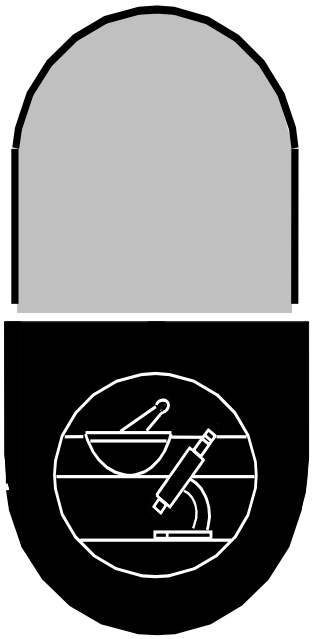
**CUMULATIVE SUPPLEMENT 3**
**MARCH 2005**



# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

## 25th EDITION

**Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research**
**Office of Generic Drugs**

**2005**

Prepared By
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

**APPROVED DRUG PRODUCTS**
**with**
**THERAPEUTIC EQUIVALENCE EVALUATIONS**

**25th EDITION**

**Cumulative Supplement 3**

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**CONTENTS**

*PAGE*

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## 25th EDITION

## CUMULATIVE SUPPLEMENT 3
## March 2005

## 1.0 INTRODUCTION

### 1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 25th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to mark to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement. Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of

the 25th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 26th Edition. The current edition Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >**A**>. The Patent and Exclusivity Data are indicated by the symbol **>ADD>** to the left of the line on which new information exists. The **>ADD>** symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol **>D>** (DELETE) to the left of the line. The information line with the **>D>** symbol is dropped in subsequent Cumulative Supplements for that item.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Drug substance and drug product patents are indicated as such with DS or DP in the Patent codes column. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms, Section B, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Refer to Section 1.3 for internet access to the most current list of Patent and Exclusivity terms.

## 1.2 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. The Electronic Orange Book Query, updated monthly, will contain the most current applicant holder name.

| FORMER APPLICANT NAME (FORMER ABBREVIATED NAME) | NEW APPLICANT NAME (NEW ABBREVIATED NAME) |
|---|---|
| FUJISAWA HEALTHCARE (FUJISAWA HLTHCARE) | ASTELLAS PHARMA US INC (ASTELLAS) |
| SHIRE LABORATORIES INC (SHIRE LABS) | SHIRE DEVELOPMENT INC (SHIRE) |
| SHIRE PHARMACEUTICAL DEVELOPMENT INC (SHIRE PHARM) | SHIRE DEVELOPMENT INC (SHIRE) |
| YAMANOUCHI PHARMA AMERICA INC (YAMANOUCHI) | ASTELLAS PHARMA US INC (ASTELLAS) |

## 1.3 AVAILABILITY OF THE EDITION

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements will not be available in a published paper version. Since 1997, the Electronic Orange Book (EOB http://www.fda.gov/cder/ob/default.htm, has been available on the internet and has become the updated-every-month Orange Book.

By April, the 25th edition and current monthly supplement will be available in an electronic downloadable Portable Document Format (PDF) at the EOB home page by clicking on the EOB Preface. The PDF annual and cumulative supplements will duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The Electronic Orange Book Query (EOB) is at http://www.fda.gov/cder/ob/default.htm. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder, applicant number or patent number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product. Currently, In addition to monthly updates, in the public interest, the EOB is updated on a daily basis with new generic product approval information and new patent information. Current month updates are accomplished by the third week of the following month.

There are historical lists of Orange Book cumulative supplement product monthly changes at http://www.fda.gov/cder/rxotcdpl/pdplarchive.htm

There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at http://www.fda.gov/cder/orange/obreadme.htm . The drug product text files are zipped into eobzip.exe. The files are updated concurrently with the monthly cumulative supplements. Appendix A and Appendix B text files of the annual Orange Book Edition are updated quarterly.

Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List, http://www.fda.gov/opacom/morechoices/fdaforms/default.html.

The current listing of the Orphan Product Designations and Approvals is available at http://www.fda.gov/orphan/designat/list.htm.

## 1.4 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

## DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 2004) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

## DEFINITIONS

### Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

### New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

### REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST
### COUNTS CUMULATIVE BY QUARTER

| CATEGORIES COUNTED | DEC 2004 | MAR 2005 | JUN 2005 | SEP 2005 |
|---|---|---|---|---|
| DRUG PRODUCTS LISTED | 11082 | 11184 | | |
| SINGLE SOURCE | 2427 (21.9%) | 2437 (21.8%) | | |
| MULTISOURCE | 8547 (77.1%) | 8637 (77.2%) | | |
| THERAPEUTICALLY EQUIVALENT | 8327 (75.1%) | 8428 (75.4%) | | |
| NOT THERAPEUTICALLY EQUIVALENT | 220 (2.0%) | 209 (1.9%) | | |
| EXCEPTIONS[1] | 108 (1.0%) | 110 (1.0%) | | |
| NEW MOLECULAR ENTITIES APPROVED | 9 | 2 | | |
| NUMBER OF APPLICANTS | 625 | 631 | | |

[1]Amino acid-containing products of varying composition (see Introduction, page xx of the List).

## 1.5 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be proceeded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

| | |
|---|---|
| NEWA | New drug product approval usually in the supplement month. |
| CAHN | Applicant holder firm name has changed. |
| CAIN | Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name. |
| CDFR | Change. Dosage Form; Route of Administration. |
| CFTG | Change. A first time generic for the innovator product. A TE Code is added. |
| CMFD | Change. The product is moved from the Discontinued Section due to a change in marketing status. |
| CMS1 | Change. Miscellaneous addition to list. |
| CMS2 | Change. Miscellaneous deletion from list. |
| CPOT | Change. Potency amount/unit. |
| CRLD | Change. Reference Listed Drug. |
| CTEC | Change. Therapeutic Equivalence Code. |
| CTNA | Change. Trade Name. |
| DISC | Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition. |
| WDAG | Withdrawn. The applicant holder has notified the FDA in writing that the product in no longer being marketed resulting in the product approval being withdrawn by mutual agreement. The product will be listed in the Discontinued Section. |
| WDRP | Withdrawn. The application approval has been withdrawn for failure to provide Annual Reports. The product will be moved to the Discontinued Section in the next edition. |

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, APAP, AND CAFFEINE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | WATSON LABS | 325MG;50MG;40MG | N89536 | 001 | Feb 16, 1988 | Feb | CAHN |

ACETAMINOPHEN; TRAMADOL HYDROCHLORIDE

TABLET; ORAL

ACETAMINOPHEN AND TRAMADOL HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | | | | | | | | |
| >A> | AB | | KALI LABS | 325MG;37.5MG | N76475 | 001 | Apr 21, 2005 | Mar | NEWA |

ULTRACET

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | ORTHO MCNEIL PHARM | 325MG;37.5MG | N21123 | 001 | Aug 15, 2001 | Mar | CFTG |
| >A> | AB | + | | 325MG;37.5MG | N21123 | 001 | Aug 15, 2001 | Mar | CFTG |

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

ACETIC ACID

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AT | + | MORTON GROVE | 2% | N40166 | 001 | Jul 26, 1996 | Jan | CRLD |
| | AT | | VINTAGE | 2% | N40607 | 001 | Feb 24, 2005 | Feb | NEWA |

VOSOL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | @ MEDPOINTE PHARM HLC | 2% | N12179 | 001 | | Jan | DISC |

ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE; ORAL

SEMPREX-D

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | CELLTECH PHARMS | 8MG;60MG | N19806 | 001 | Mar 25, 1994 | Mar | CAHN |
| >A> | | + | UCB | 8MG;60MG | N19806 | 001 | Mar 25, 1994 | Mar | CAHN |

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | 200MG | N74914 | 001 | Nov 26, 1997 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | 200MG | N74914 | 001 | Nov 26, 1997 | Mar | CAHN |

TABLET; ORAL

ACYCLOVIR

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | 400MG | N75021 | 001 | Mar 18, 1998 | Mar | CAHN |
| >D> | AB | | | 800MG | N75021 | 002 | Mar 18, 1998 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | 400MG | N75021 | 001 | Mar 18, 1998 | Mar | CAHN |
| >A> | AB | | | 800MG | N75021 | 002 | Mar 18, 1998 | Mar | CAHN |

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | @ ABBOTT | EQ 50MG BASE/ML | N75114 | 001 | Jul 26, 1999 | Feb | DISC |

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AN | + | DEY | EQ 0.083% BASE | N72652 | 001 | Feb 21, 1992 | Jan | CRLD |

ALPRAZOLAM

TABLET, ORALLY DISINTEGRATING; ORAL

NIRAVAM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | SCHWARZ PHARMA | 0.25MG | N21726 | 001 | Jan 19, 2005 | Jan | NEWA |

TABLET, ORALLY DISINTEGRATING; ORAL
NIRAVAM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | SCHWARZ PHARMA | 0.5MG | N21726 | 002 | Jan 19, 2005 | Jan | NEWA |
| | | | 1MG | N21726 | 003 | Jan 19, 2005 | Jan | NEWA |
| | + | | 2MG | N21726 | 004 | Jan 19, 2005 | Jan | NEWA |

AMANTADINE HYDROCHLORIDE

SYRUP; ORAL
AMANTADINE HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AA | COPLEY PHARM | 50MG/5ML | N73115 | 001 | Aug 23, 1991 | Mar | CAHN |
| >A> | AA | TEVA PHARMS | 50MG/5ML | N73115 | 001 | Aug 23, 1991 | Mar | CAHN |

AMINO ACIDS

INJECTABLE; INJECTION
AMINOSYN 7%

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | @ HOSPIRA | 7% (7GM/100ML) | N17673 | 002 | | Mar | CMFD |
| >A> | | | 7% (7GM/100ML) | N17673 | 002 | | Mar | CMFD |

AMINOSYN 8.5%

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | @ HOSPIRA | 8.5% (8.5GM/100ML) | N17673 | 004 | | Mar | CMFD |
| >A> | | | 8.5% (8.5GM/100ML) | N17673 | 004 | | Mar | CMFD |

AMIODARONE

INJECTABLE; INTRAVENOUS
AMIODARONE HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AP | APOTEX | 50MG/ML | N77161 | 001 | Apr 20, 2005 | Mar | NEWA |

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION
AMIODARONE HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AP | AM PHARM PARTNERS | 50MG/ML | N75761 | 001 | Oct 15, 2002 | Mar | CRLD |
| >A> | AP | + | 50MG/ML | N75761 | 001 | Oct 15, 2002 | Mar | CRLD |
| >D> | AP | APOTEX | 50MG/ML | N76394 | 001 | Apr 25, 2003 | Mar | CRLD |
| >A> | AP | + | 50MG/ML | N76394 | 001 | Apr 25, 2003 | Mar | CRLD |
| >D> | AP | BEDFORD | 50MG/ML | N76018 | 001 | Oct 15, 2002 | Mar | CRLD |
| >A> | AP | + | 50MG/ML | N76018 | 001 | Oct 15, 2002 | Mar | CRLD |
| >D> | AP | BEDFORD LABS | 50MG/ML | N76299 | 001 | Oct 24, 2002 | Mar | CRLD |
| >A> | AP | + | 50MG/ML | N76299 | 001 | Oct 24, 2002 | Mar | CRLD |
| >D> | AP | BEN VENUE | 50MG/ML | N76088 | 001 | Oct 15, 2002 | Mar | CRLD |
| >A> | AP | + | 50MG/ML | N76088 | 001 | Oct 15, 2002 | Mar | CRLD |
| >D> | AP | BIONICHE (CANADA) | 50MG/ML | N76217 | 001 | Oct 15, 2002 | Mar | CRLD |
| >A> | AP | + | 50MG/ML | N76217 | 001 | Oct 15, 2002 | Mar | CRLD |
| >D> | AP | MAYNE PHARMA USA | 50MG/ML | N76108 | 001 | Oct 15, 2002 | Mar | CRLD |
| >A> | AP | + | 50MG/ML | N76108 | 001 | Oct 15, 2002 | Mar | CRLD |
| >D> | AP | SICOR PHARMS | 50MG/ML | N76163 | 001 | Sep 05, 2003 | Mar | CRLD |
| >A> | AP | + | 50MG/ML | N76163 | 001 | Sep 05, 2003 | Mar | CRLD |

TABLET; ORAL
AMIODARONE HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | AUROSAL PHARMS | 200MG | N77069 | 001 | Apr 08, 2005 | Mar | NEWA |
| >A> | AB | | 400MG | N77069 | 002 | Apr 08, 2005 | Mar | NEWA |
| >D> | AB | COPLEY PHARM | 200MG | N74739 | 001 | Nov 30, 1998 | Mar | CAHN |
| >D> | | TARO | 100MG | N75424 | 002 | Dec 18, 2002 | Mar | CTEC |
| >A> | AB | | 100MG | N75424 | 002 | Dec 18, 2002 | Mar | CTEC |
| >A> | AB | TEVA PHARMS | 200MG | N74739 | 001 | Nov 30, 1998 | Mar | CAHN |

PACERONE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | UPSHER SMITH | 100MG | N75135 | 002 | Apr 12, 2005 | Mar | NEWA |

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL
AMOXICILLIN AND CLAVULANATE POTASSIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | HIKMA PHARMS | 200MG/5ML;EQ 28.5MG BASE/5ML | N65191 | 002 | Jan 25, 2005 | Jan | NEWA |
| | AB | | 400MG/5ML;EQ 57MG BASE/5ML | N65191 | 001 | Jan 25, 2005 | Jan | NEWA |

TABLET, CHEWABLE; ORAL
AMOXICILLIN AND CLAVULANATE POTASSIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | TEVA | 200MG;EQ 28.5MG BASE | N65205 | 001 | Feb 09, 2005 | Jan | NEWA |
| | AB | | 400MG;EQ 57MG BASE | N65205 | 002 | Feb 09, 2005 | Jan | NEWA |

AMPICILLIN SODIUM

INJECTABLE; INJECTION
AMPICILLIN SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AP | INSTITUTO BIOCHEMICO | EQ 125MG BASE/VIAL | N62797 | 001 | Jul 12, 1993 | Jan | CMFD |
| | AP | | EQ 2GM BASE/VIAL | N62797 | 002 | Jul 12, 1993 | Jan | CAHN |

ANAGRELIDE HYDROCHLORIDE

CAPSULE; ORAL
AGRYLIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | SHIRE | EQ 0.5MG BASE | N20333 | 001 | Mar 14, 1997 | Mar | CFTG |
| >A> | AB | | EQ 0.5MG BASE | N20333 | 001 | Mar 14, 1997 | Mar | CFTG |
| >D> | + | | EQ 1MG BASE | N20333 | 002 | Mar 14, 1997 | Mar | CFTG |
| >A> | AB + | | EQ 1MG BASE | N20333 | 002 | Mar 14, 1997 | Mar | CFTG |

>A> ANAGRELIDE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | BARR | EQ 0.5MG BASE | N76530 | 001 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | | EQ 1MG BASE | N76530 | 002 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | EON | EQ 0.5MG BASE | N76683 | 001 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | | EQ 1MG BASE | N76683 | 002 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | IMPAX LABS | EQ 0.5MG BASE | N76910 | 001 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | | EQ 1MG BASE | N76910 | 002 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | IVAX PHARMS | EQ 0.5MG BASE | N76468 | 001 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | | EQ 1MG BASE | N76468 | 002 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | MYLAN | EQ 0.5MG BASE | N76811 | 001 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | | EQ 1MG BASE | N76811 | 002 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | ROXANE | EQ 0.5MG BASE | N76489 | 001 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | | EQ 1MG BASE | N76489 | 002 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | WATSON LABS | EQ 0.5MG BASE | N76417 | 001 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | | EQ 1MG BASE | N76417 | 002 | Apr 18, 2005 | Mar | NEWA |

ATENOLOL

TABLET; ORAL
ATENOLOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | 50MG | N74120 | 001 | Feb 24, 1995 | Mar | CAHN |
| >D> | AB | | 100MG | N74120 | 002 | Feb 24, 1995 | Mar | CAHN |
| >D> | | MYLAN | 25MG | N73457 | 002 | Apr 26, 1999 | Mar | CTEC |
| >A> | AB | | 25MG | N73457 | 002 | Apr 26, 1999 | Mar | CTEC |
| >A> | AB | TEVA PHARMS | 50MG | N74120 | 001 | Feb 24, 1995 | Mar | CAHN |
| >A> | AB | | 100MG | N74120 | 002 | Feb 24, 1995 | Mar | CAHN |
| | AB | ZYDUS PHARMS USA | 25MG | N76900 | 001 | Jan 28, 2005 | Jan | NEWA |
| | AB | | 50MG | N76900 | 002 | Jan 28, 2005 | Jan | NEWA |
| | AB | | 100MG | N76900 | 003 | Jan 28, 2005 | Jan | NEWA |

ATOMOXETINE HYDROCHLORIDE

CAPSULE; ORAL

STRATTERA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | LILLY | 80MG | N21411 | 007 | Feb 14, 2005 | Feb | NEWA |
| | | | 100MG | N21411 | 008 | Feb 14, 2005 | Feb | NEWA |

>D> BENZYL PENICILLOYL-POLYLYSINE

>D> INJECTABLE; INJECTION

>D> PRE-PEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | HOLLISTER STIER LABS | 60UMOLAR | N50114 | 001 | | Mar | DISC |
| >A> | | @ | 60UMOLAR | N50114 | 001 | | Mar | DISC |

BETAMETHASONE DIPROPIONATE

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | EQ 0.05% BASE | N71882 | 001 | Jun 06, 1988 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | EQ 0.05% BASE | N71882 | 001 | Jun 06, 1988 | Mar | CAHN |

OINTMENT; TOPICAL

ALPHATREX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ SAVAGE LABS | EQ 0.05% BASE | N19143 | 001 | Sep 04, 1984 | Jan | DISC |

BETAMETHASONE VALERATE

LOTION; TOPICAL

BETAMETHASONE VALERATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | EQ 0.1% BASE | N71883 | 001 | Apr 22, 1988 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | EQ 0.1% BASE | N71883 | 001 | Apr 22, 1988 | Mar | CAHN |

BISOPROLOL FUMARATE

TABLET; ORAL

BISOPROLOL FUMARATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | 5MG | N75644 | 001 | Jun 26, 2001 | Mar | CAHN |
| >D> | AB | | 10MG | N75644 | 002 | Jun 26, 2001 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | 5MG | N75644 | 001 | Jun 26, 2001 | Mar | CAHN |
| >A> | AB | | 10MG | N75644 | 002 | Jun 26, 2001 | Mar | CAHN |

>A> BROMFENAC SODIUM

>A> SOLUTION/DROPS; OPHTHALMIC

>A> XIBROM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | ISTA PHARMS | 0.09% | N21664 | 001 | Mar 24, 2005 | Mar | NEWA |

BROMOCRIPTINE MESYLATE

CAPSULE; ORAL

BROMOCRIPTINE MESYLATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | MYLAN | EQ 5MG BASE | N77226 | 001 | Apr 04, 2005 | Mar | NEWA |

PARLODEL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | NOVARTIS | EQ 5MG BASE | N17962 | 002 | Mar 01, 1982 | Mar | CTEC |
| >A> | AB + | | EQ 5MG BASE | N17962 | 002 | Mar 01, 1982 | Mar | CTEC |

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPRENORPHINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AP | BEDFORD | EQ 0.3MG BASE/ML | N76931 | 001 | Mar 02, 2005 | Feb | NEWA |

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL

MIGERGOT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| BR | G AND W LABS | 100MG;2MG | N86557 | 001 | Oct 04, 1983 | Feb | CMFD |

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | 12.5MG | N74462 | 001 | Feb 13, 1996 | Mar | CAHN |
| >D> | AB | | 25MG | N74462 | 002 | Feb 13, 1996 | Mar | CAHN |
| >D> | AB | | 50MG | N74462 | 003 | Feb 13, 1996 | Mar | CAHN |
| >D> | AB | | 100MG | N74462 | 004 | Feb 13, 1996 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | 12.5MG | N74462 | 001 | Feb 13, 1996 | Mar | CAHN |
| >A> | AB | | 25MG | N74462 | 002 | Feb 13, 1996 | Mar | CAHN |
| >A> | AB | | 50MG | N74462 | 003 | Feb 13, 1996 | Mar | CAHN |
| >A> | AB | | 100MG | N74462 | 004 | Feb 13, 1996 | Mar | CAHN |

CARBAMAZEPINE

SUSPENSION; ORAL

CARBAMAZEPINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | TARO | 100MG/5ML | N75875 | 001 | Dec 21, 2000 | Mar | DISC |
| >A> | | @ | 100MG/5ML | N75875 | 001 | Dec 21, 2000 | Mar | DISC |

CARBOPLATIN

INJECTABLE; INJECTION

CARBOPLATIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AP | EON | 50MG/VIAL | N76959 | 001 | Mar 18, 2005 | Mar | NEWA |
| >A> | AP | | 150MG/VIAL | N76959 | 002 | Mar 18, 2005 | Mar | NEWA |
| >A> | AP | | 450MG/VIAL | N76959 | 003 | Mar 18, 2005 | Mar | NEWA |

CEFACLOR

CAPSULE; ORAL

CECLOR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | | | | | | | |
| >D> | AB | LILLY | EQ 250MG BASE | N50521 | 001 | | Mar | DISC |
| >A> | | @ | EQ 250MG BASE | N50521 | 001 | | Mar | DISC |
| >D> | AB | + | EQ 500MG BASE | N50521 | 002 | | Mar | DISC |
| >A> | | @ | EQ 500MG BASE | N50521 | 002 | | Mar | DISC |

CEFACLOR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | RANBAXY | EQ 500MG BASE | N64156 | 002 | Aug 28, 1997 | Mar | CRLD |
| >A> | AB | + | EQ 500MG BASE | N64156 | 002 | Aug 28, 1997 | Mar | CRLD |

FOR SUSPENSION; ORAL

CECLOR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | + CEPH INTL | EQ 375MG BASE/5ML | N62206 | 004 | Apr 20, 1988 | Mar | CRLD |
| >A> | AB | | EQ 375MG BASE/5ML | N62206 | 004 | Apr 20, 1988 | Mar | CRLD |
| >D> | AB | LILLY | EQ 125MG BASE/5ML | N50522 | 001 | | Mar | DISC |
| >A> | | @ | EQ 125MG BASE/5ML | N50522 | 001 | | Mar | DISC |
| >D> | AB | + | EQ 250MG BASE/5ML | N50522 | 002 | | Mar | DISC |
| >A> | | @ | EQ 250MG BASE/5ML | N50522 | 002 | | Mar | DISC |

CEFACLOR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | RANBAXY | EQ 375MG BASE/5ML | N64155 | 001 | Oct 02, 1997 | Mar | CRLD |
| >A> | AB | + | EQ 375MG BASE/5ML | N64155 | 001 | Oct 02, 1997 | Mar | CRLD |

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AP | | AM PHARM PARTNERS | EQ 500MG BASE/VIAL | N64169 | 001 | Aug 14, 1998 | Mar | CRLD |
| >A> | AP | + | | EQ 500MG BASE/VIAL | N64169 | 001 | Aug 14, 1998 | Mar | CRLD |
| >D> | AP | | | EQ 1GM BASE/VIAL | N64169 | 002 | Aug 14, 1998 | Mar | CRLD |
| >A> | AP | + | | EQ 1GM BASE/VIAL | N64169 | 002 | Aug 14, 1998 | Mar | CRLD |
| >D> | AP | | | EQ 10GM BASE/VIAL | N64170 | 001 | Mar 18, 1998 | Mar | CRLD |
| >A> | AP | + | | EQ 10GM BASE/VIAL | N64170 | 001 | Mar 18, 1998 | Mar | CRLD |

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | APOTHECON | EQ 250MG BASE | N63186 | 001 | Dec 30, 1994 | Mar | DISC |
| >A> | | | @ | EQ 250MG BASE | N63186 | 001 | Dec 30, 1994 | Mar | DISC |
| >D> | AB | | | EQ 500MG BASE | N63186 | 002 | Dec 30, 1994 | Mar | DISC |
| >A> | | | @ | EQ 500MG BASE | N63186 | 002 | Dec 30, 1994 | Mar | DISC |
| | AB | | BELCHER | EQ 250MG BASE | N62713 | 001 | Jul 15, 1988 | Jan | CAHN |
| | AB | | | EQ 500MG BASE | N62713 | 002 | Jul 15, 1988 | Jan | CAHN |
| | AB | | SUN PHARM INDS (IN) | EQ 250MG BASE | N62791 | 001 | Jun 11, 1987 | Jan | CAHN |
| | AB | | | EQ 500MG BASE | N62791 | 002 | Jun 11, 1987 | Jan | CAHN |
| | AB | | YUNG SHIN PHARM | EQ 250MG BASE | N65152 | 001 | Feb 24, 2005 | Feb | NEWA |
| | AB | | | EQ 500MG BASE | N65152 | 002 | Feb 24, 2005 | Feb | NEWA |

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

CODEPREX

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | CELLTECH PHARMS | EQ 4MG MALEATE/5ML;EQ 20MG BASE/5ML | N21369 | 001 | Jun 21, 2004 | Mar | CAHN |
| >A> | | + | UCB | EQ 4MG MALEATE/5ML;EQ 20MG BASE/5ML | N21369 | 001 | Jun 21, 2004 | Mar | CAHN |

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

TUSSIONEX

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | CELLTECH PHARMS | EQ 8MG MALEATE/5ML;EQ 10MG BITARTRATE/5ML | N19111 | 001 | Dec 31, 1987 | Mar | CAHN |
| >A> | | + | UCB | EQ 8MG MALEATE/5ML;EQ 10MG BITARTRATE/5ML | N19111 | 001 | Dec 31, 1987 | Mar | CAHN |

CHOLESTYRAMINE

POWDER; ORAL

CHOLESTYRAMINE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | EQ 4GM RESIN/PACKET | N74554 | 001 | Oct 02, 1996 | Mar | CAHN |
| >D> | AB | | | EQ 4GM RESIN/SCOOPFUL | N74554 | 002 | Oct 02, 1996 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | EQ 4GM RESIN/PACKET | N74554 | 001 | Oct 02, 1996 | Mar | CAHN |
| >A> | AB | | | EQ 4GM RESIN/SCOOPFUL | N74554 | 002 | Oct 02, 1996 | Mar | CAHN |

CHOLESTYRAMINE LIGHT

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | EQ 4GM RESIN/PACKET | N74555 | 001 | Sep 30, 1998 | Mar | CAHN |
| >D> | AB | | | EQ 4GM RESIN/SCOOPFUL | N74555 | 002 | Sep 30, 1998 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | EQ 4GM RESIN/PACKET | N74555 | 001 | Sep 30, 1998 | Mar | CAHN |
| >A> | AB | | | EQ 4GM RESIN/SCOOPFUL | N74555 | 002 | Sep 30, 1998 | Mar | CAHN |

CICLOPIROX

CREAM; TOPICAL

CICLOPIROX

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | TARO | 0.77% | N76790 | 001 | Apr 12, 2005 | Mar | NEWA |

CILOSTAZOL

TABLET; ORAL

CILOSTAZOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | COREPHARMA | 50MG | N77150 | 001 | Mar 11, 2005 | Feb | NEWA |
| AB | IVAX PHARMS | 100MG | N77020 | 002 | Mar 01, 2005 | Feb | NEWA |

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL

CIMETIDINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> AA | COPLEY PHARM | EQ 300MG BASE/5ML | N74859 | 001 | Jul 09, 1998 | Mar | CAHN |
| >A> AA | TEVA PHARMS | EQ 300MG BASE/5ML | N74859 | 001 | Jul 09, 1998 | Mar | CAHN |

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CIPROFLOXACIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AT | HITECH PHARMA | EQ 0.3% BASE | N76673 | 001 | Jan 21, 2005 | Jan | NEWA |

TABLET; ORAL

CIPROFLOXACIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | COBALT | EQ 100MG BASE | N76794 | 001 | Feb 10, 2005 | Jan | NEWA |
| AB | SANDOZ | EQ 100MG BASE | N75939 | 001 | Mar 03, 2005 | Feb | NEWA |
| AB | TARO | EQ 100MG BASE | N76912 | 001 | Feb 18, 2005 | Jan | NEWA |

CITALOPRAM HYDROBROMIDE

TABLET; ORAL

CITALOPRAM HYDROBROMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | MYLAN | EQ 10MG BASE | N77039 | 001 | Feb 03, 2005 | Jan | NEWA |
| AB | | EQ 20MG BASE | N77039 | 002 | Feb 03, 2005 | Jan | NEWA |
| AB | | EQ 40MG BASE | N77039 | 003 | Feb 03, 2005 | Jan | NEWA |

CLARITHROMYCIN

TABLET, EXTENDED RELEASE; ORAL

CLARITHROMYCIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | RANBAXY | 1GM | N65210 | 001 | Jan 26, 2005 | Jan | NEWA |

TABLET; ORAL

CLARITHROMYCIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | GENPHARM | 250MG | N65195 | 001 | Mar 11, 2005 | Feb | NEWA |
| AB | | 500MG | N65195 | 002 | Mar 11, 2005 | Feb | NEWA |

CLEMASTINE FUMARATE

SYRUP; ORAL

CLEMASTINE FUMARATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> AA | COPLEY PHARM | EQ 0.5MG BASE/5ML | N73095 | 001 | Apr 21, 1992 | Mar | CAHN |
| >A> AA | TEVA PHARMS | EQ 0.5MG BASE/5ML | N73095 | 001 | Apr 21, 1992 | Mar | CAHN |

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | ZYDUS PHARMS USA | EQ 75MG BASE | N65217 | 001 | Jan 31, 2005 | Jan | NEWA |
| AB | | EQ 150MG BASE | N65217 | 002 | Jan 31, 2005 | Jan | NEWA |
| AB | | EQ 300MG BASE | N65217 | 003 | Jan 31, 2005 | Jan | NEWA |

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | @ HOSPIRA | EQ 150MG BASE/ML | N62943 | 001 | Sep 29, 1988 | Mar | CMFD |

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AP | HOSPIRA | EQ 150MG BASE/ML | N62943 | 001 | Sep 29, 1988 | Mar | CMFD |

CLOBETASOL PROPIONATE

CREAM; TOPICAL
CLOBETASOL PROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB1 | COPLEY PHARM | 0.05% | N74087 | 001 | Feb 16, 1994 | Mar | CAHN |
| >A> | AB1 | TEVA PHARMS | 0.05% | N74087 | 001 | Feb 16, 1994 | Mar | CAHN |

OINTMENT; TOPICAL
CLOBETASOL PROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | 0.05% | N74089 | 001 | Feb 16, 1994 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | 0.05% | N74089 | 001 | Feb 16, 1994 | Mar | CAHN |

CLOTRIMAZOLE

CREAM; TOPICAL
CLOTRIMAZOLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | | TARO | 1% | N72640 | 001 | Aug 31, 1993 | Feb | CRLD |

LOTRIMIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | | SCHERING PLOUGH | 1% | N17619 | 001 | | Feb | DISC |

MYCELEX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | | BAYER PHARMS | 1% | N18183 | 001 | | Feb | DISC |

CROMOLYN SODIUM

SOLUTION, CONCENTRATE; ORAL
GASTROCROM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | CELLTECH PHARMS | 100MG/5ML | N20479 | 001 | Feb 29, 1996 | Mar | CAHN |
| >A> | + | UCB | 100MG/5ML | N20479 | 001 | Feb 29, 1996 | Mar | CAHN |

CYANOCOBALAMIN

SPRAY, METERED; NASAL
NASCOBAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | | NASTECH PHARM | 0.5MG/SPRAY | N21642 | 001 | Jan 31, 2005 | Jan | NEWA |
| + | | QUESTCOR PHARMS | 0.5MG/SPRAY | N21642 | 001 | Jan 31, 2005 | Feb | CAHN |

CYCLOSPORINE

CAPSULE; ORAL
CYCLOSPORINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB1 | IVAX PHARMS | 25MG | N65110 | 003 | Mar 29, 2005 | Mar | NEWA |
| >A> | AB1 | | 50MG | N65110 | 001 | Mar 29, 2005 | Mar | NEWA |
| >A> | AB1 | | 100MG | N65110 | 002 | Mar 29, 2005 | Mar | NEWA |

GENGRAF

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | BX | ABBOTT | 50MG | N65003 | 002 | May 12, 2000 | Mar | CTEC |
| >A> | AB1 | | 50MG | N65003 | 002 | May 12, 2000 | Mar | CTEC |

SOLUTION; ORAL
CYCLOSPORINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB1 | IVAX PHARMS | 100MG/ML | N65078 | 001 | Mar 25, 2005 | Mar | NEWA |

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL
CYPROHEPTADINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | | ABC HOLDING | 4MG | N88212 | 001 | May 26, 1983 | Feb | DISC |

DALTEPARIN SODIUM

INJECTABLE; INJECTION
FRAGMIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | PHARMACIA AND UPJOHN | 7,500 IU/0.3ML | N20287 | 005 | Apr 04, 2002 | Jan | NEWA |

DANTROLENE SODIUM

CAPSULE; ORAL
DANTRIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | PROCTER AND GAMBLE | 25MG | N17443 | 001 | | Feb | CFTG |
| AB | | | 50MG | N17443 | 003 | | Feb | CFTG |
| AB | + | | 100MG | N17443 | 002 | | Feb | CFTG |

DANTROLENE SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | IMPAX LABS | 25MG | N76856 | 001 | Mar 01, 2005 | Feb | NEWA |
| AB | | | 50MG | N76856 | 002 | Mar 01, 2005 | Feb | NEWA |
| AB | | | 100MG | N76856 | 003 | Mar 01, 2005 | Feb | NEWA |

>D> DESIRUDIN

>D> INJECTABLE; SUBCUTANEOUS
>D> IPRIVASK

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | CANYON | 15MG/VIAL | N21271 | 001 | Apr 04, 2003 | Mar | CAIN |

>A> DESIRUDIN RECOMBINANT

>A> INJECTABLE; SUBCUTANEOUS
>A> IPRIVASK

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | CANYON | 15MG/VIAL | N21271 | 001 | Apr 04, 2003 | Mar | CAIN |

DESLORATADINE; PSEUDOEPHEDRINE SULFATE

>A> TABLET, EXTENDED RELEASE; ORAL
>A> CLARINEX D 24 HOUR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | SCHERING | 5MG;240MG | N21605 | 001 | Mar 03, 2005 | Mar | NEWA |

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL
DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | APOTEX | 0.01MG/SPRAY | N76703 | 001 | Jan 27, 2005 | Jan | NEWA |

DESONIDE

CREAM; TOPICAL
DESONIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | 0.05% | N74027 | 001 | Sep 28, 1992 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | 0.05% | N74027 | 001 | Sep 28, 1992 | Mar | CAHN |

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | + PAR PHARM | 0.25MG | N88149 | 001 | Apr 28, 1983 | Mar | CRLD |
| >A> | | | 0.25MG | N88149 | 001 | Apr 28, 1983 | Mar | CRLD |
| >D> | BP | + ROXANE | 1.5MG | N84610 | 001 | | Mar | CRLD |
| >A> | BP | | 1.5MG | N84610 | 001 | | Mar | CRLD |

DEXTROSE

INJECTABLE; INJECTION
DEXTROSE 50% IN PLASTIC CONTAINER

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | @ HOSPIRA | 500MG/ML | N19445 | 001 | Jun 03, 1986 | Mar | CMFD |
| >A> | AP | | 500MG/ML | N19445 | 001 | Jun 03, 1986 | Mar | CMFD |

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

DICLOFENAC SODIUM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | 25MG | N74459 | 001 | Jun 25, 1997 | Mar | CAHN |
| >D> | AB | | | 50MG | N74459 | 002 | Jun 25, 1997 | Mar | CAHN |
| >D> | AB | | | 75MG | N74459 | 003 | Jun 25, 1997 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | 25MG | N74459 | 001 | Jun 25, 1997 | Mar | CAHN |
| >A> | AB | | | 50MG | N74459 | 002 | Jun 25, 1997 | Mar | CAHN |
| >A> | AB | | | 75MG | N74459 | 003 | Jun 25, 1997 | Mar | CAHN |

DICYCLOMINE HYDROCHLORIDE

SYRUP; ORAL

BENTYL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | AXCAN SCANDIPHARM | 10MG/5ML | N07961 | 002 | Oct 15, 1984 | Mar | CTEC |
| >A> | AA | + | | 10MG/5ML | N07961 | 002 | Oct 15, 1984 | Mar | CTEC |

>A> DICYCLOMINE HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AA | | MIKART | 10MG/5ML | N40169 | 001 | Mar 24, 2005 | Mar | NEWA |

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | @ | ABC HOLDING | 25MG | N88267 | 001 | Aug 25, 1983 | Feb | DISC |
| | | @ | | 25MG | N88268 | 001 | Aug 25, 1983 | Feb | DISC |

TENUATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | + | AVENTIS PHARMS | 25MG | N11722 | 002 | | Feb | CTEC |

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION

CARDIZEM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AP | + | BIOVAIL | 5MG/ML | N20027 | 001 | Oct 24, 1991 | Mar | CAHN |
| >D> | | + | | 25MG/VIAL | N20027 | 003 | Aug 18, 1995 | Mar | CAHN |
| >A> | AP | + | BIOVAIL LABS INTL | 5MG/ML | N20027 | 001 | Oct 24, 1991 | Mar | CAHN |
| >A> | | + | | 25MG/VIAL | N20027 | 003 | Aug 18, 1995 | Mar | CAHN |

TABLET, EXTENDED RELEASE; ORAL

CARDIZEM LA

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | | BIOVAIL | 120MG | N21392 | 001 | Feb 06, 2003 | Mar | CAHN |
| >D> | | | | 180MG | N21392 | 002 | Feb 06, 2003 | Mar | CAHN |
| >D> | | | | 240MG | N21392 | 003 | Feb 06, 2003 | Mar | CAHN |
| >D> | | | | 300MG | N21392 | 004 | Feb 06, 2003 | Mar | CAHN |
| >D> | | | | 360MG | N21392 | 005 | Feb 06, 2003 | Mar | CAHN |
| >D> | | + | | 420MG | N21392 | 006 | Feb 06, 2003 | Mar | CAHN |
| >A> | | | BIOVAIL LABS INTL | 120MG | N21392 | 001 | Feb 06, 2003 | Mar | CAHN |
| >A> | | | | 180MG | N21392 | 002 | Feb 06, 2003 | Mar | CAHN |
| >A> | | | | 240MG | N21392 | 003 | Feb 06, 2003 | Mar | CAHN |
| >A> | | | | 300MG | N21392 | 004 | Feb 06, 2003 | Mar | CAHN |
| >A> | | | | 360MG | N21392 | 005 | Feb 06, 2003 | Mar | CAHN |
| >A> | | + | | 420MG | N21392 | 006 | Feb 06, 2003 | Mar | CAHN |

TABLET; ORAL

CARDIZEM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | BIOVAIL | 30MG | N18602 | 001 | Nov 05, 1982 | Mar | CAHN |
| >D> | AB | | | 60MG | N18602 | 002 | Nov 05, 1982 | Mar | CAHN |
| >D> | AB | | | 90MG | N18602 | 003 | Dec 08, 1986 | Mar | CAHN |
| >D> | AB | + | | 120MG | N18602 | 004 | Dec 08, 1986 | Mar | CAHN |
| >A> | AB | | BIOVAIL LABS INTL | 30MG | N18602 | 001 | Nov 05, 1982 | Mar | CAHN |
| >A> | AB | | | 60MG | N18602 | 002 | Nov 05, 1982 | Mar | CAHN |

TABLET; ORAL
CARDIZEM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | BIOVAIL LABS INTL | 90MG | N18602 | 003 | Dec 08, 1986 | Mar | CAHN |
| >A> | AB | + | | 120MG | N18602 | 004 | Dec 08, 1986 | Mar | CAHN |

DILTIAZEM HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | 30MG | N74067 | 001 | Nov 05, 1992 | Mar | CAHN |
| >D> | AB | | | 60MG | N74067 | 002 | Nov 05, 1992 | Mar | CAHN |
| >D> | AB | | | 90MG | N74067 | 003 | Nov 05, 1992 | Mar | CAHN |
| >D> | AB | | | 120MG | N74067 | 004 | Nov 05, 1992 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | 30MG | N74067 | 001 | Nov 05, 1992 | Mar | CAHN |
| >A> | AB | | | 60MG | N74067 | 002 | Nov 05, 1992 | Mar | CAHN |
| >A> | AB | | | 90MG | N74067 | 003 | Nov 05, 1992 | Mar | CAHN |
| >A> | AB | | | 120MG | N74067 | 004 | Nov 05, 1992 | Mar | CAHN |

DOXAZOSIN MESYLATE

TABLET, EXTENDED RELEASE; ORAL
CARDURA XL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | PFIZER | EQ 4MG BASE | N21269 | 001 | Feb 22, 2005 | Feb | NEWA |
| | | + | | EQ 8MG BASE | N21269 | 002 | Feb 22, 2005 | Feb | NEWA |

DOXEPIN HYDROCHLORIDE

CONCENTRATE; ORAL
DOXEPIN HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AA | | COPLEY PHARM | EQ 10MG BASE/ML | N71609 | 001 | Nov 09, 1987 | Mar | CAHN |
| >A> | AA | | TEVA PHARMS | EQ 10MG BASE/ML | N71609 | 001 | Nov 09, 1987 | Mar | CAHN |

DOXYCYCLINE

CAPSULE; ORAL
DOXYCYCLINE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | PAR PHARM | EQ 75MG BASE | N65055 | 004 | Apr 18, 2005 | Mar | NEWA |
| >D> | | + | RANBAXY | EQ 75MG BASE | N65053 | 003 | Sep 10, 2003 | Mar | CTEC |
| >A> | AB | | | EQ 75MG BASE | N65053 | 003 | Sep 10, 2003 | Mar | CTEC |

ENALAPRIL MALEATE

TABLET; ORAL
ENALAPRIL MALEATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | @ APOTHECON | 2.5MG | N75583 | 001 | Aug 22, 2000 | Feb | DISC |
| | | | @ | 5MG | N75583 | 002 | Aug 22, 2000 | Feb | DISC |
| | | | @ | 10MG | N75583 | 003 | Aug 22, 2000 | Feb | DISC |
| | | | @ | 20MG | N75583 | 004 | Aug 22, 2000 | Feb | DISC |

VASOTEC

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | BIOVAIL | 2.5MG | N18998 | 005 | Jul 26, 1988 | Mar | CAHN |
| >D> | AB | | | 5MG | N18998 | 001 | Dec 24, 1985 | Mar | CAHN |
| >D> | AB | | | 10MG | N18998 | 002 | Dec 24, 1985 | Mar | CAHN |
| >D> | AB | + | | 20MG | N18998 | 003 | Dec 24, 1985 | Mar | CAHN |
| >A> | AB | | BIOVAIL LABS INTL | 2.5MG | N18998 | 005 | Jul 26, 1988 | Mar | CAHN |
| >A> | AB | | | 5MG | N18998 | 001 | Dec 24, 1985 | Mar | CAHN |
| >A> | AB | | | 10MG | N18998 | 002 | Dec 24, 1985 | Mar | CAHN |
| >A> | AB | + | | 20MG | N18998 | 003 | Dec 24, 1985 | Mar | CAHN |

ENALAPRIL MALEATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
VASERETIC

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | BIOVAIL | 5MG;12.5MG | N19221 | 003 | Jul 12, 1995 | Mar | CAHN |
| >D> | AB | + | | 10MG;25MG | N19221 | 001 | Oct 31, 1986 | Mar | CAHN |
| >A> | AB | | BIOVAIL LABS INTL | 5MG;12.5MG | N19221 | 003 | Jul 12, 1995 | Mar | CAHN |

TABLET; ORAL
VASERETIC

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | + | BIOVAIL LABS INTL | 10MG;25MG | N19221 | 001 | Oct 31, 1986 | Mar | CAHN |

ENALAPRILAT

INJECTABLE; INJECTION
VASOTEC

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| >D> | AP | + | BIOVAIL | 1.25MG/ML | N19309 | 001 | Feb 09, 1988 | Mar | CAHN |
| >A> | AP | + | BIOVAIL LABS INTL | 1.25MG/ML | N19309 | 001 | Feb 09, 1988 | Mar | CAHN |

>A> ENTECAVIR

>A> SOLUTION; ORAL
>A> BARACLUDE

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| >A> | | + | BRISTOL MYERS SQUIBB | 0.05MG/ML | N21798 | 001 | Mar 29, 2005 | Mar | NEWA |

>A> TABLET; ORAL
>A> BARACLUDE

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| >A> | | | BRISTOL MYERS SQUIBB | 0.5MG | N21797 | 001 | Mar 29, 2005 | Mar | NEWA |
| >A> | | + | | 1MG | N21797 | 002 | Mar 29, 2005 | Mar | NEWA |

EPINEPHRINE

INJECTABLE; IM-SC
TWINJECT 0.30

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | + | HOLLISTER STIER LABS | EQ 0.3MG /DELIVERY | N20800 | 001 | May 30, 2003 | Feb | CTNA |

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYMAX

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | AT | | MERZ PHARMS | 2% | N62508 | 002 | Jul 11, 1985 | Jan | CAHN |

ERYTHROMYCIN ESTOLATE

CAPSULE; ORAL
ERYTHROMYCIN ESTOLATE

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | @ BARR | EQ 250MG BASE | N62162 | 002 | | Feb | DISC |

ESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED REL PELLETS; ORAL
NEXIUM

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | ASTRAZENECA | EQ 20MG BASE | N21153 | 001 | Feb 20, 2001 | Jan | CRLD |

>A> ESOMEPRAZOLE SODIUM

>A> INJECTABLE; INTRAVENOUS
>A> NEXIUM IV

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| >A> | | + | ASTRAZENECA | 20MG/VIAL | N21689 | 001 | Mar 31, 2005 | Mar | NEWA |
| >A> | | + | | 40MG/VIAL | N21689 | 002 | Mar 31, 2005 | Mar | NEWA |

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL
CLIMARA

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | AB2 | + | BERLEX | 0.025MG/24HR | N20375 | 004 | Mar 05, 1999 | Jan | CFTG |
| | AB2 | + | | 0.075MG/24HR | N20375 | 003 | Mar 23, 1998 | Jan | CFTG |

ESCLIM

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | @ WOMEN FIRST HLTHCARE | 0.025MG/24HR | N20847 | 001 | Aug 04, 1998 | Jan | DISC |
| | | | @ | 0.0375MG/24HR | N20847 | 002 | Aug 04, 1998 | Jan | DISC |
| | | | @ | 0.05MG/24HR | N20847 | 003 | Aug 04, 1998 | Jan | DISC |
| | | | @ | 0.075MG/24HR | N20847 | 004 | Aug 04, 1998 | Jan | DISC |
| | | | @ | 0.1MG/24HR | N20847 | 005 | Aug 04, 1998 | Jan | DISC |

FILM, EXTENDED RELEASE; TRANSDERMAL

ESTRADIOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB2 | | MYLAN TECHNOLOGIES | 0.025MG/24HR | N75182 | 003 | Jan 26, 2005 | Jan | NEWA |
| AB2 | | | 0.075MG/24HR | N75182 | 002 | Jan 26, 2005 | Jan | NEWA |

VIVELLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ NOVARTIS | 0.025MG/24HR | N20323 | 005 | Aug 16, 2000 | Jan | DISC |
| AB1 | | | 0.05MG/24HR | N20323 | 002 | Oct 28, 1994 | Jan | CRLD |
| AB1 | | | 0.1MG/24HR | N20323 | 004 | Oct 28, 1994 | Jan | CRLD |

VIVELLE-DOT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| BX | + | NOVARTIS | 0.025MG/24HR | N20538 | 009 | May 03, 2002 | Jan | CRLD |
| BX | + | | 0.0375MG/24HR | N20538 | 005 | Jan 08, 1999 | Jan | CRLD |
| AB1 | + | | 0.05MG/24HR | N20538 | 006 | Jan 08, 1999 | Jan | CRLD |
| BX | + | | 0.075MG/24HR | N20538 | 007 | Jan 08, 1999 | Jan | CRLD |
| AB1 | + | | 0.1MG/24HR | N20538 | 008 | Jan 08, 1999 | Jan | CRLD |

ESTROGENS, CONJUGATED SYNTHETIC B

TABLET; ORAL

ENJUVIA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | @ DURAMED | 0.3MG | N21443 | 001 | Dec 20, 2004 | Mar | DISC |
| >A> | | @ | 0.45MG | N21443 | 002 | Dec 20, 2004 | Mar | DISC |

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | + | WATSON LABS | 0.035MG,0.035MG;0.5MG,1MG | N71041 | 001 | Sep 24, 1991 | Mar | CTEC |
| >A> | | + | | 0.035MG,0.035MG;0.5MG,1MG | N71041 | 001 | Sep 24, 1991 | Mar | CTEC |

NORTREL 7/7/7

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | BARR | 0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG | N75478 | 001 | Aug 30, 2002 | Mar | CTEC |
| >A> | | | 0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG | N75478 | 001 | Aug 30, 2002 | Mar | CTEC |

TABLET; ORAL-28

NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | WATSON LABS | 0.035MG,0.035MG;0.5MG,1MG | N71042 | 001 | Sep 24, 1991 | Mar | CTEC |
| >A> | | | 0.035MG,0.035MG;0.5MG,1MG | N71042 | 001 | Sep 24, 1991 | Mar | CTEC |

ORTHO-NOVUM 10/11-28

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | ORTHO MCNEIL PHARM | 0.035MG,0.035MG;0.5MG,1MG | N18354 | 002 | Jan 11, 1982 | Mar | CRLD |
| >A> | AB | + | 0.035MG,0.035MG;0.5MG,1MG | N18354 | 002 | Jan 11, 1982 | Mar | CRLD |

ORTHO-NOVUM 7/14-28

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ ORTHO MCNEIL PHARM | 0.035MG,0.035MG;0.5MG,1MG | N19004 | 002 | Apr 04, 1984 | Feb | DISC |

OVCON-35

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | + WARNER CHILCOTT | 0.035MG;0.4MG | N17716 | 001 | | Mar | CRLD |
| >A> | AB | | 0.035MG;0.4MG | N17716 | 001 | | Mar | CRLD |

ETHOSUXIMIDE

SYRUP; ORAL

ETHOSUXIMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | COPLEY PHARM | 250MG/5ML | N81306 | 001 | Jul 30, 1993 | Mar | CAHN |
| >A> | AA | TEVA PHARMS | 250MG/5ML | N81306 | 001 | Jul 30, 1993 | Mar | CAHN |

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION

FENOLDOPAM MESYLATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | SABEX 2002 | EQ 10MG BASE/ML | N77155 | 001 | Feb 15, 2005 | Jan | NEWA |

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | DURAGESIC-100 | | | | | | |
| | AB | ALZA | 100UGM/HR | N19813 | 001 | Aug 07, 1990 | Jan | CFTG |
| | | DURAGESIC-12 | | | | | | |
| | | ALZA | 12.5UGM/HR | N19813 | 005 | Feb 04, 2005 | Feb | NEWA |
| | | DURAGESIC-25 | | | | | | |
| | AB + | ALZA | 25UGM/HR | N19813 | 004 | Aug 07, 1990 | Jan | CFTG |
| | | DURAGESIC-50 | | | | | | |
| | AB | ALZA | 50UGM/HR | N19813 | 003 | Aug 07, 1990 | Jan | CFTG |
| | | DURAGESIC-75 | | | | | | |
| | AB | ALZA | 75UGM/HR | N19813 | 002 | Aug 07, 1990 | Jan | CFTG |
| | | FENTANYL | | | | | | |
| | AB | MYLAN TECHNOLOGIES | 25UGM/HR | N76258 | 001 | Jan 28, 2005 | Jan | NEWA |
| | AB | | 50UGM/HR | N76258 | 002 | Jan 28, 2005 | Jan | NEWA |
| | AB | | 75UGM/HR | N76258 | 003 | Jan 28, 2005 | Jan | NEWA |
| | AB | | 100UGM/HR | N76258 | 004 | Jan 28, 2005 | Jan | NEWA |

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ALLEGRA-D 12 HOUR | | | | | | |
| >D> | + | AVENTIS PHARMS | 60MG;120MG | N20786 | 001 | Dec 24, 1997 | Mar | CFTG |
| >A> | AB + | | 60MG;120MG | N20786 | 001 | Dec 24, 1997 | Mar | CFTG |
| >A> | | FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCL | | | | | | |
| >A> | AB | BARR | 60MG;120MG | N76236 | 001 | Apr 14, 2005 | Mar | NEWA |

FLUCONAZOLE

INJECTABLE; INJECTION

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER | | | | | | |
| >A> | AP | APOTEX | 200MG/100ML | N76888 | 001 | Mar 25, 2005 | Mar | NEWA |
| | | FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER | | | | | | |
| >A> | AP | APOTEX | 200MG/100ML | N76889 | 001 | Mar 25, 2005 | Mar | NEWA |

FLUOCINONIDE

CREAM; TOPICAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | VANOS | | | | | | |
| | + | MEDICIS | 0.1% | N21758 | 001 | Feb 11, 2005 | Feb | NEWA |

SOLUTION; TOPICAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | FLUOCINONIDE | | | | | | |
| >D> | AT | COPLEY PHARM | 0.05% | N72522 | 001 | Sep 28, 1990 | Mar | CAHN |
| >A> | AT | TEVA PHARMS | 0.05% | N72522 | 001 | Sep 28, 1990 | Mar | CAHN |

FLUPHENAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | FLUPHENAZINE HCL | | | | | | |
| >D> | AA | COPLEY PHARM | 5MG/ML | N73058 | 001 | Aug 30, 1991 | Mar | CAHN |
| >A> | AA | TEVA PHARMS | 5MG/ML | N73058 | 001 | Aug 30, 1991 | Mar | CAHN |

ELIXIR; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | FLUPHENAZINE HCL | | | | | | |
| >D> | AA | COPLEY PHARM | 2.5MG/5ML | N81310 | 001 | Apr 29, 1993 | Mar | CAHN |
| >A> | AA | TEVA PHARMS | 2.5MG/5ML | N81310 | 001 | Apr 29, 1993 | Mar | CAHN |

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | FLOVENT | | | | | | | |
| | + | GLAXOSMITHKLINE | 0.044MG/INH | N20548 | 001 | Mar 27, 1996 | Jan | CRLD |
| | + | | 0.11MG/INH | N20548 | 002 | Mar 27, 1996 | Jan | CRLD |
| | | FLOVENT HFA | | | | | | | |
| | + | GLAXOSMITHKLINE | 0.044MG/INH | N21433 | 003 | May 14, 2004 | Jan | CRLD |
| | + | | 0.11MG/INH | N21433 | 002 | May 14, 2004 | Jan | CRLD |

LOTION; TOPICAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | CUTIVATE | | | | | | | |
| >A> | + | GLAXOSMITHKLINE | 0.05% | N21152 | 001 | Mar 31, 2005 | Mar | NEWA |

FOLLITROPIN ALFA/BETA

INJECTABLE; SUBCUTANEOUS

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | FOLLISTIM AQ | | | | | | | |
| | + | ORGANON USA INC | 150 IU/0.18ML | N21211 | 003 | Feb 11, 2004 | Feb | NEWA |
| | + | | 300 IU/0.36ML | N21211 | 001 | Mar 23, 2004 | Jan | CPOT |
| | + | | 600 IU/0.72ML | N21211 | 002 | Mar 23, 2004 | Jan | CPOT |
| | + | | 900 IU/1.08ML | N21211 | 004 | Feb 11, 2005 | Feb | NEWA |

FOMIVIRSEN SODIUM

INJECTABLE; INJECTION

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | VITRAVENE PRESERVATIVE FREE | | | | | | | |
| | @ | NOVARTIS | 6.6MG/ML | N20961 | 001 | Aug 26, 1998 | Feb | DISC |

FOSINOPRIL SODIUM

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | FOSINOPRIL SODIUM | | | | | | | |
| >A> | AB | INVAGEN PHARMS | 10MG | N77222 | 001 | Apr 20, 2005 | Mar | NEWA |
| >A> | AB | | 20MG | N77222 | 002 | Apr 20, 2005 | Mar | NEWA |
| >A> | AB | | 40MG | N77222 | 003 | Apr 20, 2005 | Mar | NEWA |

FUROSEMIDE

INJECTABLE; INJECTION

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | FUROSEMIDE | | | | | | | |
| | AP + | LUITPOLD | 10MG/ML | N18579 | 001 | Nov 30, 1983 | Feb | CRLD |
| | | LASIX | | | | | | | |
| | @ | AVENTIS PHARMS | 10MG/ML | N16363 | 001 | | Feb | DISC |

GABAPENTIN

CAPSULE; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | GABAPENTIN | | | | | | | |
| >A> | AB | APOTEX | 100MG | N75360 | 001 | Apr 06, 2005 | Mar | NEWA |
| >A> | AB | | 300MG | N75360 | 002 | Apr 06, 2005 | Mar | NEWA |
| >A> | AB | | 400MG | N75360 | 003 | Apr 06, 2005 | Mar | NEWA |
| >A> | AB | EON | 100MG | N75539 | 001 | Apr 06, 2005 | Mar | NEWA |
| >A> | AB | | 300MG | N75539 | 002 | Apr 06, 2005 | Mar | NEWA |
| >A> | AB | | 400MG | N75539 | 003 | Apr 06, 2005 | Mar | NEWA |
| >A> | AB | IVAX PHARMS | 100MG | N75477 | 001 | Mar 23, 2005 | Mar | NEWA |
| >A> | AB | | 300MG | N75477 | 002 | Mar 23, 2005 | Mar | NEWA |
| >A> | AB | | 400MG | N75477 | 003 | Mar 23, 2005 | Mar | NEWA |

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE; ORAL

REMINYL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | JOHNSON AND JOHNSON | EQ 8MG BASE | | N21615 | 001 | Dec 22, 2004 | Jan | CRLD |
| | | EQ 24MG BASE | | N21615 | 003 | Dec 22, 2004 | Jan | CRLD |

GATIFLOXACIN

INJECTABLE; INJECTION

TEQUIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + BRISTOL MYERS SQUIBB | EQ 2MG /ML(200MG/100ML) | | N21062 | 001 | Dec 17, 1999 | Mar | CPOT |
| >D> | + | EQ 2MG /ML(400MG/200ML) | | N21062 | 002 | Dec 17, 1999 | Mar | CPOT |
| >D> | + | EQ 10MG /ML(400MG) | | N21062 | 004 | Dec 17, 1999 | Mar | CPOT |
| >A> | + | 400MG/40ML(10MG/ML) | | N21062 | 004 | Dec 17, 1999 | Mar | CPOT |

TEQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + BRISTOL MYERS SQUIBB | 200MG/100ML(2MG/ML) | | N21062 | 001 | Dec 17, 1999 | Mar | CPOT |
| >A> | + | 400MG/200ML(2MG/ML) | | N21062 | 002 | Dec 17, 1999 | Mar | CPOT |

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | TEVA | 1.25MG;250MG | | N76821 | 001 | Jan 27, 2005 | Jan | NEWA |
| AB | | 2.5MG;500MG | | N76821 | 002 | Jan 27, 2005 | Jan | NEWA |
| AB | | 5MG;500MG | | N76821 | 003 | Jan 27, 2005 | Jan | NEWA |

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ WATSON LABS (UTAH) | 2,000 UNITS/VIAL | | N17016 | 009 | Dec 27, 1984 | Feb | CAHN |
| | @ | 2,000 UNITS/VIAL | | N17016 | 011 | Feb 16, 1990 | Feb | CAHN |
| | @ | 5,000 UNITS/VIAL | | N17016 | 006 | | Feb | CAHN |
| AP | + | 10,000 UNITS/VIAL | | N17016 | 007 | | Feb | CAHN |
| | @ | 15,000 UNITS/VIAL | | N17016 | 010 | Feb 15, 1985 | Feb | CAHN |
| | @ | 20,000 UNITS/VIAL | | N17016 | 004 | | Feb | CAHN |

GRISEOFULVIN, MICROCRYSTALLINE

SUSPENSION; ORAL

GRIFULVIN V

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + J AND J | 125MG/5ML | | N62483 | 001 | Jan 26, 1984 | Feb | CFTG |

GRISEOFULVIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | STIEFEL | 125MG/5ML | | N65200 | 001 | Mar 02, 2005 | Feb | NEWA |

GUANABENZ ACETATE

TABLET; ORAL

GUANABENZ ACETATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | EQ 4MG BASE | | N74267 | 001 | Jun 01, 1994 | Mar | CAHN |
| >D> | AB | | EQ 8MG BASE | | N74267 | 002 | Jun 01, 1994 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | EQ 4MG BASE | | N74267 | 001 | Jun 01, 1994 | Mar | CAHN |
| >A> | AB | | EQ 8MG BASE | | N74267 | 002 | Jun 01, 1994 | Mar | CAHN |

HALOPERIDOL LACTATE

CONCENTRATE; ORAL

HALOPERIDOL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AA | + COPLEY PHARM | EQ 2MG BASE/ML | | N71617 | 001 | Dec 01, 1988 | Mar | CAHN |
| >A> | AA | + TEVA PHARMS | EQ 2MG BASE/ML | | N71617 | 001 | Dec 01, 1988 | Mar | CAHN |

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL
HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AA | | IVAX PHARMS | 1.5MG/5ML;5MG/5ML | N40285 | 001 | Jul 19, 1999 | Jan | CAHN |

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | @ | ABC HOLDING | 10MG | N88846 | 001 | Feb 26, 1985 | Feb | DISC |
| | | @ | | 25MG | N88847 | 001 | Feb 26, 1985 | Feb | DISC |
| | | @ | | 50MG | N88848 | 001 | Feb 26, 1985 | Feb | DISC |
| | | @ | | 100MG | N88849 | 001 | Feb 26, 1985 | Feb | DISC |

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | @ | ABC HOLDING | 25MG | N85683 | 001 | | Feb | DISC |
| | | @ | | 50MG | N83965 | 001 | | Feb | DISC |
| | | @ | | 50MG | N85672 | 001 | | Feb | DISC |

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL
AVALIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | SANOFI SYNTHELABO | 12.5MG;300MG | N20758 | 003 | Aug 31, 1998 | Mar | CRLD |
| >A> | | | | 12.5MG;300MG | N20758 | 003 | Aug 31, 1998 | Mar | CRLD |
| >A> | | + | | 25MG;300MG | N20758 | 004 | Mar 15, 2005 | Mar | NEWA |

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

TABLET; ORAL
>A> QUINAPRIL HCL AND HYDROCHLOROTHIAZIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | MYLAN | 12.5MG;EQ 10MG BASE | N77093 | 001 | Mar 28, 2005 | Mar | NEWA |
| >A> | AB | | | 12.5MG;EQ 20MG BASE | N77093 | 002 | Mar 28, 2005 | Mar | NEWA |
| >A> | AB | | | 25MG;EQ 20MG BASE | N77093 | 003 | Mar 28, 2005 | Mar | NEWA |

HYDROCHLOROTHIAZIDE; VALSARTAN

TABLET; ORAL
DIOVAN HCT

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | NOVARTIS | 12.5MG;160MG | N20818 | 002 | Mar 06, 1998 | Mar | CRLD |
| >A> | | | | 12.5MG;160MG | N20818 | 002 | Mar 06, 1998 | Mar | CRLD |
| >D> | | | | 25MG;160MG | N20818 | 003 | Jan 17, 2002 | Mar | CRLD |
| >A> | | + | | 25MG;160MG | N20818 | 003 | Jan 17, 2002 | Mar | CRLD |

HYDROCORTISONE

ENEMA; RECTAL
HYDROCORTISONE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | 100MG/60ML | N74171 | 001 | May 27, 1994 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | 100MG/60ML | N74171 | 001 | May 27, 1994 | Mar | CAHN |

HYDROCORTISONE VALERATE

CREAM; TOPICAL
HYDROCORTISONE VALERATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | 0.2% | N74489 | 001 | Aug 12, 1998 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | 0.2% | N74489 | 001 | Aug 12, 1998 | Mar | CAHN |

HYDROMORPHONE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

PALLADONE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | PURDUE PHARMA LP | 16MG | N21044 | 002 | Sep 24, 2004 | Feb | CRLD |
| | | + | | 32MG | N21044 | 004 | Sep 24, 2004 | Feb | CRLD |

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL

HYDROXYCHLOROQUINE SULFATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | 200MG | N40081 | 001 | Sep 30, 1994 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | 200MG | N40081 | 001 | Sep 30, 1994 | Mar | CAHN |

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION

HYDROXYPROGESTERONE CAPROATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | | @ STERIS | 125MG/ML | N17439 | 001 | | Mar | CAHN |
| >D> | | | @ | 250MG/ML | N17439 | 002 | | Mar | CAHN |
| >A> | | | @ WATSON LABS | 125MG/ML | N17439 | 001 | | Mar | CAHN |
| >A> | | | @ | 250MG/ML | N17439 | 002 | | Mar | CAHN |

IBANDRONATE SODIUM

TABLET; ORAL

BONIVA

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | + | ROCHE | EQ 2.5MG BASE | N21455 | 001 | May 16, 2003 | Feb | CMFD |
| >A> | | | | EQ 150MG BASE | N21455 | 002 | Mar 24, 2005 | Mar | NEWA |

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | @ TEVA | 10MG | N83729 | 001 | | Feb | DISC |
| | | | @ | 25MG | N83729 | 004 | | Feb | DISC |
| | | | @ | 50MG | N83729 | 003 | | Feb | DISC |

IRON DEXTRAN

INJECTABLE; INJECTION

INFED

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | BP | + | WATSON LABS (UTAH) | EQ 50MG IRON/ML | N17441 | 001 | | Feb | CAHN |

IRON SUCROSE

INJECTABLE; INTRAVENOUS

VENOFER

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | LUITPOLD | EQ 20MG BASE/ML | N21135 | 001 | Nov 06, 2000 | Mar | CPOT |
| >A> | | + | | EQ 100MG BASE/5ML(EQ 20MG BASE/ML) | N21135 | 001 | Nov 06, 2000 | Mar | CPOT |
| >A> | | | | EQ 50MG BASE/2.5ML(EQ 20MG BASE/ML) | N21135 | 002 | Mar 20, 2005 | Mar | NEWA |
| >A> | | | | EQ 75MG BASE/3.75ML(EQ 20MG BASE/ML) | N21135 | 003 | Mar 29, 2005 | Mar | NEWA |

ISRADIPINE

TABLET, EXTENDED RELEASE; ORAL

DYNACIRC CR

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | RELIANT PHARMS | 5MG | N20336 | 001 | Jun 01, 1994 | Mar | CRLD |
| >A> | | | | 5MG | N20336 | 001 | Jun 01, 1994 | Mar | CRLD |

KANAMYCIN SULFATE

CAPSULE; ORAL
KANTREX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ APOTHECON | EQ 500MG BASE | N62726 | 001 | Mar 06, 1987 | Feb | DISC |

KETOCONAZOLE

SHAMPOO; TOPICAL
KETOCONAZOLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | QLT USA | 2% | N76942 | 001 | Apr 11, 2005 | Mar | NEWA |

LACTULOSE

SOLUTION; ORAL
EVALOSE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | COPLEY PHARM | 10GM/15ML | N73497 | 001 | May 28, 1993 | Mar | CAHN |
| >A> | AA | TEVA PHARMS | 10GM/15ML | N73497 | 001 | May 28, 1993 | Mar | CAHN |

SOLUTION; ORAL, RECTAL
HEPTALAC

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | COPLEY PHARM | 10GM/15ML | N73504 | 001 | May 28, 1993 | Mar | CAHN |
| >A> | AA | TEVA PHARMS | 10GM/15ML | N73504 | 001 | May 28, 1993 | Mar | CAHN |

>D> LEPIRUDIN

>D> INJECTABLE; INJECTION
>D> REFLUDAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | BERLEX | 50MG/VIAL | N20807 | 001 | Mar 06, 1998 | Mar | CAIN |

>A> LEPIRUDIN RECOMBINANT

>A> INJECTABLE; INJECTION
>A> REFLUDAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | BERLEX | 50MG/VIAL | N20807 | 001 | Mar 06, 1998 | Mar | CAIN |

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS
ELIGARD

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | QLT USA | 22.5MG/VIAL | N21379 | 001 | Jul 24, 2002 | Jan | CAHN |

LEVALBUTEROL TARTRATE

>A> AEROSOL, METERED; INHALATION
>A> XOPENEX HFA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | SEPRACOR | EQ 0.045MG BASE/INH | N21730 | 001 | Mar 11, 2005 | Mar | NEWA |

LEVOFLOXACIN

TABLET; ORAL
LEVAQUIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | ORTHO MCNEIL PHARM | 250MG | N20634 | 001 | Dec 20, 1996 | Mar | CTEC |
| >A> | | | 250MG | N20634 | 001 | Dec 20, 1996 | Mar | CTEC |
| >D> | AB | | 500MG | N20634 | 002 | Dec 20, 1996 | Mar | CTEC |
| >A> | | | 500MG | N20634 | 002 | Dec 20, 1996 | Mar | CTEC |
| | AB | + | 750MG | N20634 | 003 | Sep 08, 2000 | Jan | CFTG |

LEVOFLOXACIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | TEVA | 750MG | N76361 | 003 | Jan 26, 2005 | Jan | NEWA |

LIDOCAINE HYDROCHLORIDE

JELLY; TOPICAL
LIDOCAINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AT | COPLEY PHARM | 2% | N81318 | 001 | Apr 29, 1993 | Mar | CAHN |

JELLY; TOPICAL
LIDOCAINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AT | TEVA PHARMS | 2% | N81318 | 001 | Apr 29, 1993 | Mar | CAHN |

LORAZEPAM

SOLUTION; ORAL
LORAZEPAM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ROXANE | 0.5MG/5ML | N74648 | 001 | Mar 18, 1997 | Jan | CMFD |

MANGAFODIPIR TRISODIUM

INJECTABLE; INJECTION
TESLASCAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ GE HEALTHCARE | 37.9MG/ML | N20652 | 001 | Nov 26, 1997 | Jan | DISC |

MEBENDAZOLE

TABLET, CHEWABLE; ORAL
MEBENDAZOLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | 100MG | N73580 | 001 | Jan 04, 1995 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | 100MG | N73580 | 001 | Jan 04, 1995 | Mar | CAHN |

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
MECLIZINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ ABC HOLDING | 12.5MG | N85253 | 001 | | Feb | DISC |
| | | @ | 25MG | N85252 | 001 | | Feb | DISC |

MEGESTROL ACETATE

SUSPENSION; ORAL
MEGESTROL ACETATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | 40MG/ML | N75681 | 001 | May 05, 2003 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | 40MG/ML | N75681 | 001 | May 05, 2003 | Mar | CAHN |

MEQUINOL; TRETINOIN

SOLUTION; TOPICAL
SOLAGE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | + BARRIER | 2%;0.01% | N20922 | 001 | Dec 10, 1999 | Feb | CAHN |

METAPROTERENOL SULFATE

SYRUP; ORAL
METAPROTERENOL SULFATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | @ COPLEY PHARM | 10MG/5ML | N73034 | 001 | Aug 30, 1991 | Mar | CAHN |
| >A> | | @ TEVA PHARMS | 10MG/5ML | N73034 | 001 | Aug 30, 1991 | Mar | CAHN |

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
METFORMIN HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | ANDRX PHARMS | 750MG | N76869 | 001 | Apr 12, 2005 | Mar | NEWA |
| >A> | AB | PUREPAC PHARM | 750MG | N76878 | 001 | Apr 13, 2005 | Mar | NEWA |
| >A> | AB | TEVA | 750MG | N76864 | 001 | Apr 12, 2005 | Mar | NEWA |
| >A> | AB | ZYDUS PHARMS USA | 500MG | N77060 | 001 | Apr 20, 2005 | Mar | NEWA |

TABLET; ORAL
METFORMIN HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | ZYDUS PHARMS USA | 500MG | N77064 | 001 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | | 850MG | N77064 | 002 | Apr 18, 2005 | Mar | NEWA |
| >A> | AB | | 1GM | N77064 | 003 | Apr 18, 2005 | Mar | NEWA |

METHAZOLAMIDE

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | METHAZOLAMIDE | | | | | | |
| >D> | AB | | COPLEY PHARM | 25MG | N40001 | 001 | Jun 30, 1993 | Mar | CAHN |
| >D> | AB | | | 50MG | N40001 | 002 | Jun 30, 1993 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | 25MG | N40001 | 001 | Jun 30, 1993 | Mar | CAHN |
| >A> | AB | | | 50MG | N40001 | 002 | Jun 30, 1993 | Mar | CAHN |

METHIMAZOLE

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | METHIMAZOLE | | | | | | |
| | AB | | CEDAR PHARMS | 5MG | N40547 | 001 | Feb 18, 2005 | Jan | NEWA |
| | AB | | | 10MG | N40547 | 002 | Feb 18, 2005 | Jan | NEWA |
| | AB | | | 20MG | N40547 | 004 | Feb 18, 2005 | Jan | NEWA |
| | AB | + | GENPHARM | 20MG | N40350 | 003 | Jun 07, 2001 | Jan | CFTG |

METHYLDOPA

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | ALDOMET | | | | | | |
| | | | @ MERCK | 500MG | N13400 | 002 | | Jan | DISC |
| | | | METHYLDOPA | | | | | | |
| | AB | + | MYLAN | 500MG | N70076 | 001 | Apr 18, 1985 | Jan | CRLD |

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | ALDOMET | | | | | | |
| | | | @ MERCK | 50MG/ML | N13401 | 001 | | Jan | DISC |
| | | | METHYLDOPATE HCL | | | | | | |
| | AP | + | LUITPOLD | 50MG/ML | N71279 | 001 | Oct 02, 1987 | Jan | CRLD |

METHYLERGONOVINE MALEATE

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | METHERGINE | | | | | | |
| | | + | NOVARTIS | 0.2MG | N06035 | 003 | | Jan | CRLD |

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | DEPO-MEDROL | | | | | | |
| | AB | + | PHARMACIA AND UPJOHN | 40MG/ML | N11757 | 001 | | Feb | CFTG |
| | AB | + | | 80MG/ML | N11757 | 004 | | Feb | CFTG |
| | | | METHYLPREDNISOLONE ACETATE | | | | | | |
| | AB | | SICOR PHARMS | 40MG/ML | N40557 | 001 | Feb 23, 2005 | Feb | NEWA |
| | AB | | | 80MG/ML | N40557 | 002 | Feb 23, 2005 | Feb | NEWA |

METOLAZONE

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | ZAROXOLYN | | | | | | |
| >D> | AB | | CELLTECH PHARMS | 2.5MG | N17386 | 001 | | Mar | CAHN |
| >D> | AB | + | | 5MG | N17386 | 002 | | Mar | CAHN |
| >D> | AB | + | | 10MG | N17386 | 003 | | Mar | CAHN |
| >A> | AB | | UCB | 2.5MG | N17386 | 001 | | Mar | CAHN |
| >A> | AB | + | | 5MG | N17386 | 002 | | Mar | CAHN |
| >A> | AB | + | | 10MG | N17386 | 003 | | Mar | CAHN |

METOPROLOL TARTRATE

TABLET; ORAL
METOPROLOL TARTRATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | 50MG | N74333 | 001 | Jan 27, 1994 | Mar | CAHN |
| >D> | AB | | 100MG | N74333 | 002 | Jan 27, 1994 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | 50MG | N74333 | 001 | Jan 27, 1994 | Mar | CAHN |
| >A> | AB | | 100MG | N74333 | 002 | Jan 27, 1994 | Mar | CAHN |

>A> MICAFUNGIN SODIUM

>A> INJECTABLE; IV (INFUSION)
>A> MYCAMINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | ASTELLAS | 50MG/VIAL | N21506 | 002 | Mar 16, 2005 | Mar | NEWA |

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION
MIDAZOLAM HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | @ HOSPIRA | EQ 1MG BASE/ML | N75293 | 001 | Jun 20, 2000 | Mar | CMFD |
| >A> | AP | | EQ 1MG BASE/ML | N75293 | 001 | Jun 20, 2000 | Mar | CMFD |
| >D> | | @ | EQ 5MG BASE/ML | N75293 | 002 | Jun 20, 2000 | Mar | CMFD |
| >A> | AP | | EQ 5MG BASE/ML | N75293 | 002 | Jun 20, 2000 | Mar | CMFD |
| | AP | INTL MEDICATED | EQ 1MG BASE/ML | N76144 | 001 | Jan 26, 2005 | Jan | NEWA |
| | AP | | EQ 5MG BASE/ML | N76144 | 002 | Jan 26, 2005 | Jan | NEWA |

MOMETASONE FUROATE

CREAM; TOPICAL
ELOCON

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | + SCHERING | 0.1% | N19625 | 001 | May 06, 1987 | Jan | CFTG |

MOMETASONE FUROATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | ALTANA | 0.1% | N76171 | 001 | Apr 08, 2005 | Mar | NEWA |
| | AB | TARO | 0.1% | N76679 | 001 | Dec 21, 2004 | Jan | NEWA |

LOTION; TOPICAL
ELOCON

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | SCHERING | 0.1% | N19796 | 001 | Mar 30, 1989 | Mar | CFTG |
| >A> | AB + | | 0.1% | N19796 | 001 | Mar 30, 1989 | Mar | CFTG |

>A> MOMETASONE FUROATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | AGIS INDS | 0.1% | N77180 | 001 | Apr 06, 2005 | Mar | NEWA |

OINTMENT; TOPICAL
MOMETASONE FUROATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | ALTANA | 0.1% | N77061 | 001 | Mar 28, 2005 | Mar | NEWA |

>A> POWDER; INHALATION
>A> ASMANEX TWISTHALER

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | SCHERING | 0.22MG/INH | N21067 | 001 | Mar 30, 2005 | Mar | NEWA |

MOMETASONE FUROATE MONOHYDRATE

SPRAY, METERED; NASAL
NASONEX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | SCHERING PLOUGH | EQ 0.05MG BASE/SPRAY | N20762 | 001 | Oct 01, 1997 | Mar | CAHN |
| >A> | + | SHIRE | EQ 0.05MG BASE/SPRAY | N20762 | 001 | Oct 01, 1997 | Mar | CAHN |

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL
AVINZA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | BX | + LIGAND | 30MG | N21260 | 001 | Mar 20, 2002 | Mar | CRLD |
| >A> | BX | | 30MG | N21260 | 001 | Mar 20, 2002 | Mar | CRLD |
| >D> | BX | + | 60MG | N21260 | 002 | Mar 20, 2002 | Mar | CRLD |

CAPSULE, EXTENDED RELEASE; ORAL

AVINZA

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | BX | | LIGAND | 60MG | N21260 | 002 | Mar 20, 2002 | Mar | CRLD |
| >D> | | + | | 90MG | N21260 | 003 | Mar 20, 2002 | Mar | CRLD |
| >A> | | | | 90MG | N21260 | 003 | Mar 20, 2002 | Mar | CRLD |

KADIAN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | ALPHARMA US PHARMS | 20MG | N20616 | 001 | Jul 03, 1996 | Mar | CRLD |
| >A> | | | | 20MG | N20616 | 001 | Jul 03, 1996 | Mar | CRLD |
| >D> | BX | + | | 30MG | N20616 | 004 | Mar 09, 2001 | Mar | CRLD |
| >A> | BX | | | 30MG | N20616 | 004 | Mar 09, 2001 | Mar | CRLD |
| >D> | | + | | 50MG | N20616 | 002 | Jul 03, 1996 | Mar | CRLD |
| >A> | | | | 50MG | N20616 | 002 | Jul 03, 1996 | Mar | CRLD |
| >D> | BX | + | | 60MG | N20616 | 005 | Mar 09, 2001 | Mar | CRLD |
| >A> | BX | | | 60MG | N20616 | 005 | Mar 09, 2001 | Mar | CRLD |

NADOLOL

TABLET; ORAL

NADOLOL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | 80MG | N74368 | 001 | Aug 31, 1994 | Mar | CAHN |
| >D> | AB | | | 120MG | N74368 | 002 | Aug 31, 1994 | Mar | CAHN |
| >D> | AB | | | 160MG | N74368 | 003 | Aug 31, 1994 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | 80MG | N74368 | 001 | Aug 31, 1994 | Mar | CAHN |
| >A> | AB | | | 120MG | N74368 | 002 | Aug 31, 1994 | Mar | CAHN |
| >A> | AB | | | 160MG | N74368 | 003 | Aug 31, 1994 | Mar | CAHN |

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | | @ HOSPIRA | 0.4MG/ML | N70172 | 001 | Sep 24, 1986 | Mar | CMFD |
| >A> | AP | | | 0.4MG/ML | N70172 | 001 | Sep 24, 1986 | Mar | CMFD |

NAPROXEN

TABLET; ORAL

NAPROXEN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | 250MG | N74207 | 001 | Dec 21, 1993 | Mar | CAHN |
| >D> | AB | | | 375MG | N74207 | 002 | Dec 21, 1993 | Mar | CAHN |
| >D> | AB | | | 500MG | N74207 | 003 | Dec 21, 1993 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | 250MG | N74207 | 001 | Dec 21, 1993 | Mar | CAHN |
| >A> | AB | | | 375MG | N74207 | 002 | Dec 21, 1993 | Mar | CAHN |
| >A> | AB | | | 500MG | N74207 | 003 | Dec 21, 1993 | Mar | CAHN |

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | COPLEY PHARM | EQ 250MG BASE | N74289 | 001 | Jan 27, 1994 | Mar | CAHN |
| >D> | AB | | | EQ 500MG BASE | N74289 | 002 | Jan 27, 1994 | Mar | CAHN |
| >A> | AB | | TEVA PHARMS | EQ 250MG BASE | N74289 | 001 | Jan 27, 1994 | Mar | CAHN |
| >A> | AB | | | EQ 500MG BASE | N74289 | 002 | Jan 27, 1994 | Mar | CAHN |

NIACIN

TABLET, EXTENDED RELEASE; ORAL

>A> NIACIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | BARR | 1GM | N76250 | 001 | Apr 14, 2005 | Mar | NEWA |

NIASPAN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | KOS | 1GM | N20381 | 004 | Jul 28, 1997 | Mar | CFTG |
| >A> | AB | + | | 1GM | N20381 | 004 | Jul 28, 1997 | Mar | CFTG |

NICARDIPINE HYDROCHLORIDE

INJECTABLE; INJECTION

CARDENE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | + | ESP PHARMA | 2.5MG/ML | N19734 | 001 | Jan 30, 1992 | Mar | CAHN |
| >D> | | + | ROCHE PALO | 2.5MG/ML | N19734 | 001 | Jan 30, 1992 | Mar | CAHN |

NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

NITROFURANTOIN (MONOHYDRATE/MACROCRYSTALS)

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | EON | 75MG;25MG | N77066 | 001 | Apr 05, 2005 | Mar | NEWA |
| >A> | AB | | RANBAXY | 75MG;25MG | N76951 | 001 | Mar 30, 2005 | Mar | NEWA |

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

>A> OCTREOTIDE ACETATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AP | | BEDFORD | EQ 0.2MG BASE/ML | N76330 | 001 | Apr 08, 2005 | Mar | NEWA |
| >A> | AP | | | EQ 1MG BASE/ML | N76330 | 002 | Apr 08, 2005 | Mar | NEWA |

>A> OCTREOTIDE ACETATE (PRESERVATIVE FREE)

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AP | | BEDFORD | EQ 0.05MG BASE/ML | N76313 | 001 | Mar 28, 2005 | Mar | NEWA |
| >A> | AP | | | EQ 0.1MG BASE/ML | N76313 | 003 | Mar 28, 2005 | Mar | NEWA |
| >A> | AP | | | EQ 0.5MG BASE/ML | N76313 | 002 | Mar 28, 2005 | Mar | NEWA |

SANDOSTATIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | NOVARTIS | EQ 0.05MG BASE/ML | N19667 | 001 | Oct 21, 1988 | Mar | CFTG |
| >A> | AP | + | | EQ 0.05MG BASE/ML | N19667 | 001 | Oct 21, 1988 | Mar | CFTG |
| >D> | | + | | EQ 0.1MG BASE/ML | N19667 | 002 | Oct 21, 1988 | Mar | CFTG |
| >A> | AP | + | | EQ 0.1MG BASE/ML | N19667 | 002 | Oct 21, 1988 | Mar | CFTG |
| >D> | | + | | EQ 0.2MG BASE/ML | N19667 | 004 | Jun 12, 1991 | Mar | CFTG |
| >A> | AP | + | | EQ 0.2MG BASE/ML | N19667 | 004 | Jun 12, 1991 | Mar | CFTG |
| >D> | | + | | EQ 0.5MG BASE/ML | N19667 | 003 | Oct 21, 1988 | Mar | CFTG |
| >A> | AP | + | | EQ 0.5MG BASE/ML | N19667 | 003 | Oct 21, 1988 | Mar | CFTG |
| >D> | | + | | EQ 1MG BASE/ML | N19667 | 005 | Jun 12, 1991 | Mar | CFTG |
| >A> | AP | + | | EQ 1MG BASE/ML | N19667 | 005 | Jun 12, 1991 | Mar | CFTG |

OLSALAZINE SODIUM

CAPSULE; ORAL

DIPENTUM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | CELLTECH PHARMS | 250MG | N19715 | 001 | Jul 31, 1990 | Mar | CAHN |
| >A> | | + | UCB | 250MG | N19715 | 001 | Jul 31, 1990 | Mar | CAHN |

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

PRILOSEC

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | + | ASTRAZENECA | 40MG | N19810 | 002 | Jan 15, 1998 | Mar | CTEC |
| >A> | | | | 40MG | N19810 | 002 | Jan 15, 1998 | Mar | CTEC |

OXALIPLATIN

INJECTABLE; IV (INFUSION)

ELOXATIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | | SANOFI | 50MG/VIAL | N21492 | 001 | Aug 09, 2002 | Mar | CRLD |
| >A> | | + | | 50MG/VIAL | N21492 | 001 | Aug 09, 2002 | Mar | CRLD |
| | | + | SANOFI SYNTHELABO | 50MG/10ML (5MG/ML) | N21759 | 001 | Jan 31, 2005 | Jan | NEWA |
| | | + | | 100MG/20ML (5MG/ML) | N21759 | 002 | Jan 31, 2005 | Jan | NEWA |

PACLITAXEL

FOR SUSPENSION; IV (INFUSION)

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | ABRAXANE | | | | | | | |
| | + | AM BIOSCIENCE | 100MG/VIAL | N21660 | 001 | Jan 07, 2005 | Jan | | NEWA |

PEMOLINE

TABLET, CHEWABLE; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | PEMOLINE | | | | | | | |
| >D> | AB | COPLEY PHARM | 37.5MG | N75555 | 001 | Feb 18, 2000 | Mar | | CAHN |
| >A> | AB | TEVA PHARMS | 37.5MG | N75555 | 001 | Feb 18, 2000 | Mar | | CAHN |

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | PEMOLINE | | | | | | | |
| >D> | AB | COPLEY PHARM | 18.75MG | N75030 | 003 | Feb 22, 2000 | Mar | | CAHN |
| >D> | AB | | 37.5MG | N75030 | 001 | Jan 29, 1999 | Mar | | CAHN |
| >D> | AB | | 75MG | N75030 | 002 | Jan 29, 1999 | Mar | | CAHN |
| >A> | AB | TEVA PHARMS | 18.75MG | N75030 | 003 | Feb 22, 2000 | Mar | | CAHN |
| >A> | AB | | 37.5MG | N75030 | 001 | Jan 29, 1999 | Mar | | CAHN |
| >A> | AB | | 75MG | N75030 | 002 | Jan 29, 1999 | Mar | | CAHN |

PENTOBARBITAL SODIUM

CAPSULE; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | SODIUM PENTOBARBITAL | | | | | | | |
| | @ | VALEANT PHARM INTL | 100MG | N83264 | 001 | | Jan | | DISC |

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | BONTRIL PDM | | | | | | | |
| AA | + | VALEANT | 35MG | N85272 | 001 | | Feb | | CRLD |
| | | CAM-METRAZINE | | | | | | | |
| | @ | ABC HOLDING | 35MG | N83922 | 001 | | Feb | | DISC |
| | @ | | 35MG | N85318 | 001 | | Feb | | DISC |
| | @ | | 35MG | N85320 | 001 | | Feb | | DISC |
| | @ | | 35MG | N85321 | 001 | | Feb | | DISC |
| | @ | | 35MG | N85511 | 001 | | Feb | | DISC |
| | @ | CAMALL | 35MG | N85756 | 001 | | Feb | | DISC |
| | | PHENDIMETRAZINE TARTRATE | | | | | | | |
| | @ | ABC HOLDING | 35MG | N85761 | 001 | | Feb | | DISC |
| | @ | | 35MG | N85941 | 001 | Jun 27, 1983 | Feb | | DISC |
| | @ | EON | 35MG | N85830 | 001 | | Feb | | DISC |
| | | X-TROZINE | | | | | | | |
| | @ | SHIRE RICHWOOD | 35MG | N86553 | 001 | | Feb | | DISC |
| | @ | | 35MG | N86554 | 001 | | Feb | | DISC |

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | ONA-MAST | | | | | | | |
| | @ | MAST MM | 30MG | N86511 | 001 | | Feb | | DISC |
| | @ | | 30MG | N86516 | 001 | | Feb | | DISC |
| | | PHENTERMINE HCL | | | | | | | |
| | @ | ABC HOLDING | 18.75MG | N88576 | 001 | May 23, 1984 | Feb | | DISC |
| | @ | | 30MG | N85417 | 001 | | Feb | | DISC |
| | @ | | 30MG | N86732 | 002 | | Feb | | DISC |
| | @ | | 30MG | N87215 | 001 | | Feb | | DISC |
| | @ | | 37.5MG | N87915 | 001 | Dec 22, 1983 | Feb | | DISC |
| | @ | | 37.5MG | N87918 | 001 | Dec 22, 1983 | Feb | | DISC |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | CAPSULE; ORAL | | | | | | | |
| | | PHENTERMINE HCL | | | | | | | |
| | | @ ABC HOLDING | 37.5MG | N87930 | 001 | Oct 14, 1983 | Feb | DISC | |
| | | @ | 37.5MG | N88610 | 001 | Jun 04, 1984 | Feb | DISC | |
| | | @ | 37.5MG | N88611 | 001 | Jun 04, 1984 | Feb | DISC | |
| | | @ | 37.5MG | N88625 | 001 | Aug 23, 1984 | Feb | DISC | |
| | | @ CAMALL | 15MG | N86735 | 001 | | Feb | DISC | |
| | | @ | 30MG | N87226 | 001 | | Feb | DISC | |
| | | TABLET; ORAL | | | | | | | |
| | | ONA MAST | | | | | | | |
| | | @ MAST MM | 8MG | N86260 | 001 | | Feb | DISC | |
| | | PHENTERMINE HCL | | | | | | | |
| | | @ ABC HOLDING | 8MG | N83923 | 001 | | Feb | DISC | |
| | | @ | 8MG | N85319 | 001 | | Feb | DISC | |
| | | @ | 37.5MG | N87805 | 001 | Dec 06, 1982 | Feb | DISC | |
| | | @ | 37.5MG | N88596 | 001 | Apr 04, 1984 | Feb | DISC | |
| >A> | AA | LANNETT | 37.5MG | N40555 | 001 | Apr 15, 2005 | Mar | NEWA | |
| | | PHENTERMINE RESIN COMPLEX | | | | | | | |
| | | CAPSULE, EXTENDED RELEASE; ORAL | | | | | | | |
| | | IONAMIN | | | | | | | |
| >D> | | CELLTECH PHARMS | EQ 15MG BASE | N11613 | 004 | | Mar | CAHN | |
| >D> | | + | EQ 30MG BASE | N11613 | 002 | | Mar | CAHN | |
| >A> | | UCB | EQ 15MG BASE | N11613 | 004 | | Mar | CAHN | |
| >A> | | + | EQ 30MG BASE | N11613 | 002 | | Mar | CAHN | |
| | | PHENYTOIN SODIUM | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | PHENYTOIN | | | | | | | |
| >D> | | + ELKINS SINN | 50MG/ML | N84307 | 001 | | Mar | CTEC | |
| >A> | AP | + | 50MG/ML | N84307 | 001 | | Mar | CTEC | |
| | | PHENYTOIN SODIUM | | | | | | | |
| >D> | | @ HOSPIRA | 50MG/ML | N89521 | 001 | Mar 17, 1987 | Mar | CMFD | |
| >A> | AP | | 50MG/ML | N89521 | 001 | Mar 17, 1987 | Mar | CMFD | |
| >D> | | @ | 50MG/ML | N89744 | 001 | Dec 18, 1987 | Mar | CMFD | |
| >A> | AP | | 50MG/ML | N89744 | 001 | Dec 18, 1987 | Mar | CMFD | |
| | | PIROXICAM | | | | | | | |
| | | CAPSULE; ORAL | | | | | | | |
| | | PIROXICAM | | | | | | | |
| >D> | AB | COPLEY PHARM | 10MG | N74103 | 001 | Aug 28, 1992 | Mar | CAHN | |
| >D> | AB | | 20MG | N74103 | 002 | Aug 28, 1992 | Mar | CAHN | |
| >A> | AB | TEVA PHARMS | 10MG | N74103 | 001 | Aug 28, 1992 | Mar | CAHN | |
| >A> | AB | | 20MG | N74103 | 002 | Aug 28, 1992 | Mar | CAHN | |
| | | POTASSIUM CHLORIDE | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER | | | | | | | |
| >D> | | @ HOSPIRA | 14.9MG/ML | N20161 | 005 | Nov 30, 1992 | Mar | CMFD | |
| >A> | AP | | 14.9MG/ML | N20161 | 005 | Nov 30, 1992 | Mar | CMFD | |
| >D> | | @ | 745MG/100ML | N20161 | 001 | Nov 30, 1992 | Mar | CMFD | |
| >A> | AP | | 745MG/100ML | N20161 | 001 | Nov 30, 1992 | Mar | CMFD | |
| | | POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER | | | | | | | |
| >D> | | @ HOSPIRA | 1.49GM/100ML | N20161 | 002 | Nov 30, 1992 | Mar | CMFD | |
| >A> | AP | | 1.49GM/100ML | N20161 | 002 | Nov 30, 1992 | Mar | CMFD | |

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL

UROCIT-K

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | MISSION PHARMA | 5MEQ | N19071 | 001 | Aug 30, 1985 | Jan | CTNA |
| | + | | 10MEQ | N19071 | 002 | Aug 31, 1992 | Jan | CTNA |

>A> PRAMLINTIDE ACETATE

>A> INJECTABLE; SUBCUTANEOUS

>A> SYMLIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | AMYLIN | EQ 3MG BASE/5ML (EQ 0.6MG BASE/ML) | N21332 | 001 | Mar 16, 2005 | Mar | NEWA |

PREDNISOLONE

SYRUP; ORAL

PREDNISOLONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | COPLEY PHARM | 15MG/5ML | N40322 | 001 | Jan 19, 2000 | Mar | CAHN |
| | AA | IVAX PHARMS | 15MG/5ML | N40287 | 001 | May 28, 1999 | Jan | CAHN |
| >A> | AA | TEVA PHARMS | 15MG/5ML | N40322 | 001 | Jan 19, 2000 | Mar | CAHN |

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL

PEDIAPRED

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | + CELLTECH PHARMS | EQ 5MG BASE/5ML | N19157 | 001 | May 28, 1986 | Mar | CAHN |
| >A> | AA | + UCB | EQ 5MG BASE/5ML | N19157 | 001 | May 28, 1986 | Mar | CAHN |

PRIMIDONE

TABLET; ORAL

PRIMIDONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | VINTAGE PHARMS | 50MG | N40586 | 001 | Feb 24, 2005 | Feb | NEWA |
| | AB | | 250MG | N40586 | 002 | Feb 24, 2005 | Feb | NEWA |

PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCHLORPERAZINE MALEATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | EQ 5MG BASE | N40120 | 001 | Jul 11, 1996 | Mar | CAHN |
| >D> | AB | | EQ 10MG BASE | N40120 | 002 | Jul 11, 1996 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | EQ 5MG BASE | N40120 | 001 | Jul 11, 1996 | Mar | CAHN |
| >A> | AB | | EQ 10MG BASE | N40120 | 002 | Jul 11, 1996 | Mar | CAHN |

PROGESTERONE

INJECTABLE; INJECTION

PROGESTERONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AO | + WATSON LABS (UTAH) | 50MG/ML | N17362 | 002 | | Feb | CAHN |

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ABLE | 12.5MG | N40558 | 001 | Jul 01, 2004 | Jan | CTEC |

PROPOFOL

INJECTABLE; INJECTION

PROPOFOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | BEDFORD | 10MG/ML | N74848 | 001 | Apr 19, 2005 | Mar | NEWA |

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL
QUINAPRIL HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | EON | EQ 5MG BASE | N76803 | 001 | Mar 02, 2005 | Feb | NEWA |
| AB | | EQ 10MG BASE | N76803 | 002 | Mar 02, 2005 | Feb | NEWA |
| AB | | EQ 20MG BASE | N76803 | 003 | Mar 02, 2005 | Feb | NEWA |
| AB | | EQ 40MG BASE | N76803 | 004 | Mar 02, 2005 | Feb | NEWA |
| AB | PAR PHARM | EQ 5MG BASE | N76036 | 001 | Jan 28, 2005 | Jan | NEWA |
| AB | | EQ 10MG BASE | N76036 | 002 | Jan 28, 2005 | Jan | NEWA |
| AB | | EQ 20MG BASE | N76036 | 003 | Jan 28, 2005 | Jan | NEWA |
| AB | | EQ 40MG BASE | N76036 | 004 | Jan 28, 2005 | Jan | NEWA |

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
QUINIDINE SULFATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + COPLEY PHARM | 300MG | N40045 | 001 | Jun 30, 1994 | Mar | CAHN |
| >A> | + TEVA PHARMS | 300MG | N40045 | 001 | Jun 30, 1994 | Mar | CAHN |

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
RANITIDINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | BEN VENUE | EQ 25MG BASE/ML | N74777 | 001 | Mar 02, 2005 | Feb | NEWA |

SODIUM BENZOATE; SODIUM PHENYLACETATE

SOLUTION; IV (INFUSION)
AMMONUL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + UCYCLYD | 10%;10% (5GM/50ML;5GM/50ML) | N20645 | 001 | Feb 17, 2005 | Feb | NEWA |

SODIUM CHLORIDE

SOLUTION; IRRIGATION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | @ HOSPIRA | 450MG/100ML | N18380 | 001 | | Mar | CMFD |
| >A> | AT | 450MG/100ML | N18380 | 001 | | Mar | CMFD |

>D> SOMATREM

>D> INJECTABLE; INJECTION
>D> PROTROPIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + GENENTECH | 5MG/VIAL | N19107 | 001 | Oct 17, 1985 | Mar | DISC |
| >A> | @ | 5MG/VIAL | N19107 | 001 | Oct 17, 1985 | Mar | DISC |
| >D> | + | 10MG/VIAL | N19107 | 002 | Oct 24, 1989 | Mar | DISC |
| >A> | @ | 10MG/VIAL | N19107 | 002 | Oct 24, 1989 | Mar | DISC |

SOMATROPIN RECOMBINANT

INJECTABLE; SUBCUTANEOUS
SEROSTIM LQ

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | SERONO | 6MG/0.05VIAL | N20604 | 005 | Feb 11, 2005 | Feb | NEWA |

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | INTERPHARM | 400MG;80MG | N76899 | 001 | Jan 27, 2005 | Jan | NEWA |
| AB | | 800MG;160MG | N76899 | 002 | Jan 27, 2005 | Jan | NEWA |

TACROLIMUS

CAPSULE; ORAL
PROGRAF
\+ FUJISAWA HLTHCARE EQ 1MG BASE N50708 001 Apr 08, 1994 Jan CRLD

TAMOXIFEN CITRATE

TABLET; ORAL
TAMOXIFEN CITRATE
@ PHARMACHEMIE EQ 10MG BASE N74539 001 Mar 31, 2003 Feb DISC

TELITHROMYCIN

TABLET; ORAL
KETEK
AVENTIS PHARMS 300MG N21144 002 Feb 09, 2005 Feb NEWA

TERBUTALINE SULFATE

TABLET; ORAL
TERBUTALINE SULFATE
>A> AB LANNETT 2.5MG N77152 001 Mar 25, 2005 Mar NEWA
>A> AB 5MG N77152 002 Mar 25, 2005 Mar NEWA

TERCONAZOLE

CREAM; VAGINAL
TERCONAZOLE
AB ALTANA 0.4% N76712 001 Feb 18, 2005 Jan NEWA

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION
TESTOSTERONE CYPIONATE
AO PADDOCK 200MG/ML N40530 001 Jan 31, 2005 Jan NEWA

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
>D> SUMYCIN
>D> AB APOTHECON 250MG N60429 001 Mar DISC
>A> @ 250MG N60429 001 Mar DISC
>D> AB \+ 500MG N60429 003 Mar DISC
>A> @ 500MG N60429 003 Mar DISC
TETRACYCLINE HCL
>D> AB IVAX PHARMS 500MG N60704 002 Mar CRLD
>A> AB \+ 500MG N60704 002 Mar CRLD
@ MAST MM 250MG N62085 001 Feb DISC

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
THIORIDAZINE HCL
>D> AA \+ COPLEY PHARM 30MG/ML N89602 001 Nov 09, 1987 Mar CAHN
>D> AA \+ 100MG/ML N89603 001 Nov 09, 1987 Mar CAHN
>A> AA \+ TEVA PHARMS 30MG/ML N89602 001 Nov 09, 1987 Mar CAHN
>A> AA \+ 100MG/ML N89603 001 Nov 09, 1987 Mar CAHN

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL
THIOTHIXENE HCL
>D> AA COPLEY PHARM EQ 5MG BASE/ML N71554 001 Oct 16, 1987 Mar CAHN

CONCENTRATE; ORAL
THIOTHIXENE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AA | TEVA PHARMS | EQ 5MG BASE/ML | N71554 | 001 | Oct 16, 1987 | Mar | CAHN |

TOREMIFENE CITRATE

TABLET; ORAL
FARESTON

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | GTX INC | EQ 60MG BASE | N20497 | 001 | May 29, 1997 | Jan | CAHN |

TORSEMIDE

TABLET; ORAL
TORSEMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | ROXANE | 5MG | N76943 | 001 | Mar 01, 2005 | Feb | NEWA |
| | AB | | 10MG | N76943 | 002 | Mar 01, 2005 | Feb | NEWA |
| | AB | | 20MG | N76943 | 003 | Mar 01, 2005 | Feb | NEWA |

TRETINOIN

SOLUTION; TOPICAL
TRETINOIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AT | COPLEY PHARM | 0.05% | N74873 | 001 | Jun 19, 1998 | Mar | CAHN |
| >A> | AT | TEVA PHARMS | 0.05% | N74873 | 001 | Jun 19, 1998 | Mar | CAHN |

TRICHLORMETHIAZIDE

TABLET; ORAL
NAQUA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ SCHERING | 4MG | N12265 | 002 | | Feb | DISC |

TRICHLORMETHIAZIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ ABC HOLDING | 4MG | N85568 | 001 | | Feb | DISC |
| | | @ PAR PHARM | 2MG | N87007 | 001 | | Feb | DISC |
| | | @ | 4MG | N87005 | 001 | | Feb | DISC |

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL
PRIMSOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ TARO PHARMS NORTH | EQ 25MG BASE/5ML | N74374 | 001 | Jun 23, 1995 | Jan | CAHN |
| | + | | EQ 50MG BASE/5ML | N74973 | 001 | Jan 24, 2000 | Jan | CAHN |

URSODIOL

CAPSULE; ORAL
URSODIOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | COPLEY PHARM | 300MG | N75592 | 001 | May 25, 2000 | Mar | CAHN |
| >A> | AB | TEVA PHARMS | 300MG | N75592 | 001 | May 25, 2000 | Mar | CAHN |

VALPROIC ACID

SYRUP; ORAL
VALPROIC ACID

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | COPLEY PHARM | 250MG/5ML | N73178 | 001 | Aug 25, 1992 | Mar | CAHN |
| >A> | AA | TEVA PHARMS | 250MG/5ML | N73178 | 001 | Aug 25, 1992 | Mar | CAHN |

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
VERELAN PM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | ELAN PHARM | 100MG | N20943 | 001 | Nov 25, 1998 | Mar | CRLD |
| >A> | | | 100MG | N20943 | 001 | Nov 25, 1998 | Mar | CRLD |
| >D> | + | | 200MG | N20943 | 002 | Nov 25, 1998 | Mar | CRLD |
| >A> | | | 200MG | N20943 | 002 | Nov 25, 1998 | Mar | CRLD |

VINORELBINE TARTRATE

INJECTABLE; INJECTION

VINORELBINE TARTRATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AP | AM PHARM | EQ 10MG BASE/ML | N76849 | 001 | Apr 18, 2005 | Mar | NEWA |

ASPIRIN

TABLET; ORAL

BAYER EXTRA STRENGTH ASPIRIN FOR MIGRAINE PAIN

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | @ BAYER | 500MG | N21317 | 001 | Oct 18, 2001 | Mar | CMFD |
| >A> | | 500MG | N21317 | 001 | Oct 18, 2001 | Mar | CMFD |

CLOTRIMAZOLE

TABLET; VAGINAL

GYNIX

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | COPLEY PHARM | 100MG | N73249 | 001 | Feb 13, 1998 | Mar | CAHN |
| >A> | TEVA PHARMS | 100MG | N73249 | 001 | Feb 13, 1998 | Mar | CAHN |

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | PERRIGO | 10MG | N75400 | 001 | Mar 18, 2005 | Mar | NEWA |
| | WOCKHARDT | 10MG | N77146 | 001 | Mar 07, 2005 | Feb | NEWA |

LORATADINE

SYRUP; ORAL

CLARITIN HIVES RELIEF

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | @ SCHERING | 1MG/ML | N20641 | 003 | Nov 19, 2003 | Jan | DISC |

MICONAZOLE NITRATE

CREAM; VAGINAL

MICONAZOLE 3

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | TARO | 4% | N76773 | 001 | Mar 02, 2005 | Feb | NEWA |

**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

**CUMULATIVE SUPPLEMENT NUMBER 03 MARCH 2005**

NO MARCH 2005 APPROVALS

# ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of List of Orphan Designations and Approvals is available at:

http://www.fda.gov/orphan/designat/list.htm

**DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION**

NO MARCH 2005 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnote for information regarding report content

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | PATENT CODE(S) | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| >ADD> | 021457 001 | ALBUTEROL SULFATE;ALBUTEROL SULFATE HF | 5695743 | JUL 06, 2010 | DP U491 | | |
| >ADD> | | | 5766573 | NOV 29, 2009 | U356 | | |
| | | | 5605674 | FEB 25, 2014 | DP | | |
| | | | 6352684 | NOV 28, 2009 | DP | | |
| | 021726 001 | ALPRAZOLAM;NIRAVAM | 6221392 | APR 09, 2018 | DP | | |
| | | | 6024981 | APR 09, 2018 | DP | | |
| | 021726 002 | ALPRAZOLAM;NIRAVAM | 6221392 | APR 09, 2018 | DP | | |
| | | | 6024981 | APR 09, 2018 | DP | | |
| | 021726 003 | ALPRAZOLAM;NIRAVAM | 6221392 | APR 09, 2018 | DP | | |
| | | | 6024981 | APR 09, 2018 | DP | | |
| | 021726 004 | ALPRAZOLAM;NIRAVAM | 6221392 | APR 09, 2018 | DP | | |
| | | | 6024981 | APR 09, 2018 | DP | | |
| | 021713 001 | ARIPIPRAZOLE;ABILIFY | | | | NCE | NOV 15, 2007 |
| | | | | | | I-437 | SEP 29, 2007 |
| | | | | | | I-401 | AUG 28, 2006 |
| | 021248 001 | ARSENIC TRIOXIDE;TRISENOX | 6855339 | NOV 10, 2018 | U617 | | |
| | | | 6861076 | NOV 10, 2018 | U617 | | |
| >ADD> | 021411 007 | ATOMOXETINE HYDROCHLORIDE;STRATTERA | 5658590 | JAN 11, 2015 | U494 | NCE | NOV 26, 2007 |
| >ADD> | | | 5658590*PED | JAN 11, 2015 | | PED | MAY 26, 2008 |
| >ADD> | 021411 008 | ATOMOXETINE HYDROCHLORIDE;STRATTERA | 5658590 | JAN 11, 2015 | U494 | NCE | NOV 26, 2007 |
| >ADD> | | | 5658590*PED | JAN 11, 2015 | | PED | MAY 26, 2008 |
| >ADD> | 021602 001 | BORTEZOMIB;VELCADE | | | | I-452 | MAR 25, 2008 |
| >ADD> | 021664 001 | BROMFENAC SODIUM;XIBROM | | | | NP | MAR 24, 2008 |
| | 020838 001 | CANDESARTAN CILEXETIL;ATACAND | | | | I-448 | FEB 22, 2008 |
| | 020838 002 | CANDESARTAN CILEXETIL;ATACAND | | | | I-448 | FEB 22, 2008 |
| | 020838 003 | CANDESARTAN CILEXETIL;ATACAND | | | | I-448 | FEB 22, 2008 |
| | 020838 004 | CANDESARTAN CILEXETIL;ATACAND | | | | I-448 | FEB 22, 2008 |
| | 021710 001 | CARBAMAZEPINE;EQUETRO | 5326570 | JUL 23, 2011 | DP U627 | | |
| | | | 5912013 | JUN 15, 2016 | DP | | |
| | 021710 002 | CARBAMAZEPINE;EQUETRO | 5326570 | JUL 23, 2011 | DP U627 | | |
| | | | 5912013 | JUN 15, 2016 | DP | | |
| | 021710 003 | CARBAMAZEPINE;EQUETRO | 5326570 | JUL 23, 2011 | DP U627 | | |
| | | | 5912013 | JUN 15, 2016 | DP | | |
| >ADD> | 021197 001 | CETRORELIX;CETROTIDE | 6863891 | FEB 19, 2013 | U426 | | |
| >ADD> | 021197 002 | CETRORELIX;CETROTIDE | 6863891 | FEB 19, 2013 | U426 | | |
| | 021673 001 | CLOFARABINE;CLOLAR | 5661136 | AUG 26, 2014 | U626 | | |
| | | | 5384310 | MAY 23, 2009 | DS DP | | |
| | | | 4918179 | JUN 14, 2005 | DS | | |
| >ADD> | 020222 001 | COLESTIPOL HYDROCHLORIDE;COLESTID | 5490987 | FEB 13, 2013 | DP | | |
| | 021572 001 | DAPTOMYCIN;CUBICIN | 6852689 | SEP 24, 2019 | U282 | | |
| | 021572 002 | DAPTOMYCIN;CUBICIN | 6852689 | SEP 24, 2019 | U282 | | |
| >ADD> | 021513 001 | DARIFENACIN HYDROBROMIDE;ENABLEX | 6106864 | AUG 21, 2016 | DP U630 | | |
| >ADD> | | | 5096890 | MAR 13, 2010 | DS DP U631 | | |
| >ADD> | 021513 002 | DARIFENACIN HYDROBROMIDE;ENABLEX | 6106864 | AUG 21, 2016 | DP U630 | | |
| >ADD> | | | 5096890 | MAR 13, 2010 | DS DP U631 | | |
| >ADD> | 021271 001 | DESIRUDIN RECOMBINANT;IPRIVASK | | | | NCE | APR 04, 2008 |
| | 021605 001 | DESLORATADINE;CLARINEX D 24 HOUR | | | | NCE | DEC 21, 2006 |
| | | | | | | PED | JUN 21, 2007 |
| >ADD> | | | | | | NC | MAR 03, 2008 |
| | 076068 001 | DEXRAZOXANE HYDROCHLORIDE;DEXRAZOXANE | | | | PC | AUG 27, 2005 |
| | 021168 001 | DIVALPROEX SODIUM;DEPAKOTE ER | 6720004 | DEC 18, 2018 | DP | | |
| | 021168 002 | DIVALPROEX SODIUM;DEPAKOTE ER | 6720004 | DEC 18, 2018 | DP | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | PATENT CODE(S) | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 021269 001 | DOXAZOSIN MESYLATE;CARDURA XL | | | | NDF | FEB 22, 2008 |
| >ADD> | 021269 002 | DOXAZOSIN MESYLATE;CARDURA XL | 4837111 | MAR 21, 2008 | DP | NDF | FEB 22, 2008 |
| >ADD> | 021504 001 | EPINEPHRINE;LIDOSITE TOPICAL SYS | 6862473 | SEP 30, 2013 | DP | | |
| | 021437 001 | EPLERENONE;INSPRA | 4559332 | APR 09, 2005 | DS DP U537 | | |
| | 021437 002 | EPLERENONE;INSPRA | 4559332 | APR 09, 2005 | DS DP U537 | | |
| | 021437 003 | EPLERENONE;INSPRA | 4559332 | APR 09, 2005 | DS DP U537 | | |
| | 021337 001 | ERTAPENEM SODIUM;INVANZ | 5478820 | FEB 02, 2013 | | NCE | NOV 21, 2006 |
| | | | 5652233 | FEB 02, 2013 | | PED | MAY 21, 2007 |
| | | | 5952323 | MAY 15, 2017 | | | |
| | | | 5478820*PED | AUG 02, 2013 | | | |
| | | | 5652233*PED | AUG 02, 2013 | | | |
| | | | 5952323*PED | NOV 15, 2017 | | | |
| | 076323 001 | ESMOLOL HYDROCHLORIDE;ESMOLOL HCL | | | | PC | MAY 01, 2005 |
| >ADD> | 021153 001 | ESOMEPRAZOLE MAGNESIUM;NEXIUM | 4738974 | APR 19, 2006 | DS DP U373 | | |
| >ADD> | | | 4738974*PED | OCT 19, 2006 | U635 | | |
| >ADD> | | | 6875872 | MAY 27, 2014 | DS U373 | | |
| >ADD> | | | 6875872*PED | NOV 27, 2014 | | | |
| >ADD> | 021153 002 | ESOMEPRAZOLE MAGNESIUM;NEXIUM | 4738974 | APR 19, 2006 | DS DP U373 | | |
| >ADD> | | | 4738974*PED | OCT 19, 2006 | U635 | | |
| >ADD> | | | 6875872 | MAY 27, 2014 | DS U373 | | |
| >ADD> | | | 6875872*PED | NOV 27, 2014 | | | |
| >ADD> | 021443 001 | ESTROGENS, CONJUGATED SYNTHETIC B;ENJUVIA | 6855703 | FEB 12, 2021 | DS DP U284 | NP | DEC 20, 2007 |
| >ADD> | | | 6660726 | MAR 08, 2021 | DS DP U196 | | |
| | | | | | U284 | | |
| >ADD> | 021443 002 | ESTROGENS, CONJUGATED SYNTHETIC B;ENJUVIA | 6855703 | FEB 12, 2021 | DS DP U284 | NP | DEC 20, 2007 |
| >ADD> | | | 6660726 | MAR 08, 2021 | DS DP U196 | | |
| | | | | | U284 | | |
| >ADD> | 021443 003 | ESTROGENS, CONJUGATED SYNTHETIC B;ENJUVIA | 6855703 | FEB 12, 2021 | DS DP U284 | | |
| >ADD> | | | 6660726 | MAR 08, 2021 | DS DP U196 | | |
| | | | | | U284 | | |
| >ADD> | 021443 004 | ESTROGENS, CONJUGATED SYNTHETIC B;ENJUVIA | 6855703 | FEB 12, 2021 | DS DP U284 | | |
| >ADD> | | | 6660726 | MAR 08, 2021 | DS DP U196 | | |
| | | | | | U284 | | |
| >ADD> | 021476 001 | ESZOPICLONE;LUNESTA | 6864257 | AUG 30, 2012 | U629 | | |
| | | | 6444673 | JAN 16, 2012 | DS DP | | |
| | | | 6319926 | JAN 16, 2012 | U620 | | |
| >ADD> | 021476 002 | ESZOPICLONE;LUNESTA | 6864257 | AUG 30, 2012 | U629 | | |
| | | | 6444673 | JAN 16, 2012 | DS DP | | |
| | | | 6319926 | JAN 16, 2012 | U620 | | |
| >ADD> | 021476 003 | ESZOPICLONE;LUNESTA | 6864257 | AUG 30, 2012 | U629 | | |
| | | | 6444673 | JAN 16, 2012 | DS DP | | |
| | | | 6319926 | JAN 16, 2012 | U620 | | |
| | 021712 001 | FAMOTIDINE;FLUXID | 6024981 | APR 09, 2018 | DP | | |
| | | | 6221392 | APR 09, 2018 | DP | | |
| | 021712 002 | FAMOTIDINE;FLUXID | 6024981 | APR 09, 2018 | DP | | |
| | | | 6221392 | APR 09, 2018 | DP | | |
| | 020747 001 | FENTANYL CITRATE;ACTIQ | 5785989 | MAY 01, 2005 | | | |
| | 020747 002 | FENTANYL CITRATE;ACTIQ | 5785989 | MAY 01, 2005 | | | |
| | 020747 003 | FENTANYL CITRATE;ACTIQ | 5785989 | MAY 01, 2005 | | | |
| | 020747 004 | FENTANYL CITRATE;ACTIQ | 5785989 | MAY 01, 2005 | | | |
| | 020747 005 | FENTANYL CITRATE;ACTIQ | 5785989 | MAY 01, 2005 | | | |
| | 020747 006 | FENTANYL CITRATE;ACTIQ | 5785989 | MAY 01, 2005 | | | |

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PATENT AND EXCLUSIVITY DATA
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|---|---|---|---|---|---|---|---|
| | 019813 005 | FENTANYL;DURAGESIC-12 | | | | NPP | MAY 20, 2006 |
| | | | | | | PED | NOV 20, 2006 |
| | 021758 001 | FLUOCINONIDE;VANOS | | | | NP | FEB 11, 2008 |
| | 021077 001 | FLUTICASONE PROPIONATE;ADVAIR DISKUS 100/50 | 6536427 | MAR 01, 2011 | DP | | |
| | 021077 002 | FLUTICASONE PROPIONATE;ADVAIR DISKUS 250/50 | 6536427 | MAR 01, 2011 | DP | | |
| | 021077 003 | FLUTICASONE PROPIONATE;ADVAIR DISKUS 500/50 | 6536427 | MAR 01, 2011 | DP | | |
| >ADD> | 021152 001 | FLUTICASONE PROPIONATE;CUTIVATE | | | | NDF | MAR 31, 2008 |
| >ADD> | | | | | | PED | SEP 30, 2008 |
| | 021169 001 | GALANTAMINE HYDROBROMIDE;REMINYL | 6358527 | JUN 06, 2017 | DP U322 | | |
| | 021169 002 | GALANTAMINE HYDROBROMIDE;REMINYL | 6358527 | JUN 06, 2017 | DP U322 | | |
| | 021169 003 | GALANTAMINE HYDROBROMIDE;REMINYL | 6358527 | JUN 06, 2017 | DP U322 | | |
| | 020509 001 | GEMCITABINE HYDROCHLORIDE;GEMZAR | 4808614 | MAY 15, 2010 | DS | I-428 | MAY 19, 2007 |
| | | | 5464826 | NOV 07, 2012 | U146 | PED | NOV 19, 2007 |
| | | | 4808614*PED | NOV 15, 2010 | | | |
| | | | 5464826*PED | MAY 07, 2013 | | | |
| | 020509 002 | GEMCITABINE HYDROCHLORIDE;GEMZAR | 5464826 | NOV 07, 2012 | U146 | I-428 | MAY 19, 2007 |
| | | | 4808614 | MAY 15, 2010 | DS | PED | NOV 19, 2007 |
| | | | 4808614*PED | NOV 15, 2010 | | | |
| | | | 5464826*PED | MAY 07, 2013 | | | |
| | 020239 003 | GRANISETRON HYDROCHLORIDE;KYTRIL | 4886808 | DEC 29, 2007 | DS DP U89 | I-369 | AUG 16, 2005 |
| | 020239 004 | GRANISETRON HYDROCHLORIDE;KYTRIL | | | | I-369 | AUG 16, 2005 |
| >ADD> | 021455 002 | IBANDRONATE SODIUM;BONIVA | | | | D-96 | MAR 24, 2008 |
| >ADD> | | | | | | NS | MAR 24, 2008 |
| >ADD> | | | | | | NCE | MAY 16, 2008 |
| | 021335 001 | IMATINIB MESYLATE;GLEEVEC | 5521184 | JAN 04, 2015 | | | |
| | 021335 002 | IMATINIB MESYLATE;GLEEVEC | 5521184 | JAN 04, 2015 | | | |
| | 021588 001 | IMATINIB MESYLATE;GLEEVEC | 5521184 | JAN 04, 2015 | | | |
| | 021588 002 | IMATINIB MESYLATE;GLEEVEC | 5521184 | JAN 04, 2015 | | | |
| >ADD> | 076104 001 | ITRACONAZOLE;ITRACONAZOLE | | | | PC | AUG 08, 2005 |
| | 020726 001 | LETROZOLE;FEMARA | | | | I-446 | OCT 29, 2007 |
| | 021731 001 | LEUPROLIDE ACETATE;ELIGARD | RE37950 | OCT 03, 2008 | DP U621 | | |
| | | | 4938763 | OCT 03, 2008 | DP U621 | | |
| | | | 5278201 | JAN 11, 2011 | DP | | |
| | | | 5324519 | JUN 28, 2011 | DP | | |
| | | | 5599552 | FEB 04, 2014 | DP U621 | | |
| | | | 5739176 | OCT 03, 2008 | DP U621 | | |
| | | | 6395293 | SEP 28, 2013 | DP | | |
| | | | 6565874 | OCT 28, 2018 | DP U621 | | |
| | | | 6626870 | MAR 27, 2020 | DP | | |
| | | | 6773714 | OCT 28, 2018 | U621 | | |
| >ADD> | 021730 001 | LEVALBUTEROL TARTRATE;XOPENEX HFA | | | | NP | MAR 11, 2008 |
| | 021130 001 | LINEZOLID;ZYVOX | 5688792 | NOV 18, 2014 | DS U319 | NCE | APR 18, 2005 |
| | | | 6559305 | JAN 29, 2021 | DS | NPP | DEC 19, 2005 |
| | | | 6514529 | MAR 15, 2021 | DP | I-402 | JUL 22, 2006 |
| | | | 5688792*PED | MAY 18, 2015 | | I-431 | JUN 23, 2007 |
| | | | 6514529*PED | SEP 15, 2021 | | PED | JAN 22, 2007 |
| | | | 6559305*PED | JUL 29, 2021 | | PED | OCT 18, 2005 |
| | | | | | | PED | DEC 23, 2007 |
| | | | | | | PED | JUN 19, 2006 |
| | 021130 002 | LINEZOLID;ZYVOX | 5688792 | NOV 18, 2014 | DS U319 | NCE | APR 18, 2005 |
| | | | 6559305 | JAN 29, 2021 | DS | NPP | DEC 19, 2005 |
| | | | 6514529 | MAR 15, 2021 | DP | I-402 | JUL 22, 2006 |
| | | | 5688792*PED | MAY 18, 2015 | | I-431 | JUN 23, 2007 |
| | | | 6514529*PED | SEP 15, 2021 | | PED | JAN 22, 2007 |
| | | | 6559305*PED | JUL 29, 2021 | | PED | OCT 18, 2005 |
| | | | | | | PED | DEC 23, 2007 |

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|---|---|---|---|---|---|---|---|
| | | | | | | PED | JUN 19, 2006 |
| | 021131 001 | LINEZOLID;ZYVOX | 5688792 | NOV 18, 2014 | U319 | NCE | APR 18, 2005 |
| | | | 6559305 | JAN 29, 2021 | DS | NPP | DEC 19, 2005 |
| | | | 5688792*PED | MAY 18, 2015 | | I-402 | JUL 22, 2006 |
| | | | 6559305*PED | JUL 29, 2021 | | I-431 | JUN 23, 2007 |
| | | | | | | PED | JUN 19, 2006 |
| | | | | | | PED | JAN 22, 2007 |
| | | | | | | PED | OCT 18, 2005 |
| | | | | | | PED | DEC 23, 2007 |
| | 021132 001 | LINEZOLID;ZYVOX | 5688792 | NOV 18, 2014 | DS U319 | NCE | APR 18, 2005 |
| | | | 6559305 | JAN 29, 2021 | DS | NPP | DEC 19, 2005 |
| | | | 5688792*PED | MAY 18, 2015 | | I-402 | JUL 22, 2006 |
| | | | 6559305*PED | JUL 29, 2021 | | I-431 | JUN 23, 2007 |
| | | | | | | PED | OCT 18, 2005 |
| | | | | | | PED | JAN 22, 2007 |
| | | | | | | PED | DEC 23, 2007 |
| | | | | | | PED | JUN 19, 2006 |
| >ADD> | 021316 001 | LOVASTATIN;ALTOPREV | 6485748 | DEC 12, 2017 | DP | | |
| >ADD> | 021316 002 | LOVASTATIN;ALTOPREV | 6485748 | DEC 12, 2017 | DP | | |
| >ADD> | 021316 003 | LOVASTATIN;ALTOPREV | 6485748 | DEC 12, 2017 | DP | | |
| >ADD> | 021316 004 | LOVASTATIN;ALTOPREV | 6485748 | DEC 12, 2017 | DP | | |
| >ADD> | 021583 001 | MEDROXYPROGESTERONE ACETATE;DEPO-SUBQ PROVERA 10 | 6495534 | MAY 15, 2020 | DP | I-451 | MAR 25, 2008 |
| >ADD> | 020938 001 | MELOXICAM;MOBIC | | | | NCE | APR 13, 2005 |
| >ADD> | | | | | | I-430 | JUL 16, 2007 |
| >ADD> | | | | | | PED | OCT 13, 2005 |
| >ADD> | | | | | | PED | JAN 16, 2008 |
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| >ADD> | 021506 002 | MICAFUNGIN SODIUM;MYCAMINE | | | | NCE | MAR 16, 2010 |
| >ADD> | 020717 001 | MODAFINIL;PROVIGIL | | | | I-449 | JAN 23, 2007 |
| >ADD> | 020717 002 | MODAFINIL;PROVIGIL | | | | I-449 | JAN 23, 2007 |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnote for information regarding report content

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | PATENT CODE(S) | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 020762 001 | MOMETASONE FUROATE MONOHYDRATE;NASONEX | 5837699 | JAN 27, 2014 | DP U625 | | |
| | | | 6127353 | OCT 03, 2017 | DS DP | | |
| | | | 6723713 | JAN 27, 2014 | U625 | | |
| >ADD> | 021067 001 | MOMETASONE FUROATE;ASMANEX TWISTHALER | | | | NP | MAR 30, 2008 |
| | 021204 001 | NATEGLINIDE;STARLIX | RE34878 | SEP 08, 2009 | | | |
| | | | 6844008 | NOV 14, 2017 | DP U214 | | |
| | 021204 002 | NATEGLINIDE;STARLIX | RE34878 | SEP 08, 2009 | | | |
| | | | 6844008 | NOV 14, 2017 | DP U214 | | |
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| | 021706 001 | OMEPRAZOLE;ZEGERID | 5840737 | JUL 16, 2016 | DS U623 | | |
| | | | 6489346 | JUL 16, 2016 | DS DP U624 | | |
| | | | 6645988 | JUL 16, 2016 | DS DP U623 | | |
| | | | 6780882 | JUL 16, 2016 | DS DP U624 | | |
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| | 021759 001 | OXALIPLATIN;ELOXATIN | | | | NCE | AUG 09, 2007 |
| | | | | | | I-441 | NOV 04, 2007 |
| | 021759 002 | OXALIPLATIN;ELOXATIN | | | | NCE | AUG 09, 2007 |
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| | 021014 001 | OXCARBAZEPINE;TRILEPTAL | | | | NCE | JAN 14, 2005 |
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| | 021014 002 | OXCARBAZEPINE;TRILEPTAL | | | | NCE | JAN 14, 2005 |
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| | | | | | | PED | JUL 14, 2005 |
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| | | | | | | PED | JUL 14, 2005 |
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| | 021756 001 | PEGAPTANIB SODIUM;MACUGEN | 6051698 | SEP 17, 2012 | DS | | |
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| | | | 5932462 | AUG 03, 2016 | DS | | |
| | | | 6113906 | OCT 27, 2013 | DS | | |
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| | | | 6426335 | JUN 11, 2010 | U622 | | |
| | | | 6147204 | JUN 11, 2010 | DS | | |
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| | 021446 001 | PREGABALIN;LYRICA | 6001876 | JUL 16, 2017 | U55 | | |
| | | | 6197819 | MAR 06, 2018 | DS DP | | |
| | 021446 002 | PREGABALIN;LYRICA | 6001876 | JUL 16, 2017 | U55 | | |
| | | | 6197819 | MAR 06, 2018 | DS DP | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnote for information regarding report content

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | PATENT CODE(S) | EXCLUS CODE | EXCLUS EXPIRES |
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| | 021446 003 | PREGABALIN;LYRICA | 6001876 | JUL 16, 2017 | U55 | | |
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| | 021446 004 | PREGABALIN;LYRICA | 6001876 | JUL 16, 2017 | U55 | | |
| | | | 6197819 | MAR 06, 2018 | DS DP | | |
| | 021446 005 | PREGABALIN;LYRICA | 6001876 | JUL 16, 2017 | U55 | | |
| | | | 6197819 | MAR 06, 2018 | DS DP | | |
| | 021446 006 | PREGABALIN;LYRICA | 6001876 | JUL 16, 2017 | U55 | | |
| | | | 6197819 | MAR 06, 2018 | DS DP | | |
| | 021446 007 | PREGABALIN;LYRICA | 6001876 | JUL 16, 2017 | U55 | | |
| | | | 6197819 | MAR 06, 2018 | DS DP | | |
| | 021446 008 | PREGABALIN;LYRICA | 6001876 | JUL 16, 2017 | U55 | | |
| | | | 6197819 | MAR 06, 2018 | DS DP | | |
| | 021511 001 | RIBAVIRIN;COPEGUS | | | | I-447 | FEB 25, 2008 |
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| | | | | | U628 | | |
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| | 020645 001 | SODIUM BENZOATE;AMMONUL | | | | NDF | FEB 17, 2008 |
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| >ADD> | 021144 002 | TELITHROMYCIN;KETEK | | | | NCE | APR 01, 2009 |
| >ADD> | 021029 001 | TEMOZOLOMIDE;TEMODAR | 5260291 | AUG 11, 2013 | DS DP U619 | ODE | MAR 15, 2012 |
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| | 020505 001 | TOPIRAMATE;TOPAMAX | | | | I-41 | AUG 11, 2007 |
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| | 020505 003 | TOPIRAMATE;TOPAMAX | | | | I-41 | AUG 11, 2007 |
| | 020505 004 | TOPIRAMATE;TOPAMAX | | | | I-41 | AUG 11, 2007 |
| | 020505 005 | TOPIRAMATE;TOPAMAX | | | | I-41 | AUG 11, 2007 |
| | 020505 006 | TOPIRAMATE;TOPAMAX | | | | I-41 | AUG 11, 2007 |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | PATENT CODE(S) | EXCLUS CODE | EXCLUS EXPIRES |
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| | 020844 001 | TOPIRAMATE;TOPAMAX SPRINKLE | | | | I-41 | AUG 11, 2007 |
| | 020844 002 | TOPIRAMATE;TOPAMAX SPRINKLE | | | | I-41 | AUG 11, 2007 |
| | 020844 003 | TOPIRAMATE;TOPAMAX SPRINKLE | | | | I-41 | AUG 11, 2007 |
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| | 021060 001 | ZICONOTIDE;PRIALT | 5795864 | JUN 27, 2015 | DP | | |
| | | | 5364842 | DEC 30, 2011 | U48 | | |
| | | | 5859186 | DEC 30, 2011 | U55 | | |
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| | | | 5859186 | DEC 30, 2011 | U55 | | |
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| | | | | | U55 | | |

Footnote:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).

2. Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:
   DS = Drug Substance claim
   DP = Drug Product claim
   U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at http://www.fda.gov/cder/orange/patex.htm

3. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.

4. *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.

# PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 25th Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

The current complete list of Patent terms is available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/pattermsall.cfm