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ISR Number: 6030082 Case Number: 6878471 I/F Code: I Report Date: 20090105  
Drug Name: **PROVENTIL-**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1010959567  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS EVERY 4 HOURS EVERY 4 HOURS INHAL  
Event Date: 20090105  
FDA Date: 20090106  
Follow Number:  
Image ID: 6030082-5  
Age: 59 YR Gender: F Weight: 200 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG EFFECT DECREASED  
INCREASED UPPER AIRWAY SECRETION  
LUNG INFECTION  
PNEUMONIA  
PRODUCT QUALITY ISSUE

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ISR Number: 6030487 Case Number: 6878541 I/F Code: I Report Date: 20090103  
Drug Name: **PROVENTIL-**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1010960911  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose: 1-2 PUFFS BY MOUTH EVERY 4-6 HRS  
Event Date: 20081001  
FDA Date: 20090105  
Follow Number:  
Image ID: 6030487-2  
Age: 31 YR Gender: F Weight: 201 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: 20081231  
Therapy End: 20081229  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PRODUCT QUALITY ISSUE

ISR Number: 6030490 Case Number: 6878548 I/F Code: I Report Date: 20090103  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1010960916  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date:  
FDA Date: 20090105  
Follow Number:  
Image ID: 6030490-2  
Age: 42 YR Gender: M Weight: 180 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 6030495 Case Number: 6878586 I/F Code: I Report Date: 20090103  
Drug Name: **PROVENTIL-**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1010960934  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: GJC004A  
Expiration Date: 20080310  
Indication: ASTHMA  
Route:  
Dose: 2 INHALATIONS 4 TIMES A DAY INHAL  
Event Date: 20090103  
FDA Date: 20090105  
Follow Number:  
Image ID: 6030495-1  
Age: 39 YR Gender: M Weight: 220 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20081231  
Therapy End: 20081226  
Duration:  
Adverse Reactions:  
ASTHMA  
CHEST DISCOMFORT  
CONDITION AGGRAVATED  
DYSPTNOEA  
PRODUCT QUALITY ISSUE

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ISR Number: 6045423 Case Number: 6892608 I/F Code: I Report Date: 20090115  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011014403  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: 80156  
Expiration Date: 20090310  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 INHALATIONS AS NEEDED INHAL  
Event Date: 20090115  
FDA Date: 20090116  
Follow Number:  
Image ID: 6045423-2  
Age: 57 YR Gender: F Weight: 159 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start: 20090115  
Therapy End: 20090101  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    PEAK EXPIRATORY FLOW RATE DECREASED  
    PRODUCT QUALITY ISSUE

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ISR Number: 6046280 Case Number: 6892763 I/F Code: I Report Date: 20090118  
Drug Name: **PROVENTIL-**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011018452  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: 80004  
Expiration Date: 20100131  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 INHALATIONS EVERY 4 HRS. AS NE INHAL  
Event Date: 20081009  
FDA Date: 20090121  
Follow Number:  
Image ID: 6046280-0  
Age: 69 YR Gender: F Weight: 105 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: OT Dechallenge Code: D Rechallenge Code: Y Death Date:  
Therapy Start: 20081009  
Therapy End: 20081009  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
HYPERSENSITIVITY  
REACTION TO DRUG EXCIPIENTS

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ISR Number: 6052529 Case Number: 6897702 I/F Code: I Report Date: 20090116  
Drug Name: **PROVENTIL-HFA**  
NDA Number: 20503  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011038710  
Mfg. Date: 20090109  
Mfg. Number: 2009SP000645  
Mfg. Sender: SCHERING-PLOUGH CORPORATION  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route:  
Dose:  
Event Date:  
FDA Date: 20090121  
Follow Number:  
Image ID: 6052529-0  
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:  
NEOPLASM

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ISR Number: 6056775 Case Number: 6900219 I/F Code: I Report Date: 20090124  
Drug Name: **PROVENTIL-**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011052614  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication:  
Route:  
Dose: 1 OR 2 PUFF EVER4 TO 6 HOURS  
Event Date: 20090122  
FDA Date: 20090126  
Follow Number:  
Image ID: 6056775-1  
Age: 37 YR Gender: F Weight: 200 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: LT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
ASTHMA  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
PRODUCT QUALITY ISSUE

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ISR Number: 6056793 Case Number: 6900243 I/F Code: I Report Date: 20090123  
Drug Name: **PROVENTIL-**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011052652  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: 80065  
Expiration Date: 20100131  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 Q6H PRN PO  
Event Date: 20090120  
FDA Date: 20090126  
Follow Number:  
Image ID: 6056793-3  
Age: 22 Gender: M Weight: 160 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20090123  
Therapy End: 20080801  
Duration:  
Adverse Reactions:  
DEPRESSED MOOD  
DRUG INEFFECTIVE  
PRODUCT QUALITY ISSUE

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ISR Number: 6057531 Case Number: 6900391 I/F Code: I Report Date: 20090126  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011054890  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: N/A  
Expiration Date: 20110116  
Indication: ASTHMA  
Route:  
Dose:  
Event Date: 20090125  
FDA Date: 20090127  
Follow Number:  
Image ID: 6057531-0  
Age: 39 YR Gender: F Weight:  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:  
Therapy Start: 20090124  
Therapy End: 20081201  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    DYSPNOEA  
    PRODUCT QUALITY ISSUE

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ISR Number: 6058009 Case Number: 6903923 I/F Code: I Report Date: 20090126  
Drug Name: **PROVENTIL-**  
NDA Number: 20503  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011056910  
Mfg. Date: 20090123  
Mfg. Number: 2009SP001643  
Mfg. Sender: SCHERING-PLOUGH CORPORATION  
Lot Number:  
Expiration Date:  
Indication: DRUG USE FOR UNKNOWN INDICATION  
Route: RESPIRATORY (INHALATION)  
Dose: UNK; PO  
Event Date:  
FDA Date: 20090127  
Follow Number:  
Image ID: 6058009-0  
Age: 47 YR Gender: F Weight:  
Occupation: CN  
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:  
ASTHMA  
NASAL OPERATION

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ISR Number: 6100460 Case Number: 6931462 I/F Code: I Report Date: 20090226  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011212908  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: GJC008A  
Expiration Date: 20100331  
Indication: CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS 6HR INHAL TWO WEEKS PRIOR TO  
Event Date: 20090226  
FDA Date: 20090227  
Follow Number:  
Image ID: 6100460-4  
Age: 56 Gender: M Weight: 275 LBS  
Occupation:  
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:  
Therapy End: 20090226  
Duration:  
Adverse Reactions:  
CHRONIC OBSTRUCTIVE PULMONARY DISEASE  
CONDITION AGGRAVATED  
DRUG INEFFECTIVE  
PRODUCT QUALITY ISSUE

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ISR Number: 6107229 Case Number: 6942586 I/F Code: I Report Date: 20090304  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011237576  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: ALL  
Expiration Date: 20100331  
Indication: DYSPNOEA  
Route: RESPIRATORY (INHALATION)  
Dose: 90 MCG EVERY 4 HOURS PRN INHAL  
Event Date:  
FDA Date: 20090305  
Follow Number:  
Image ID: 6107229-5  
Age: Gender: 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: 20090304  
Therapy End: 20090101  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 6107240 Case Number: 6941277 I/F Code: I Report Date: 20090305  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011237594  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route:  
Dose:  
Event Date:  
FDA Date: 20090305  
Follow Number:  
Image ID: 6107240-4  
Age: Gender: F Weight: 210 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 6112379 Case Number: 6946715 I/F Code: I Report Date: 20090310  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011256313  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: ORAL  
Dose: 1 - 2 PUFFS AS NEEDED PO  
Event Date:  
FDA Date: 20090311  
Follow Number:  
Image ID: 6112379-3  
Age: 37 YR Gender: F Weight: 150 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start: 20090310  
Therapy End: 20090101  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 6112381 Case Number: 6946731 I/F Code: I Report Date: 20090310  
Drug Name: **PROVENTIL-**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011256315  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: 19246914B00116  
Expiration Date: 20080831  
Indication: ASTHMA  
Route: ORAL  
Dose: 1 - 2 PUFFS AS NEEDED PO, REST OF LIFE  
Event Date: 20090204  
FDA Date: 20090311  
Follow Number:  
Image ID: 6112381-1  
Age: 18 YR Gender: F Weight: 125 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:  
Therapy End:  
Duration:  
Adverse Reactions:  
DRUG INEFFECTIVE

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ISR Number: 6122071 Case Number: 6949479 I/F Code: I Report Date: 20090313  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011292168  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: DYSPNOEA  
Route: ORAL  
Dose: 120 MCG DAILY PO  
Event Date: 20090313  
FDA Date: 20090316  
Follow Number:  
Image ID: 6122071-7  
Age: 69 YR Gender: M Weight: 220 LBS  
Occupation: CN  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N  
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
    DEVICE INEFFECTIVE  
    PRODUCT QUALITY ISSUE

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ISR Number: 6124415 Case Number: 6952956 I/F Code: I Report Date: 20090316  
Drug Name: **PROVENTIL-**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011301944  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: GHF060A  
Expiration Date: 20080630  
Indication: ASTHMA  
Route:  
Dose: 2 PUFFS EVERY HOURS AS N INHAL  
Event Date: 20090101  
FDA Date: 20090317  
Follow Number:  
Image ID: 6124415-9  
Age: 64 YR Gender: M Weight: 220 LBS  
Occupation:  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y  
Outcome Code: OT Dechallenge Code: N Rechallenge Code: Death Date:  
Therapy Start: 20080314  
Therapy End: 20080101  
Duration:  
Adverse Reactions:  
    DRUG INEFFECTIVE  
    FOOD INTERACTION  
    PRODUCT QUALITY ISSUE

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ISR Number: 6137254 Case Number: 6960805 I/F Code: I Report Date: 20090325  
Drug Name: **PROVENTIL-HFA**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011352959  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number: 80019  
Expiration Date: 20100331  
Indication: ASTHMA  
Route: ORAL  
Dose: 2 PUFFS AS NEEDED PO  
Event Date: 20090325  
FDA Date: 20090326  
Follow Number:  
Image ID: 6137254-X  
Age: 52 YR Gender: M Weight: 202 LBS  
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: 20090325  
Therapy End: 20081201  
Duration:  
Adverse Reactions:  
TINNITUS

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ISR Number: 6142073 Case Number: 6963989 I/F Code: I Report Date: 20090327  
Drug Name: **PROVENTIL-**  
NDA Number:  
Role Code: PS VAL/VBM: 1  
Seq Number: 1011371778  
Mfg. Date:  
Mfg. Number:  
Mfg. Sender:  
Lot Number:  
Expiration Date:  
Indication: ASTHMA  
Route: RESPIRATORY (INHALATION)  
Dose: 2 PUFFS BEFORE EXERCISE/PR INHAL  
Event Date: 20090101  
FDA Date: 20090331  
Follow Number:  
Image ID: 6142073-4  
Age: 60 YR Gender: F Weight: 160 LBS  
Occupation: OT  
Country: UNITED STATES  
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N  
Outcome Code: Dechallenge Code: D Rechallenge Code: Death Date:  
Therapy Start:  
Therapy End:  
Duration:  
Adverse Reactions:  
MUSCLE SPASMS