1008046898

Mfg. Date: 20061120

Mfg. Number: CC06-072

Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.

Lot Number: 16506

Expiration Date: 20071201

Indication: ASTHMA

Route:

Dose: ACTUATIONS AS NEEDED

Event Date: 20061114

FDA Date: 20070111

Follow Number:

Image ID: 5209659-2

Age: 19 YR Gender: F Weight:

Occupation: PH

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

DYSGEUSIA

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5209662 Case Number: 6223251 I/F Code: I Report Date: 20070103  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008046902  
Mfg. Date: 20061204  
Mfg. Number: CC06-073  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20061114  
FDA Date: 20070111  
Follow Number:  
Image ID: 5209662-2  
Age: 49 YR Gender: F Weight: 190 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5209672 Case Number: 6223274 I/F Code: I Report Date: 20070108  
 Drug Name: **ALBUTEROL**  
 NDA Number: 72273  
 Role Code: PS VAL/VBM: 1  
 Seq Number: 1008046917  
 Mfg. Date: 20070108  
 Mfg. Number: CC07-06  
 Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
 Lot Number: 10106  
 Expiration Date: 20070701  
 Indication: ASTHMA  
 Route:  
 Dose: USED AS NEEDED  
 Event Date:  
 FDA Date: 20070111  
 Follow Number:  
 Image ID: 5209672-5  
 Age: Gender: F Weight:  
 Occupation: MD  
 Country: UNITED STATES  
 Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
 Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
 Therapy Start:  
 Therapy End:  
 Duration:  
 Adverse Reactions:  
 DRUG INEFFECTIVE

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ISR Number: 5209673 Case Number: 6223312 I/F Code: I Report Date: 20070108  
Drug Name: **ALBUTEROL**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008046918  
Mfg. Date: 20070104  
Mfg. Number: CC07-03  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: INHALANT  
Event Date:  
FDA Date: 20070111  
Follow Number:  
Image ID: 5209673-7  
Age: Gender: Weight:  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N 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: 5216838 Case Number: 6228121 I/F Code: I Report Date: 20070109  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008071382  
Mfg. Date: 20070108  
Mfg. Number: 2007-00138  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 113906  
Expiration Date: 20080501  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20061219  
FDA Date: 20070119  
Follow Number:  
Image ID: 5216838-7  
Age: Gender: M Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5216840 Case Number: 6228122 I/F Code: I Report Date: 20070109  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008071384  
Mfg. Date: 20070108  
Mfg. Number: 2007-00181  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 10106  
Expiration Date: 20070701  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20061219  
FDA Date: 20070119  
Follow Number:  
Image ID: 5216840-5  
Age: Gender: M Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5216841 Case Number: 6228130 I/F Code: I Report Date: 20070109  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008071385  
Mfg. Date: 20070108  
Mfg. Number: 2007-00182  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 16406  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20061219  
FDA Date: 20070119  
Follow Number:  
Image ID: 5216841-7  
Age: Gender: M Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5242995 Case Number: 6251886 I/F Code: I Report Date: 20070207  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008168451  
Mfg. Date: 20070206  
Mfg. Number: CC07-25  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: UNKNOWN  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070206  
FDA Date: 20070215  
Follow Number:  
Image ID: 5242995-2  
Age: Gender: M Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5269916 Case Number: 6273555 I/F Code: I Report Date: 20070307  
Drug Name: **ALBUTEROL**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008268988  
Mfg. Date: 20070220  
Mfg. Number: CC07-49  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date:  
FDA Date: 20070314  
Follow Number:  
Image ID: 5269916-0  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
HYPERSENSITIVITY

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ISR Number: 5313040 Case Number: 6308732 I/F Code: I Report Date: 20070417  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008430008  
Mfg. Date: 20070417  
Mfg. Number: CC07-63  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070411  
FDA Date: 20070424  
Follow Number:  
Image ID: 5313040-5  
Age: Gender: F Weight:  
Occupation: OT  
Country: UNITED STATES  
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:  
DRUG INEFFECTIVE

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ISR Number: 5322598 Case Number: 6316092 I/F Code: I Report Date: 20070418  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008470039  
Mfg. Date: 20070418  
Mfg. Number: CC07-68  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 18906  
Expiration Date: 20080201  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20070321  
FDA Date: 20070507  
Follow Number:  
Image ID: 5322598-1  
Age: Gender: F Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
ASTHMA

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ISR Number: 5322609 Case Number: 6316095 I/F Code: I Report Date: 20070427  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008470093  
Mfg. Date: 20070418  
Mfg. Number: MSB FILE #2007-00765  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 18006  
Expiration Date: 20080201  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20070507  
Follow Number:  
Image ID: 5322609-3  
Age: Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
BLISTER  
PHARYNGOLARYNGEAL PAIN  
TONGUE BLISTERING

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ISR Number: 5323496 Case Number: 6316200 I/F Code: I Report Date: 20070430  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008473479  
Mfg. Date: 20070423  
Mfg. Number: CC07-76  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070423  
FDA Date: 20070508  
Follow Number:  
Image ID: 5323496-X  
Age: Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DEVICE FAILURE  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5331619 Case Number: 6322674 I/F Code: I Report Date: 20070418  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008505531  
Mfg. Date: 20070418  
Mfg. Number:  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 14806  
Expiration Date: 20071101  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20070321  
FDA Date: 20070516  
Follow Number:  
Image ID: 5331619-1  
Age: Gender: F Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
ASTHMA

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ISR Number: 5339800 Case Number: 6330203 I/F Code: I Report Date: 20070518  
Drug Name: **ALBUTEROL**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008533495  
Mfg. Date: 20070518  
Mfg. Number: CC07-92  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070515  
FDA Date: 20070524  
Follow Number:  
Image ID: 5339800-2  
Age: Gender: M Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
UNEVALUABLE EVENT

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ISR Number: 5347089 Case Number: 6333911 I/F Code: I Report Date: 20070524  
Drug Name: **ALBUTEROL**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008554292  
Mfg. Date: 20070524  
Mfg. Number: CC07-93  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date:  
FDA Date: 20070604  
Follow Number:  
Image ID: 5347089-3  
Age: Gender: Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    BURNING SENSATION  
    LUNG DISORDER  
    NAUSEA

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ISR Number: 5360295 Case Number: 6339811 I/F Code: I Report Date: 20070612  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008597494  
Mfg. Date: 20070612  
Mfg. Number: CC07-105  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20070606  
FDA Date: 20070614  
Follow Number:  
Image ID: 5360295-7  
Age: Gender: F Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5360700 Case Number: 6340976 I/F Code: I Report Date: 20070606  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008598786  
Mfg. Date: 20070604  
Mfg. Number: CC07-99  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 102407  
Expiration Date: 20080801  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20070604  
FDA Date: 20070614  
Follow Number:  
Image ID: 5360700-6  
Age: Gender: Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5360703 Case Number: 6340977 I/F Code: I Report Date: 20070606  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008598790  
Mfg. Date: 20070606  
Mfg. Number: CC07-101  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 1UNIT MONTHLY  
Event Date: 20070606  
FDA Date: 20070614  
Follow Number:  
Image ID: 5360703-1  
Age: Gender: M Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5361465 Case Number: 6340992 I/F Code: I Report Date: 20070607  
Drug Name: **ALBUTEROL**  
NDA Number: 18473  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008601242  
Mfg. Date: 20070607  
Mfg. Number: CC07-104  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20070607  
FDA Date: 20070614  
Follow Number:  
Image ID: 5361465-4  
Age: Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG EFFECT DECREASED

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ISR Number: 5384933 Case Number: 6357655 I/F Code: I Report Date: 20070627  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008688669  
Mfg. Date: 20070626  
Mfg. Number: CC07-114  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 111406  
Expiration Date: 20080401  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED;  
Event Date: 20070626  
FDA Date: 20070709  
Follow Number:  
Image ID: 5384933-8  
Age: Gender: Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5386349 Case Number: 6358943 I/F Code: I Report Date: 20070605  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008694524  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: 18106  
Expiration Date: 20080201  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20070523  
FDA Date: 20070705  
Follow Number:  
Image ID: 5386349-7  
Age: 55 YR Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration: 3 YR  
Adverse Reactions:  
    DEVICE FAILURE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5407938 Case Number: 6380972 I/F Code: I Report Date: 20070730  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008783758  
Mfg. Date: 20070727  
Mfg. Number: CC07-131  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20070723  
FDA Date: 20070803  
Follow Number:  
Image ID: 5407938-7  
Age: Gender: F Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
BRONCHOSPASM

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ISR Number: 5412055 Case Number: 6384593 I/F Code: I Report Date: 20070801  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008799881  
Mfg. Date: 20070801  
Mfg. Number: CC07-133  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 112806  
Expiration Date: 20080401  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20070809  
Follow Number:  
Image ID: 5412055-6  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPNOEA  
    OXYGEN SATURATION DECREASED  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5412831 Case Number: 6383966 I/F Code: I Report Date: 20070806  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008802263  
Mfg. Date: 20070801  
Mfg. Number: CC07-136  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20070810  
Follow Number:  
Image ID: 5412831-X  
Age: Gender: M Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5417706 Case Number: 6386145 I/F Code: I Report Date: 20070814

Drug Name: **ALBUTEROL**

NDA Number: 72273

Role Code: PS VAL/VBM: 1

Seq Number: 1008818602

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication:

Route:

Dose: 2 ACTUATIONS AS NEEDED

Event Date: 20070808

FDA Date: 20070815

Follow Number:

Image ID: 5417706-8

Age: 47 YR Gender: F Weight: 242 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- BLOOD PRESSURE INCREASED
- DRUG INEFFECTIVE
- HEART RATE INCREASED
- MALAISE
- VOMITING

ISR Number: 5442080 Case Number: 6408321 I/F Code: I Report Date: 20070824

Drug Name: **ALBUTEROL**

NDA Number: 72273

Role Code: PS VAL/VBM: 1

Seq Number: 1008885202

Mfg. Date: 20070814

Mfg. Number: CC07-147

Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose: 2 PUFFS, 6X DAILY PRN

Event Date:

FDA Date: 20070829

Follow Number:

Image ID: 5442080-0

Age: Gender: M Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- DRUG INEFFECTIVE
- INCORRECT DOSE ADMINISTERED
- MEDICAL DEVICE COMPLICATION
- PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5453499 Case Number: 6426419 I/F Code: I Report Date: 20070905

Drug Name: **ALBUTEROL**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1008927096

Mfg. Date: 20070905

Mfg. Number: CC07-153

Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.

Lot Number: 15006

Expiration Date:

Indication: ASTHMA

Route:

Dose: 2 PUFFS 6 TIMES DAILY

Event Date:

FDA Date: 20070913

Follow Number:

Image ID: 5453499-6

Age: Gender: F Weight:

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG INEFFECTIVE

PNEUMONIA

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ISR Number: 5463547 Case Number: 6431210 I/F Code: I Report Date: 20070907  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008956956  
Mfg. Date: 20070906  
Mfg. Number: CC07-154  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date: 20070906  
FDA Date: 20070919  
Follow Number:  
Image ID: 5463547-5  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5472267 Case Number: 6438936 I/F Code: I Report Date: 20070917  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1008989528  
Mfg. Date: 20070917  
Mfg. Number: CC07-158  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 14806  
Expiration Date: 20071101  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20070927  
Follow Number:  
Image ID: 5472267-2  
Age: Gender: M Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5479053 Case Number: 6442107 I/F Code: I Report Date: 20070927  
Drug Name: **ALBUTEROL**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009014341  
Mfg. Date: 20070925  
Mfg. Number: CC07-165  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS EVERY 4 HOURS  
Event Date:  
FDA Date: 20071002  
Follow Number:  
Image ID: 5479053-8  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: Y Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

ISR Number: 5480678 Case Number: 6442551 I/F Code: I Report Date: 20070925  
 Drug Name: **ALBUTEROL**  
 NDA Number: 72273  
 Role Code: PS VAL/VBM: 1  
 Seq Number: 1009021334  
 Mfg. Date: 20070925  
 Mfg. Number: CC07-162  
 Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
 Lot Number: 115006  
 Expiration Date: 20080601  
 Indication: ASTHMA  
 Route:  
 Dose: 2 ACTUATIONS AS NEEDED  
 Event Date:  
 FDA Date: 20071003  
 Follow Number:  
 Image ID: 5480678-4  
 Age: Gender: F Weight:  
 Occupation: CN  
 Country: UNITED STATES  
 Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
 Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
 Therapy Start:  
 Therapy End:  
 Duration:  
 Adverse Reactions:  
 DRUG INEFFECTIVE

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ISR Number: 5489408 Case Number: 6451822 I/F Code: I Report Date: 20061204  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009053790  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: 113406  
Expiration Date: 20080501  
Indication:  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20071016  
Follow Number:  
Image ID: 5489408-3  
Age: Gender: Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20061201  
Therapy End: 20061130  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    INCORRECT DOSE ADMINISTERED  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5500706 Case Number: 6459428 I/F Code: I Report Date: 20071017  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009096849  
Mfg. Date: 20071017  
Mfg. Number: CC07-176  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 15006  
Expiration Date: 20071101  
Indication: ASTHMA  
Route:  
Dose: USED AS NEEDED  
Event Date:  
FDA Date: 20071025  
Follow Number:  
Image ID: 5500706-7  
Age: Gender: Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG EFFECT DECREASED  
    DYSпноEA

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ISR Number: 5502964 Case Number: 6460399 I/F Code: I Report Date: 20071026

Drug Name: **ARMSTRONG 2 PUFFS ARMSTRONG ALBUTEROL**

NDA Number: 72273

Role Code: PS VAL/VBM: 2

Seq Number: 1009106358

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 721

Expiration Date: 20080901

Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Route:

Dose: 2 ACTUATIONS AS NEEDED

Event Date: 20070701

FDA Date: 20071029

Follow Number:

Image ID: 5502964-1

Age: 47 YR Gender: F Weight: 262 LBS

Occupation: CN

Country: UNITED STATES

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

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

Therapy Start: 20071027

Therapy End: 20070702

Duration:

Adverse Reactions:

- BLOOD PRESSURE INCREASED
- CHEST PAIN
- DRUG INEFFECTIVE
- MALAISE
- PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5506149 Case Number: 6463562 I/F Code: I Report Date: 20071024  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009117740  
Mfg. Date: 20071022  
Mfg. Number: CC07-181  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 112007  
Expiration Date: 20090101  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20071101  
Follow Number:  
Image ID: 5506149-4  
Age: 40 YR Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    COUGH  
    RASH

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ISR Number: 5507154 Case Number: 6464981 I/F Code: I Report Date: 20071025  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009121410  
Mfg. Date: 20071024  
Mfg. Number: CC07-183  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 18106  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20071102  
Follow Number:  
Image ID: 5507154-4  
Age: Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSGEUSIA

ISR Number: 5512304 Case Number: 6471214 I/F Code: I Report Date: 20071102

Drug Name: **ALBUTEROL**

NDA Number: 18473

Role Code: PS VAL/VBM: 1

Seq Number: 1009140747

Mfg. Date: 20071024

Mfg. Number: CC07-182

Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose:

Event Date:

FDA Date: 20071109

Follow Number:

Image ID: 5512304-X

Age: Gender: F Weight:

Occupation: PH

Country: UNITED STATES

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

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

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG EFFECT DECREASED

PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5567730 Case Number: 6516115 I/F Code: I Report Date: 20071113  
Drug Name: **ALBUTEROL**  
NDA Number: 17559  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009314043  
Mfg. Date: 20071112  
Mfg. Number: CC07-196  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 4BBS827  
Expiration Date: 20061031  
Indication: ASTHMA  
Route:  
Dose: 2 DOSES / DAY ORAL AER I  
Event Date:  
FDA Date: 20071218  
Follow Number:  
Image ID: 5567730-X  
Age: 69 YR Gender: F Weight: 113 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5594194 Case Number: 6532352 I/F Code: I Report Date: 20080104  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009405478  
Mfg. Date: 20080103  
Mfg. Number: CC08-01  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 103707  
Expiration Date: 20080901  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20080115  
Follow Number:  
Image ID: 5594194-2  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    HEADACHE

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ISR Number: 5597530 Case Number: 6533838 I/F Code: I Report Date: 20080109  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009417834  
Mfg. Date: 20080105  
Mfg. Number: CC08-09  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20080116  
Follow Number:  
Image ID: 5597530-6  
Age: Gender: M Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
CYANOSIS  
LIP PAIN  
PHARMACEUTICAL PRODUCT COMPLAINT

ISR Number: 5598461 Case Number: 6535497 I/F Code: I Report Date: 20080108  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009421252  
Mfg. Date: 20080107  
Mfg. Number: CC08-05  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20080116  
Follow Number:  
Image ID: 5598461-8  
Age: Gender: F Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PHARMACEUTICAL PRODUCT COMPLAINT

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ISR Number: 5619304 Case Number: 6557537 I/F Code: I Report Date: 20080128  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009492147  
Mfg. Date: 20080125  
Mfg. Number: CC08-24  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 ACUTATIONS AS NEEDED  
Event Date:  
FDA Date: 20080206  
Follow Number:  
Image ID: 5619304-X  
Age: Gender: F Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5624646 Case Number: 6560185 I/F Code: F Report Date: 20080129  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009511685  
Mfg. Date: 20071210  
Mfg. Number: CC07-27  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 100507  
Expiration Date: 20080701  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20080208  
Follow Number: 1  
Image ID: 5624646-8  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5631605 Case Number: 6569108 I/F Code: I Report Date: 20080204  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009536763  
Mfg. Date: 20080130  
Mfg. Number: CC08-35  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 112106  
Expiration Date: 20080401  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20080212  
Follow Number:  
Image ID: 5631605-8  
Age: Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
THROAT IRRITATION

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ISR Number: 5639622 Case Number: 6573684 I/F Code: I Report Date: 20080209  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009565204  
Mfg. Date: 20080207  
Mfg. Number: CC08-158  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC  
Lot Number: 109807  
Expiration Date: 20081201  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20080222  
Follow Number:  
Image ID: 5639622-9  
Age: Gender: M Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

ISR Number: 5639637 Case Number: 6572390 I/F Code: I Report Date: 20070212  
Drug Name:  
NDA Number:  
Role Code: VAL/VBM:  
Seq Number:  
Mfg. Date: 20080207  
Mfg. Number: CC08-167  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose:  
Event Date:  
FDA Date: 20080222  
Follow Number:  
Image ID: 5639637-0  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:

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ISR Number: 5639638 Case Number: 6572391 I/F Code: I Report Date: 20080209  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009565239  
Mfg. Date: 20080207  
Mfg. Number: CC08-157  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 1013807  
Expiration Date: 20080901  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATION AS NEEDED  
Event Date:  
FDA Date: 20080222  
Follow Number:  
Image ID: 5639638-2  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End: 20080101  
Duration:  
Adverse Reactions:  
COUGH  
DRUG INEFFECTIVE

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ISR Number: 5672584 Case Number: 6572390 I/F Code: I Report Date: 20080307  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009674515  
Mfg. Date: 20080207  
Mfg. Number: CC08-167  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 110206  
Expiration Date: 20080301  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20080317  
Follow Number:  
Image ID: 5672584-7  
Age: Gender: F Weight:  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 5679818 Case Number: 6607546 I/F Code: I Report Date: 20080321  
Drug Name: **ALBUTEROL**  
NDA Number: 72273  
Role Code: PS VAL/VBM: 1  
Seq Number: 1009700200  
Mfg. Date: 20080317  
Mfg. Number: CC08-246  
Mfg. Sender: ARMSTRONG PHARMACEUTICALS, INC.  
Lot Number: 115507  
Expiration Date: 20090301  
Indication: ASTHMA  
Route:  
Dose: 2 ACTUATIONS AS NEEDED  
Event Date:  
FDA Date: 20080324  
Follow Number:  
Image ID: 5679818-3  
Age: Gender: F Weight:  
Occupation: PH  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Confidential:  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSGEUSIA