CUMULATIVE
SUPPLEMENT 3
MARCH 2004

# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

## 24th EDITION


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





2004

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

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Please Note:

The 24th Edition of the Orange Book will be the last paper version. All the components of the paper Orange Book are and have been available on the Internet since 1997. Refer to the Introduction 1.3, Availability of the Edition, for specific locations. Additional details will be made available in future Cumulative Supplement publications.

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

**24th EDITION**

**CUMULATIVE SUPPLEMENT 3**
**March 2004**

# 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, 24th 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have never been marketed, are for exportation, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 23rd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 24th Edition. The current edition Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. 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. 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 A, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

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.

## 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

APPLICANT NAME CHANGES

| FORMER APPLICANT NAME (FORMER ABBREVIATED NAME) | NEW APPLICANT NAME (NEW ABBREVIATED NAME) |
|---|---|
| BERLEX (BERLEX) | BERLEX INC (BERLEX INC) |
| BERLEX LABORATORIES INC (BERLEX LABS) | BERLEX INC (BERLEX INC) |
| BERLEX LABORATORIES INC SUB SCHERING AG (BERLEX) | BERLEX INC (BERLEX INC) |

## 1.3 RIBAVIRIN 200MG ORAL CAPSULE

The footnote for Ribabvirin 200MG capsule product 001 was inadvertently omitted from the 24th Edition. The footnote: Indicated for use and comarketed with interferon alfa-2b, recombinant (Intron A), as Rebetron Combination Therapy.

## 1.4 AVAILABILITY OF THE EDITION

The 24th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800 or toll free 866-512-1800. The cost is $110.00 annually. A GPO Orange Book Subscription form is provided at the end of each cumulative supplement.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

The Electronic Orange Book Query (EOB) is at http://www.fda.gov/cder/ob. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant 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. The data is updated concurrently with the publication of the monthly cumulative supplements.

The Internet version of the Orange Book annual edition is at
http://www.fda.gov/cder/orange/adp.htm.

The Internet version of the monthly supplement is at
http://www.fda.gov/cder/orange/supplement/cspreface.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 zipobtxt.exe. The files are updated concurrently with the publication of the monthly cumulative supplements. Appendix A and Appendix B text files of the paper annual Orange Book are updated quarterly.

The 24th annual edition of the 2003 Orange Book Patent and Exclusivity List is at
http://www.fda.gov/cder/orange/24bookpub.pdf.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at http://www.fda.gov/cder/orange/supplement/patents.pdf.

The Patent Term Extension and new Patents, Docket Number *95S-0117, is at
http://www.fda.gov/cder/orange/docket.pdf. It is updated approximately weekly.

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 Program Support Center Forms Download Website,
http://forms/psc.gov/forms/FDA/fda.html

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

## 1.5 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 2003) 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 2003 | MAR 2004 | JUN 2004 | SEP 2004 |
|---|---|---|---|---|
| DRUG PRODUCTS LISTED | 10665 | 10668 | | |
| SINGLE SOURCE | 2423 (22.7%) | 2404 (22.5%) | | |
| MULTISOURCE | 8134 (76.3%) | 8156 (76.5%) | | |
| THERAPEUTICALLY EQUIVALENT | 7856 (73.7%) | 7885 (73.9%) | | |
| NOT THERAPEUTICALLY EQUIVALENT | 278 (2.6%) | 271 (2.5%) | | |
| EXCEPTIONS[1] | 108 (1.0%) | 108 (1.0%) | | |
| NEW MOLECULAR ENTITIES APPROVED | 6 | 3 | | |
| NUMBER OF APPLICANTS | 601 | 586 | | |

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

## 1.6 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 Approval 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. |
| 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. |

ACETYLCYSTEINE

INJECTABLE; INTRAVENOUS

ACETADOTE

\+ CUMBERLAND PHARMS 6GM /30ML(200MG/ML) N21539 001 Jan 23, 2004 Jan NEWA

ACITRETIN

CAPSULE; ORAL

SORIATANE

>A> CONNETICS 10MG N19821 001 Oct 28, 1996 Mar CAHN
>A> + 25MG N19821 002 Oct 28, 1996 Mar CAHN
>D> HLR 10MG N19821 001 Oct 28, 1996 Mar CAHN
>D> + 25MG N19821 002 Oct 28, 1996 Mar CAHN

ALBUTEROL SULFATE

TABLET, EXTENDED RELEASE; ORAL

ALBUTEROL SULFATE

\+ PLIVA EQ 4MG BASE N76130 002 Sep 26, 2002 Jan CRLD
\+ EQ 8MG BASE N76130 003 Sep 26, 2002 Jan CRLD

VOLMAX

@ MURO EQ 4MG BASE N19604 002 Dec 23, 1992 Jan DISC
@ EQ 8MG BASE N19604 001 Dec 23, 1992 Jan DISC

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

AMIODARONE HYDROCHLORIDE

AP INTL MEDICATION SYS 50MG/ML N21594 001 Feb 04, 2004 Feb NEWA

AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM

TABLET; ORAL

CADUET

PFIZER EQ 5MG BASE;EQ 10MG BASE N21540 001 Jan 30, 2004 Jan NEWA
EQ 5MG BASE;EQ 20MG BASE N21540 002 Jan 30, 2004 Jan NEWA
EQ 5MG BASE;EQ 40MG BASE N21540 003 Jan 30, 2004 Jan NEWA
EQ 5MG BASE;EQ 80MG BASE N21540 004 Jan 30, 2004 Jan NEWA
EQ 10MG BASE;EQ 10MG BASE N21540 005 Jan 30, 2004 Jan NEWA
EQ 10MG BASE;EQ 20MG BASE N21540 006 Jan 30, 2004 Jan NEWA
EQ 10MG BASE;EQ 40MG BASE N21540 007 Jan 30, 2004 Jan NEWA
\+ EQ 10MG BASE;EQ 80MG BASE N21540 008 Jan 30, 2004 Jan NEWA

>D> AMLODIPINE MALEATE

>D> TABLET; ORAL

>D> AMVAZ

>D> @ DR REDDYS LABS INC 2.5MG N21435 001 Oct 31, 2003 Mar DISC
>A> @ 2.5MG N21435 001 Oct 31, 2003 Mar DISC
>D> @ 5MG N21435 002 Oct 31, 2003 Mar DISC
>A> @ 5MG N21435 002 Oct 31, 2003 Mar DISC
>D> @ 10MG N21435 003 Oct 31, 2003 Mar DISC
>A> @ 10MG N21435 003 Oct 31, 2003 Mar DISC

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

>A> AMOXICILLIN AND CLAVULANATE POTASSIUM
>A> AB TEVA 600MG/5ML;EQ 42.9MG BASE/5ML N65162 001 Mar 12, 2004 Mar NEWA

FOR SUSPENSION; ORAL

AUGMENTIN ES-600

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | GLAXOSMITHKLINE | 600MG/5ML;EQ 42.9MG BASE/5ML | N50755 | 001 | Jun 22, 2001 | Mar | CFTG |
| >A> | AB | + | | 600MG/5ML;EQ 42.9MG BASE/5ML | N50755 | 001 | Jun 22, 2001 | Mar | CFTG |

ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K

INJECTABLE; IV (INFUSION)

INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE)

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | SABEX 2002 | 80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.14MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG/VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL | N21646 | 001 | Jan 29, 2004 | Jan | NEWA |

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E; VITAMIN K

INJECTABLE; IV (INFUSION)

M.V.I. ADULT

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | AAIPHARMA LLC | 200MG/VIAL;0.06MG/VIAL;0.005MG/VIAL;15MG/VIAL;0.005MG/VIAL;0.6MG/VIAL;40MG/VIAL;6MG/VIAL;3.6MG/VIAL;6MG/VIAL;1MG/VIAL;10MG/VIAL;0.15MG/VIAL | N21625 | 001 | Jan 30, 2004 | Jan | NEWA |

M.V.I. ADULT (PHARMACY BULK PACKAGE)

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | AAIPHARMA LLC | 200MG/5ML;0.06MG/5ML;0.005MG/5ML;15MG/5ML;0.005MG/5ML;0.6MG/5ML;40MG/5ML;6MG/5ML;3.6MG/5ML;6MG/5ML;1MG/5ML;10MG/5ML;0.15MG/5ML | N21643 | 001 | Feb 18, 2004 | Feb | NEWA |

AZITHROMYCIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | | CAPSULE; ORAL | | | | | | |
| >D> | | | ZITHROMAX | | | | | | |
| >D> | | + | PFIZER | EQ 250MG BASE | N50670 | 001 | Nov 01, 1991 | Mar | DISC |
| >A> | | | @ | EQ 250MG BASE | N50670 | 001 | Nov 01, 1991 | Mar | DISC |

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

CORTISPORIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AT | + | MONARCH PHARMS | 400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM | N50416 | 002 | | Mar | CRLD |
| >A> | AT | | | 400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM | N50416 | 002 | | Mar | CRLD |

NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC AND HYDROCORTISONE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AT | | BAUSCH AND LOMB | 400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM | N64068 | 001 | Oct 30, 1995 | Mar | CRLD |
| >A> | AT | + | | 400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM | N64068 | 001 | Oct 30, 1995 | Mar | CRLD |

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATE AND BACITRACIN ZINC

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AT | | AKORN | 400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM | N65088 | 001 | Feb 06, 2004 | Feb | NEWA |

NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AT | | BAUSCH AND LOMB | 400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM | N64064 | 001 | Oct 30, 1995 | Mar | CRLD |
| >A> | AT | + | | 400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM | N64064 | 001 | Oct 30, 1995 | Mar | CRLD |

NEOSPORIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AT | + | MONARCH PHARMS | 400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM | N50417 | 001 | | Mar | CRLD |
| >A> | AT | | | 400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM | N50417 | 001 | | Mar | CRLD |

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

BACITRACIN ZINC AND POLYMYXIN B SULFATE

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| >D> | AT | | BAUSCH AND LOMB | 500 UNITS/GM;10,000 UNITS/GM | N64046 | 001 | Jan 26, 1995 | Mar | CRLD |
| >A> | AT | + | | 500 UNITS/GM;10,000 UNITS/GM | N64046 | 001 | Jan 26, 1995 | Mar | CRLD |

POLYSPORIN

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| >D> | AT | + | MONARCH PHARMS | 500 UNITS/GM;10,000 UNITS/GM | N61229 | 001 | | Mar | CRLD |
| >A> | AT | | | 500 UNITS/GM;10,000 UNITS/GM | N61229 | 001 | | Mar | CRLD |

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL

BENAZEPRIL HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | ANDRX PHARMS | 5MG | N76267 | 001 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 10MG | N76267 | 002 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 20MG | N76267 | 003 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 40MG | N76267 | 004 | Feb 11, 2004 | Feb | NEWA |
| AB | | EON | 5MG | N76402 | 001 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 10MG | N76402 | 002 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 20MG | N76402 | 003 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 40MG | N76402 | 004 | Feb 11, 2004 | Feb | NEWA |
| AB | | GENPHARM | 5MG | N76476 | 001 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 10MG | N76476 | 002 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 20MG | N76476 | 003 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 40MG | N76476 | 004 | Feb 11, 2004 | Feb | NEWA |
| AB | | IVAX PHARMS | 5MG | N76333 | 001 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 10MG | N76333 | 002 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 20MG | N76333 | 003 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 40MG | N76333 | 004 | Feb 11, 2004 | Feb | NEWA |
| AB | | KV PHARM | 5MG | N76118 | 001 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 10MG | N76118 | 002 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 20MG | N76118 | 003 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 40MG | N76118 | 004 | Feb 11, 2004 | Feb | NEWA |
| AB | | MYLAN | 5MG | N76430 | 001 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 10MG | N76430 | 002 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 20MG | N76430 | 003 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 40MG | N76430 | 004 | Feb 11, 2004 | Feb | NEWA |
| AB | | RANBAXY | 5MG | N76344 | 001 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 10MG | N76344 | 002 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 20MG | N76344 | 003 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 40MG | N76344 | 004 | Feb 11, 2004 | Feb | NEWA |
| AB | | TEVA | 5MG | N76211 | 001 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 10MG | N76211 | 002 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 20MG | N76211 | 003 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 40MG | N76211 | 004 | Feb 11, 2004 | Feb | NEWA |

LOTENSIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | NOVARTIS | 5MG | N19851 | 001 | Jun 25, 1991 | Feb | CFTG |
| AB | | | 10MG | N19851 | 002 | Jun 25, 1991 | Feb | CFTG |
| AB | | | 20MG | N19851 | 003 | Jun 25, 1991 | Feb | CFTG |
| AB | + | | 40MG | N19851 | 004 | Jun 25, 1991 | Feb | CFTG |

BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

BENAZEPRIL HCL AND HYDROCHLOROTHIAZIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | ANDRX PHARMS | 5MG;6.25MG | N76342 | 001 | Feb 11, 2004 | Feb | NEWA |
| AB | | | 10MG;12.5MG | N76342 | 002 | Feb 11, 2004 | Feb | NEWA |

TABLET; ORAL

BENAZEPRIL HCL AND HYDROCHLOROTHIAZIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | | ANDRX PHARMS | 20MG;12.5MG | N76342 | 003 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 20MG;25MG | N76342 | 004 | Feb 11, 2004 | Feb NEWA |
| | AB | | EON | 5MG;6.25MG | N76631 | 001 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 10MG;12.5MG | N76631 | 002 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 20MG;12.5MG | N76631 | 003 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 20MG;25MG | N76631 | 004 | Feb 11, 2004 | Feb NEWA |
| | AB | | GENPHARM | 5MG;6.25MG | N76612 | 001 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 10MG;12.5MG | N76612 | 002 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 20MG;12.5MG | N76612 | 003 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 20MG;25MG | N76612 | 004 | Feb 11, 2004 | Feb NEWA |
| | AB | | IVAX PHARMS | 5MG;6.25MG | N76348 | 001 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 10MG;12.5MG | N76348 | 002 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 20MG;12.5MG | N76348 | 003 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 20MG;25MG | N76348 | 004 | Feb 11, 2004 | Feb NEWA |
| | AB | | MYLAN | 5MG;6.25MG | N76688 | 001 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 10MG;12.5MG | N76688 | 002 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 20MG;12.5MG | N76688 | 003 | Feb 11, 2004 | Feb NEWA |
| | AB | | | 20MG;25MG | N76688 | 004 | Feb 11, 2004 | Feb NEWA |

LOTENSIN HCT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | | NOVARTIS | 5MG;6.25MG | N20033 | 001 | May 19, 1992 | Feb CFTG |
| | AB | | | 10MG;12.5MG | N20033 | 002 | May 19, 1992 | Feb CFTG |
| | AB | | | 20MG;12.5MG | N20033 | 004 | May 19, 1992 | Feb CFTG |
| | AB | + | | 20MG;25MG | N20033 | 003 | May 19, 1992 | Feb CFTG |

## BENZOYL PEROXIDE; ERYTHROMYCIN

GEL; TOPICAL

BENZAMYCIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | + | DERMIK LABS | 5%;3% | N50557 | 001 | Oct 26, 1984 | Mar CFTG |
| >A> | AB | + | | 5%;3% | N50557 | 001 | Oct 26, 1984 | Mar CFTG |

ERYTHROMYCIN AND BENZOYL PEROXIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | ATRIX | 5%;3% | N65112 | 001 | Mar 29, 2004 | Mar NEWA |

## BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL

BETAMETHASONE DIPROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | | ATRIX | EQ 0.05% BASE | N76603 | 001 | Jan 23, 2004 | Jan NEWA |

## BETAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

BETAMETHASONE SODIUM PHOSPHATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | @ STERIS | EQ 3MG BASE/ML | N85738 | 001 | | Feb DISC |

CELESTONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | @ SCHERING | EQ 3MG BASE/ML | N17561 | 001 | | Feb DISC |

## BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

BUPROPION HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | | IMPAX LABS | 100MG | N75913 | 001 | Jan 28, 2004 | Jan NEWA |
| >A> | AB | | | 150MG | N75913 | 002 | Mar 22, 2004 | Mar NEWA |

BUPROPRION HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | EON | 150MG | N75932 | 002 | Mar 22, 2004 | Mar NEWA |

WELLBUTRIN SR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | + | GLAXOSMITHKLINE | 150MG | N20358 | 003 | Oct 04, 1996 | Mar CFTG |
| >A> | AB | + | | 150MG | N20358 | 003 | Oct 04, 1996 | Mar CFTG |

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL
BUSPIRONE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | TEVA | 30MG | N75022 | 004 | Mar 25, 2004 | Mar | NEWA |

CALCITRIOL

INJECTABLE; INJECTION
CALCITRIOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AP | MAYNE PHARMA USA | 0.001MG/ML | N75816 | 001 | Jan 16, 2004 | Jan | NEWA |
| | AP | | 0.002MG/ML | N75816 | 002 | Jan 16, 2004 | Jan | NEWA |

CARBAMAZEPINE

CAPSULE, EXTENDED RELEASE; ORAL
CARBATROL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | SHIRE PHARM | 100MG | N20712 | 003 | Sep 30, 1997 | Mar | CRLD |
| >A> | | | 100MG | N20712 | 003 | Sep 30, 1997 | Mar | CRLD |
| >D> | + | | 200MG | N20712 | 001 | Sep 30, 1997 | Mar | CRLD |
| >A> | | | 200MG | N20712 | 001 | Sep 30, 1997 | Mar | CRLD |

CARBOPLATIN

INJECTABLE; IV (INFUSION)
PARAPLATIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | BRISTOL MYERS SQUIBB | EQ 600MG /60ML(10MG/ML) | N20452 | 004 | Jan 15, 2004 | Jan | NEWA |

CEFACLOR

CAPSULE; ORAL
CEFACLOR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | CARLSBAD | EQ 250MG BASE | N65146 | 001 | Jan 22, 2004 | Jan | NEWA |
| | AB | | EQ 500MG BASE | N65146 | 002 | Jan 22, 2004 | Jan | NEWA |

CEFIXIME

SUSPENSION; ORAL
SUPRAX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | LUPIN | 100MG/5ML | N65129 | 001 | Feb 23, 2004 | Feb | NEWA |

TABLET; ORAL
SUPRAX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | LUPIN | 400MG | N65130 | 001 | Feb 12, 2004 | Feb | NEWA |

CEFUROXIME SODIUM

INJECTABLE; IM-IV
CEFUROXIME

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | HIKMA FARMACEUTICA | EQ 750MG BASE/VIAL | N65048 | 001 | Jan 09, 2004 | Jan | NEWA |

INJECTABLE; INJECTION
CEFUROXIME

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AP | HIKMA FARMACEUTICA | EQ 1.5GM BASE/VIAL | N65048 | 002 | Jan 09, 2004 | Jan | NEWA |
| | AP | | EQ 7.5GM BASE/VIAL | N65046 | 001 | Jan 09, 2004 | Jan | NEWA |

CETIRIZINE HYDROCHLORIDE

TABLET, CHEWABLE; ORAL
ZYRTEC

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | PFIZER | 5MG | N21621 | 001 | Mar 16, 2004 | Mar | NEWA |
| >A> | + | | 10MG | N21621 | 002 | Mar 16, 2004 | Mar | NEWA |

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL

CHLORHEXIDINE GLUCONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AT | MORTON GROVE | 0.12% | N75006 | 001 | Mar 03, 2004 | Mar | NEWA |

>A> CINACALCET HYDROCHLORIDE

>A> TABLET; ORAL

>A> SENSIPAR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | AMGEN | EQ 30MG BASE | N21688 | 001 | Mar 08, 2004 | Mar | NEWA |
| >A> | | | EQ 60MG BASE | N21688 | 002 | Mar 08, 2004 | Mar | NEWA |
| >A> | + | | EQ 90MG BASE | N21688 | 003 | Mar 08, 2004 | Mar | NEWA |

CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CIPRO XR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | BAYER PHARMS | 425.2MG;EQ 574.9MG BASE | N21473 | 002 | Aug 28, 2003 | Feb | CDFR |

CLEMASTINE FUMARATE

TABLET; ORAL

CLEMASTINE FUMARATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | TEVA | 2.68MG | N73283 | 001 | Jan 31, 1992 | Mar | CRLD |
| >A> | AB + | | 2.68MG | N73283 | 001 | Jan 31, 1992 | Mar | CRLD |

>D> TAVIST

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB + | NOVARTIS | 2.68MG | N17661 | 001 | | Mar | DISC |
| >A> | @ | | 2.68MG | N17661 | 001 | | Mar | DISC |

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | COREPHARMA | EQ 150MG BASE | N65194 | 001 | Mar 22, 2004 | Mar | NEWA |
| >A> | AB | | EQ 300MG BASE | N65194 | 002 | Mar 22, 2004 | Mar | NEWA |

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL

CLINDAMYCIN PHOSPHATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AT | TARO PHARM INDS | EQ 1% BASE | N65184 | 001 | Mar 31, 2004 | Mar | NEWA |

CLOBETASOL PROPIONATE

SHAMPOO; TOPICAL

CLOBEX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | GALDERMA LABS | 0.05% | N21644 | 001 | Feb 05, 2004 | Feb | NEWA |

CLOZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL

FAZACLO

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ALAMO PHARMS | 25MG | N21590 | 001 | Feb 10, 2004 | Feb | NEWA |
| | + | | 100MG | N21590 | 002 | Feb 10, 2004 | Feb | NEWA |

COLISTIMETHATE SODIUM

INJECTABLE; INJECTION

COLISTIMETHATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AP | PADDOCK | EQ 150MG BASE/VIAL | N65177 | 001 | Mar 19, 2004 | Mar | NEWA |

CROMOLYN SODIUM

AEROSOL, METERED; INHALATION

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | INTAL | | | | | | |
| | + | | KING PHARMS | 0.8MG/INH | N18887 | 001 | Dec 05, 1985 | Jan | CAHN |

SOLUTION; INHALATION

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | INTAL | | | | | | |
| AN | + | | KING PHARMS | 10MG/ML | N18596 | 001 | May 28, 1982 | Jan | CAHN |

CYTARABINE

INJECTABLE; INJECTION

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | CYTARABINE | | | | | | |
| AP | | | AM PHARM | 100MG/ML | N76512 | 001 | Jan 15, 2004 | Jan | NEWA |
| AP | + | | MAYNE PHARMA USA | 100MG/ML | N75383 | 001 | Nov 22, 1999 | Jan | CFTG |

DEFEROXAMINE MESYLATE

INJECTABLE; INJECTION

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | | DEFEROXAMINE MESYLATE | | | | | | |
| >A> | AP | | ABBOTT | 2GM/VIAL | N76019 | 002 | Mar 17, 2004 | Mar | NEWA |
| >A> | AP | | | 500MG/VIAL | N76019 | 001 | Mar 17, 2004 | Mar | NEWA |
| | | | DESFERAL | | | | | | |
| >D> | | + | NOVARTIS | 2GM/VIAL | N16267 | 002 | May 25, 2000 | Mar | CFTG |
| >A> | AP | + | | 2GM/VIAL | N16267 | 002 | May 25, 2000 | Mar | CFTG |
| >D> | | + | | 500MG/VIAL | N16267 | 001 | | Mar | CFTG |
| >A> | AP | + | | 500MG/VIAL | N16267 | 001 | | Mar | CFTG |

DEMECLOCYCLINE HYDROCHLORIDE

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | DECLOMYCIN | | | | | | |
| >D> | | | ESP PHARMA | 150MG | N50261 | 002 | | Mar | CFTG |
| >A> | AB | | | 150MG | N50261 | 002 | | Mar | CFTG |
| >D> | | + | | 300MG | N50261 | 003 | | Mar | CFTG |
| >A> | AB | + | | 300MG | N50261 | 003 | | Mar | CFTG |
| >A> | | | DEMECLOCYCLINE HCL | | | | | | |
| >A> | AB | | IMPAX LABS | 150MG | N65094 | 001 | Mar 22, 2004 | Mar | NEWA |
| >A> | AB | | | 300MG | N65094 | 002 | Mar 22, 2004 | Mar | NEWA |

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | CYCLESSA | | | | | | |
| AB | + | | ORGANON USA INC | 0.1MG,0.125MG,0.15MG;0.025MG,0.025MG,0.025MG | N21090 | 001 | Dec 20, 2000 | Feb | CFTG |
| | | | VELIVET | | | | | | |
| AB | | | DURAMED PHARMS BARR | 0.1MG,0.125MG,0.15MG;0.025MG,0.025MG,0.025MG | N76455 | 001 | Feb 24, 2004 | Feb | NEWA |

DICLOFENAC POTASSIUM

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | DICLOFENAC POTASSIUM | | | | | | |
| >A> | AB | | TORPHARM | 50MG | N76561 | 001 | Mar 18, 2004 | Mar | NEWA |

DICLOXACILLIN SODIUM

CAPSULE; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | DICLOXACILLIN SODIUM | | | | | | |
| >D> | | | APOTHECON | EQ 125MG BASE | N61454 | 002 | | Mar | CAHN |
| >D> | AB | | | EQ 250MG BASE | N61454 | 001 | | Mar | CAHN |
| >D> | AB | + | | EQ 500MG BASE | N61454 | 003 | | Mar | CAHN |

CAPSULE; ORAL
DICLOXACILLIN SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | SANDOZ | EQ 125MG BASE | N61454 | 002 | | Mar | CAHN |
| >A> | AB | | EQ 250MG BASE | N61454 | 001 | | Mar | CAHN |
| >A> | AB | + | EQ 500MG BASE | N61454 | 003 | | Mar | CAHN |

DILTIAZEM HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
CARDIZEM LA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | BIOVAIL | 120MG | N21392 | 001 | Feb 06, 2003 | Jan | CRLD |
| | | | 180MG | N21392 | 002 | Feb 06, 2003 | Jan | CRLD |
| | | | 240MG | N21392 | 003 | Feb 06, 2003 | Jan | CRLD |
| | | | 300MG | N21392 | 004 | Feb 06, 2003 | Jan | CRLD |
| | | | 360MG | N21392 | 005 | Feb 06, 2003 | Jan | CRLD |

DIMYRISTOYL LECITHIN; PERFLEXANE

INJECTABLE; INTRAVENOUS
IMAGENT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | IMCOR PH | 0.92MG/VIAL;0.092MG/VIAL | N21191 | 001 | May 31, 2002 | Feb | CAHN |

DIVALPROEX SODIUM

TABLET, DELAYED RELEASE; ORAL
DEPAKOTE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ABBOTT | EQ 125MG VALPROIC ACID | N18723 | 003 | Oct 26, 1984 | Jan | CRLD |
| | | | EQ 250MG VALPROIC ACID | N18723 | 001 | Mar 10, 1983 | Jan | CRLD |

DOXEPIN HYDROCHLORIDE

CONCENTRATE; ORAL
DOXEPIN HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | | PHARM ASSOC | EQ 10MG BASE/ML | N75924 | 001 | Jan 15, 2004 | Jan | NEWA |

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL
ERYC

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | WARNER CHILCOTT | 250MG | N62338 | 001 | | Jan | CMFD |

ERYTHROMYCIN ESTOLATE

SUSPENSION; ORAL
ERYTHROMYCIN ESTOLATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ALPHARMA | EQ 125MG BASE/5ML | N62353 | 001 | Nov 18, 1982 | Jan | CTEC |
| | + | | EQ 250MG BASE/5ML | N62409 | 001 | Dec 16, 1982 | Jan | CRLD |
| | | ILOSONE | | | | | | |
| | | @ LILLY | EQ 125MG BASE/5ML | N50010 | 001 | | Jan | DISC |
| | | @ | EQ 250MG BASE/5ML | N50010 | 002 | | Jan | DISC |

ESTRADIOL

GEL, METERED; TOPICAL
ESTROGEL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | SOLVAY | 0.06% | N21166 | 002 | Feb 09, 2004 | Feb | NEWA |

GEL; TOPICAL
ESTROGEL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | SOLVAY | 0.06% | N21166 | 001 | Feb 09, 2004 | Mar | CRLD |
| >A> | + | | 0.06% | N21166 | 001 | Feb 09, 2004 | Mar | CRLD |
| | | | 0.06% | N21166 | 001 | Feb 09, 2004 | Feb | NEWA |

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL

CENESTIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | DURAMED | 0.45MG | N20992 | 005 | Feb 05, 2004 | Feb | NEWA |

ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL

MYAMBUTOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ ELAN PHARMS | 100MG | N16320 | 001 | | Feb | CAHN |
| | | @ | 200MG | N16320 | 002 | | Feb | CAHN |
| | | @ | 400MG | N16320 | 003 | | Feb | CAHN |
| | | @ | 500MG | N16320 | 004 | | Feb | CAHN |

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL

PREVEN EMERGENCY CONTRACEPTIVE KIT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | DURAMED | 0.05MG;0.25MG | N20946 | 001 | Sep 01, 1998 | Feb | CAHN |

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

ORTHO-NOVUM 1/35-28

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | ORTHO MCNEIL PHARM | 0.035MG;1MG | N17919 | 002 | | Mar | CRLD |
| >A> | AB | + | 0.035MG;1MG | N17919 | 002 | | Mar | CRLD |

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28

PREVIFEM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | ANDRX PHARMS | 0.035MG;0.25MG | N76334 | 001 | Jan 09, 2004 | Jan | NEWA |
| >A> | | TRI-PREVIFEM | | | | | | |
| >A> | AB | ANDRX PHARMS | 0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.025MG | N76335 | 001 | Mar 26, 2004 | Mar | NEWA |

FENTANYL CITRATE

TROCHE/LOZENGE; ORAL

ACTIQ

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | CEPHALON | EQ 0.2MG BASE | N20747 | 001 | Nov 04, 1998 | Feb | CAHN |
| | | | EQ 0.4MG BASE | N20747 | 002 | Nov 04, 1998 | Feb | CAHN |
| | | | EQ 0.6MG BASE | N20747 | 003 | Nov 04, 1998 | Feb | CAHN |
| | | | EQ 0.8MG BASE | N20747 | 004 | Nov 04, 1998 | Feb | CAHN |
| | | | EQ 1.2MG BASE | N20747 | 005 | Nov 04, 1998 | Feb | CAHN |
| | + | | EQ 1.6MG BASE | N20747 | 006 | Nov 04, 1998 | Feb | CAHN |

>D> FOLLITROPIN ALFA

>D> INJECTABLE; INJECTION

>D> GONAL-F

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | SERONO | 1,200 IU/VIAL | N20378 | 004 | Feb 28, 2001 | Mar | CAIN |

FOLLITROPIN ALFA/BETA

>A> INJECTABLE; IM-SC

>A> FOLLISTIM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | BX | ORGANON USA INC | 75 IU/VIAL | N20582 | 001 | Sep 29, 1997 | Mar | CDFR |
| >A> | BX | | 150 IU/VIAL | N20582 | 002 | Sep 29, 1997 | Mar | CDFR |

>D> INJECTABLE; INJECTION

>D> FOLLISTIM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | BX | ORGANON USA INC | 75 IU/VIAL | N20582 | 001 | Sep 29, 1997 | Mar | CDFR |
| >D> | BX | | 150 IU/VIAL | N20582 | 002 | Sep 29, 1997 | Mar | CDFR |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | | INJECTABLE; INJECTION | | | | | | |
| >D> | | | GONAL-F | | | | | | |
| >D> | BX | | SERONO | 75 IU/VIAL | N20378 | 001 | Sep 29, 1997 | Mar | CDFR |
| >D> | BX | | | 150 IU/VIAL | N20378 | 002 | Sep 29, 1997 | Mar | CDFR |
| | | | INJECTABLE; SUBCUTANEOUS | | | | | | |
| >A> | | | FOLLISTIM AQ | | | | | | |
| >A> | | | ORGANON USA INC | 300 IU/0.525ML | N21211 | 001 | Mar 23, 2004 | Mar | NEWA |
| >A> | | + | | 600 IU/0.885ML | N21211 | 002 | Mar 23, 2004 | Mar | NEWA |
| >A> | | | GONAL-F | | | | | | |
| >A> | | | SERONO INC | 37.5 IU/VIAL | N21765 | 001 | Mar 25, 2004 | Mar | NEWA |
| >A> | BX | | | 75 IU/VIAL | N20378 | 001 | Sep 29, 1997 | Mar | CDFR |
| >A> | | | | 75 IU/VIAL | N21765 | 002 | Mar 25, 2004 | Mar | NEWA |
| >A> | BX | | | 150 IU/VIAL | N20378 | 002 | Sep 29, 1997 | Mar | CDFR |
| >A> | | + | | 150 IU/VIAL | N21765 | 003 | Mar 25, 2004 | Mar | NEWA |
| >A> | | | | 450 IU/VIAL | N20378 | 005 | Mar 26, 2004 | Mar | NEWA |
| >A> | | + | | 1,200 IU/VIAL | N20378 | 004 | Feb 28, 2001 | Mar | CAIN |
| | | | FOMIVIRSEN SODIUM | | | | | | |
| | | | INJECTABLE; INJECTION | | | | | | |
| | | | VITRAVENE PRESERVATIVE FREE | | | | | | |
| | | + | NOVARTIS | 6.6MG/ML | N20961 | 001 | Aug 26, 1998 | Jan | CAHN |
| | | | FUROSEMIDE | | | | | | |
| | | | TABLET; ORAL | | | | | | |
| | | | FUROSEMIDE | | | | | | |
| >A> | AB | | VINTAGE PHARMS | 20MG | N76796 | 001 | Mar 26, 2004 | Mar | NEWA |
| >A> | AB | | | 40MG | N76796 | 002 | Mar 26, 2004 | Mar | NEWA |
| >A> | AB | | | 80MG | N76796 | 003 | Mar 26, 2004 | Mar | NEWA |
| | | | GENTAMICIN SULFATE | | | | | | |
| | | | SOLUTION/DROPS; OPHTHALMIC | | | | | | |
| | | | GARAMYCIN | | | | | | |
| | AT | + | SCHERING | EQ 0.3% BASE | N50039 | 002 | | Jan | CDFR |
| | | | GENTAMICIN SULFATE | | | | | | |
| | AT | | ALTANA | EQ 3% BASE | N65121 | 001 | Jan 30, 2004 | Jan | NEWA |
| | | | GLYBURIDE; METFORMIN HYDROCHLORIDE | | | | | | |
| | | | TABLET; ORAL | | | | | | |
| | | | GLUCOVANCE | | | | | | |
| | AB | | BRISTOL MYERS SQUIBB | 1.25MG;250MG | N21178 | 001 | Jul 31, 2000 | Feb | CFTG |
| | AB | | | 2.5MG;500MG | N21178 | 002 | Jul 31, 2000 | Feb | CFTG |
| | AB | + | | 5MG;500MG | N21178 | 003 | Jul 31, 2000 | Feb | CFTG |
| | | | GLYBURIDE AND METFORMIN HCL | | | | | | |
| | AB | | IVAX PHARMS | 1.25MG;250MG | N76345 | 001 | Feb 18, 2004 | Feb | NEWA |
| | AB | | | 2.5MG;500MG | N76345 | 002 | Feb 18, 2004 | Feb | NEWA |
| | AB | | | 5MG;500MG | N76345 | 003 | Feb 18, 2004 | Feb | NEWA |
| | | | HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE | | | | | | |
| | | | TABLET; ORAL | | | | | | |
| | | | ACCURETIC | | | | | | |
| >D> | | | PFIZER PHARMS | 12.5MG;EQ 10MG BASE | N20125 | 001 | Dec 28, 1999 | Mar | CFTG |
| >A> | AB | | | 12.5MG;EQ 10MG BASE | N20125 | 001 | Dec 28, 1999 | Mar | CFTG |
| >D> | | | | 12.5MG;EQ 20MG BASE | N20125 | 002 | Dec 28, 1999 | Mar | CFTG |
| >A> | AB | | | 12.5MG;EQ 20MG BASE | N20125 | 002 | Dec 28, 1999 | Mar | CFTG |
| >D> | | + | | 25MG;EQ 20MG BASE | N20125 | 003 | Dec 28, 1999 | Mar | CFTG |
| >A> | AB | + | | 25MG;EQ 20MG BASE | N20125 | 003 | Dec 28, 1999 | Mar | CFTG |

TABLET; ORAL
QUINARETIC

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | AMIDE PHARM | 12.5MG;EQ 10MG BASE | N76374 | 001 | Mar 31, 2004 | Mar | NEWA |
| >A> | AB | | 12.5MG;EQ 20MG BASE | N76374 | 002 | Mar 31, 2004 | Mar | NEWA |
| >A> | AB | | 25MG;EQ 20MG BASE | N76374 | 003 | Mar 31, 2004 | Mar | NEWA |

HYDROCODONE BITARTRATE; IBUPROFEN

TABLET; ORAL
HYDROCODONE BITARTRATE AND IBUPROFEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | INTERPHARM | 5MG;200MG | N76642 | 002 | Mar 18, 2004 | Mar | NEWA |

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AT | VINTAGE PHARMS | 2.5% | N40503 | 001 | Mar 12, 2004 | Mar | NEWA |

HYDROCORTISONE BUTYRATE

SOLUTION; TOPICAL
HYDROCORTISONE BUTYRATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AT | TARO PHARM INDS | 0.1% | N76364 | 001 | Jan 14, 2004 | Jan | NEWA |

LOCOID

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AT + | FERNDALE LABS | 0.1% | N19116 | 001 | Feb 25, 1987 | Jan | CFTG |

IDARUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
IDARUBICIN HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | GENSIA SICOR PHARMS | 5MG/VIAL | N65037 | 003 | May 01, 2002 | Feb | CTEC |

IOPROMIDE

INJECTABLE; INJECTION
ULTRAVIST (PHARMACY BULK)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | BERLEX | 49.9% | N21425 | 003 | Mar 12, 2004 | Mar | NEWA |
| >D> | + | | 300MG/ML | N21425 | 001 | Sep 20, 2002 | Mar | CPOT |
| >A> | + | | 62.3% | N21425 | 001 | Sep 20, 2002 | Mar | CPOT |
| >D> | + | | 370MG/ML | N21425 | 002 | Sep 20, 2002 | Mar | CPOT |
| >A> | + | | 76.9% | N21425 | 002 | Sep 20, 2002 | Mar | CPOT |

ISONIAZID

INJECTABLE; INJECTION
NYDRAZID

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | SANDOZ | 100MG/ML | N08662 | 001 | | Feb | CAHN |

KETOCONAZOLE

SHAMPOO; TOPICAL
KETOCONAZOLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | CLAY PARK | 2% | N76419 | 001 | Jan 07, 2004 | Jan | NEWA |

NIZORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB + | MCNEIL CONS SPECLT | 2% | N19927 | 001 | Aug 31, 1990 | Jan | CFTG |

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION
KETOROLAC TROMETHAMINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AP + | BEDFORD | 15MG/ML | N75222 | 001 | Apr 26, 1999 | Jan | CRLD |
| | AP + | | 30MG/ML | N75222 | 002 | Apr 26, 1999 | Jan | CRLD |

TORADOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ ROCHE PALO | 15MG/ML | N19698 | 001 | Nov 30, 1989 | Jan | DISC |

INJECTABLE; INJECTION
TORADOL
@ ROCHE PALO 30MG/ML N19698 002 Nov 30, 1989 Jan DISC

KETOTIFEN FUMARATE
SOLUTION/DROPS; OPHTHALMIC
ZADITOR
\+ NOVARTIS EQ 0.025% BASE N21066 001 Jul 02, 1999 Feb CAHN

LEVOCABASTINE HYDROCHLORIDE
SUSPENSION/DROPS; OPHTHALMIC
LIVOSTIN
\+ NOVARTIS EQ 0.05% BASE N20219 001 Nov 10, 1993 Feb CAHN

LEVOFLOXACIN
SOLUTION/DROPS; OPHTHALMIC
>A> IQUIX
>A> \+ SANTEN 1.5% N21571 001 Mar 01, 2004 Mar NEWA

LEVONORGESTREL
TABLET; ORAL
PLAN B
\+ DURAMED 0.75MG N21045 001 Jul 28, 1999 Feb CAHN

LIDOCAINE HYDROCHLORIDE; OXYTETRACYCLINE
INJECTABLE; INJECTION
TERRAMYCIN
\+ PFIZER 2%;50MG/ML N60567 001 Feb CRLD
\+ 2%;125MG/ML N60567 002 Feb CRLD

LITHIUM CARBONATE
TABLET, EXTENDED RELEASE; ORAL
LITHIUM CARBONATE
AB ROXANE 450MG N76691 001 Jan 05, 2004 Jan NEWA

LOVASTATIN; NIACIN
TABLET, EXTENDED RELEASE; ORAL
ADVICOR
\+ KOS 20MG;500MG N21249 001 Dec 17, 2001 Feb CRLD
\+ 20MG;750MG N21249 002 Dec 17, 2001 Feb CRLD

MERCAPTOPURINE
TABLET; ORAL
MERCAPTOPURINE
AB PROMETHEUS LABS 50MG N40461 001 Feb 11, 2004 Feb NEWA
AB ROXANE 50MG N40528 001 Feb 13, 2004 Feb NEWA
PURINETHOL
AB \+ TEVA 50MG N09053 002 Feb CFTG

MESNA
INJECTABLE; INTRAVENOUS
MESNA
AP BEDFORD 100MG/ML N75739 001 Jan 09, 2004 Jan NEWA

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

GLUCOPHAGE XR

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | BRISTOL MYERS SQUIBB | 500MG | N21202 | 001 | Oct 13, 2000 | Jan | CFTG |

METFORMIN HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | IVAX PHARMS | 500MG | N76545 | 001 | Dec 01, 2003 | Jan | NEWA |

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

DESOXYN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | + | OVATION PHARMS | 5MG | N05378 | 002 | | Feb | CFTG |

METHAMPHETAMINE HCL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | ABLE | 5MG | N40529 | 001 | Feb 25, 2004 | Feb | NEWA |

METHIMAZOLE

TABLET; ORAL

TAPAZOLE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | KING PHARMS | 5MG | N07517 | 002 | | Mar | CAHN |
| >A> | AB | | | 10MG | N07517 | 004 | | Mar | CAHN |
| >D> | AB | | LILLY | 5MG | N07517 | 002 | | Mar | CAHN |
| >D> | AB | | | 10MG | N07517 | 004 | | Mar | CAHN |

METOLAZONE

TABLET; ORAL

METOLAZONE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | TEVA | 2.5MG | N76600 | 001 | Jan 06, 2004 | Jan | NEWA |
| >A> | AB | | | 5MG | N76833 | 001 | Mar 01, 2004 | Mar | NEWA |

MYKROX

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | @ | CELLTECH PHARMS | 0.5MG | N19532 | 001 | Oct 30, 1987 | Jan | DISC |

METOPROLOL TARTRATE

TABLET; ORAL

LOPRESSOR

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | + | NOVARTIS | 100MG | N17963 | 002 | | Mar | CRLD |
| >A> | AB | | | 100MG | N17963 | 002 | | Mar | CRLD |

METOPROLOL TARTRATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | | CARACO | 25MG | N76670 | 001 | Jan 15, 2004 | Mar | CTEC |
| >A> | AB | | | 25MG | N76670 | 001 | Jan 15, 2004 | Mar | CTEC |
| | | | | 25MG | N76670 | 001 | Jan 15, 2004 | Jan | NEWA |
| >D> | | + | MYLAN | 25MG | N76704 | 001 | Jan 16, 2004 | Mar | CTEC |
| >A> | AB | | | 25MG | N76704 | 001 | Jan 16, 2004 | Mar | CTEC |
| | | + | | 25MG | N76704 | 001 | Jan 16, 2004 | Jan | NEWA |
| | AB | | | 50MG | N76704 | 002 | Jan 16, 2004 | Jan | NEWA |
| >D> | AB | | | 100MG | N76704 | 003 | Jan 16, 2004 | Mar | CRLD |
| >A> | AB | + | | 100MG | N76704 | 003 | Jan 16, 2004 | Mar | CRLD |
| | AB | | | 100MG | N76704 | 003 | Jan 16, 2004 | Jan | NEWA |

METRONIDAZOLE

CAPSULE; ORAL

METRONIDAZOLE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | KALI LABS | 375MG | N76522 | 001 | Jan 29, 2004 | Jan | NEWA |

MINOCYCLINE HYDROCHLORIDE

TABLET; ORAL
MINOCYCLINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MEDICIS | EQ 50MG BASE | N65131 | 001 | Apr 16, 2003 | Jan | CFTG |
| AB | | | EQ 75MG BASE | N65131 | 002 | Apr 16, 2003 | Jan | CFTG |
| AB | + | | EQ 100MG BASE | N65131 | 003 | Apr 16, 2003 | Jan | CFTG |
| AB | | RANBAXY | EQ 50MG BASE | N65156 | 001 | Jan 06, 2004 | Jan | NEWA |
| AB | | | EQ 75MG BASE | N65156 | 002 | Jan 06, 2004 | Jan | NEWA |
| AB | | | EQ 100MG BASE | N65156 | 003 | Jan 06, 2004 | Jan | NEWA |

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
ORAMORPH SR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | BC | AAIPHARMA | 60MG | N19977 | 002 | Aug 15, 1991 | Mar | CRLD |
| >A> | BC | + | 60MG | N19977 | 002 | Aug 15, 1991 | Mar | CRLD |

MYCOPHENOLIC ACID

TABLET, EXTENDED RELEASE; ORAL
MYFORTIC

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | NOVARTIS | 180MG | N50791 | 001 | Feb 27, 2004 | Feb | NEWA |
| | + | | 360MG | N50791 | 002 | Feb 27, 2004 | Feb | NEWA |

NABILONE

CAPSULE; ORAL
CESAMET

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ VALEANT | 1MG | N18677 | 001 | Dec 26, 1985 | Jan | CAHN |

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | @ KING PHARMS | 10MG/ML | N74471 | 001 | Mar 19, 1998 | Mar | DISC |
| >A> | | @ | 10MG/ML | N74471 | 001 | Mar 19, 1998 | Mar | DISC |

NAPROXEN

TABLET; ORAL
NAPROXEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | WESTWARD | 250MG | N76494 | 001 | Jan 14, 2004 | Jan | NEWA |
| AB | | | 375MG | N76494 | 002 | Jan 14, 2004 | Jan | NEWA |
| AB | | | 500MG | N76494 | 003 | Jan 14, 2004 | Jan | NEWA |

NEDOCROMIL SODIUM

AEROSOL, METERED; INHALATION
TILADE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | KING PHARMS | 1.75MG/INH | N19660 | 001 | Dec 30, 1992 | Jan | CAHN |

NIACIN

TABLET; ORAL
NIACIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ MK LABS | 500MG | N83525 | 001 | | Feb | DISC |
| | | @ TABLICAPS | 500MG | N84237 | 001 | | Feb | DISC |

NIACOR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | + | UPSHER SMITH | 500MG | N40378 | 001 | May 03, 2000 | Feb | CRLD |

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | | NIFEDIPINE | | | | | | |
| >A> | AB2 | | MARTEC | 90MG | N75414 | 003 | Mar 23, 2004 | Mar | NEWA |
| | | | PROCARDIA XL | | | | | | |
| >D> | BC | + | PFIZER | 90MG | N19684 | 003 | Sep 06, 1989 | Mar | CFTG |
| >A> | AB2 | + | | 90MG | N19684 | 003 | Sep 06, 1989 | Mar | CFTG |

NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | MACROBID | | | | | | |
| >D> | | + | PROCTER AND GAMBLE | 75MG;25MG | N20064 | 001 | Dec 24, 1991 | Mar | CFTG |
| >A> | AB | + | | 75MG;25MG | N20064 | 001 | Dec 24, 1991 | Mar | CFTG |
| >A> | | | NITROFURANTOIN (MONOHYDRATE/MACROCRYSTALS) | | | | | | |
| >A> | AB | | MYLAN | EQ 75MG BASE;25MG | N76648 | 001 | Mar 22, 2004 | Mar | NEWA |

OLANZAPINE

INJECTABLE; INTRAMUSCULAR

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | | ZYPREXA | | | | | | |
| >A> | | + | LILLY | 10MG/VIAL | N21253 | 001 | Mar 29, 2004 | Mar | NEWA |

OXACILLIN SODIUM

INJECTABLE; INJECTION

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | OXACILLIN SODIUM | | | | | | |
| >D> | AP | | APOTHECON | EQ 250MG BASE/VIAL | N61490 | 001 | | Mar | CRLD |
| >A> | AP | + | | EQ 250MG BASE/VIAL | N61490 | 001 | | Mar | CRLD |
| >A> | AP | + | | EQ 2GM BASE/VIAL | N61490 | 004 | | Mar | NEWA |
| >D> | AP | + | | EQ 2GM BASE/VIAL | N62737 | 002 | Dec 23, 1986 | Mar | CRLD |
| >A> | AP | | | EQ 2GM BASE/VIAL | N62737 | 002 | Dec 23, 1986 | Mar | CRLD |

>D> OXAMNIQUINE

CAPSULE; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | | VANSIL | | | | | | |
| >D> | | + | PFIZER | 250MG | N18069 | 001 | | Mar | DISC |
| >A> | | | @ | 250MG | N18069 | 001 | | Mar | DISC |

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | | OXYCODONE HCL | | | | | | |
| >A> | AB | | ENDO PHARMS | 10MG | N75923 | 001 | Mar 23, 2004 | Mar | NEWA |
| >A> | AB | | | 20MG | N75923 | 002 | Mar 23, 2004 | Mar | NEWA |
| >A> | AB | | | 40MG | N75923 | 003 | Mar 23, 2004 | Mar | NEWA |
| >A> | AB | | TEVA | 80MG | N76168 | 001 | Mar 23, 2004 | Mar | NEWA |
| | | | OXYCONTIN | | | | | | |
| >D> | | | PURDUE PHARMA LP | 10MG | N20553 | 001 | Dec 12, 1995 | Mar | CFTG |
| >A> | AB | | | 10MG | N20553 | 001 | Dec 12, 1995 | Mar | CFTG |
| >D> | | | | 20MG | N20553 | 002 | Dec 12, 1995 | Mar | CFTG |
| >A> | AB | | | 20MG | N20553 | 002 | Dec 12, 1995 | Mar | CFTG |
| >D> | | + | | 40MG | N20553 | 003 | Dec 12, 1995 | Mar | CFTG |
| >A> | AB | + | | 40MG | N20553 | 003 | Dec 12, 1995 | Mar | CFTG |
| >D> | | + | | 80MG | N20553 | 004 | Jan 06, 1997 | Mar | CFTG |
| >A> | AB | + | | 80MG | N20553 | 004 | Jan 06, 1997 | Mar | CFTG |

TABLET; ORAL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | OXYCODONE HCL | | | | | | |
| | AB | | AMIDE PHARM | 15MG | N76636 | 001 | Feb 06, 2004 | Feb | NEWA |

TABLET; ORAL
OXYCODONE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | AMIDE PHARM | 30MG | N76636 | 002 | Feb 06, 2004 | Feb | NEWA |

ROXICODONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + | AAIPHARMA | 15MG | N21011 | 001 | Aug 31, 2000 | Feb | CFTG |
| AB | | | 30MG | N21011 | 002 | Aug 31, 2000 | Feb | CFTG |

PARICALCITOL

INJECTABLE; INJECTION
ZEMPLAR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | ABBOTT | 0.002MG/ML | N20819 | 002 | Feb 01, 2000 | Mar | NEWA |

PAROXETINE HYDROCHLORIDE

TABLET; ORAL
PAROXETINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | ALPHAPHARM | EQ 10MG BASE | N75716 | 001 | Mar 08, 2004 | Mar | NEWA |
| >A> | AB | | EQ 20MG BASE | N75716 | 002 | Mar 08, 2004 | Mar | NEWA |
| >A> | AB | | EQ 30MG BASE | N75716 | 003 | Mar 08, 2004 | Mar | NEWA |
| >A> | AB | | EQ 40MG BASE | N75716 | 004 | Mar 08, 2004 | Mar | NEWA |
| >A> | AB | SANDOZ | EQ 10MG BASE | N75566 | 001 | Mar 08, 2004 | Mar | NEWA |
| >A> | AB | | EQ 20MG BASE | N75566 | 002 | Mar 08, 2004 | Mar | NEWA |
| >A> | AB | | EQ 30MG BASE | N75566 | 003 | Mar 08, 2004 | Mar | NEWA |
| >A> | AB | | EQ 40MG BASE | N75566 | 004 | Mar 08, 2004 | Mar | NEWA |

PEMETREXED DISODIUM

INJECTABLE; IV (INFUSION)
ALIMTA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | LILLY | EQ 500MG BASE/VIAL | N21462 | 001 | Feb 04, 2004 | Feb | NEWA |

PHENYTOIN

SUSPENSION; ORAL
PHENYTOIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | TARO | 125MG/5ML | N40521 | 001 | Mar 08, 2004 | Mar | NEWA |

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

FOR SOLUTION; ORAL
NULYTELY

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | + | BRAINTREE | 420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 1.2GM/BOT | N19797 | 001 | Apr 22, 1991 | Feb | CFTG |

NULYTELY-FLAVORED

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | + | BRAINTREE | 420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 1.2GM/BOT | N19797 | 002 | Nov 18, 1994 | Feb | CFTG |

TRILYTE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | | SCHWARZ PHARMA | 420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 1.2GM/BOT | N76491 | 001 | Feb 05, 2004 | Feb | NEWA |

PREDNISONE

TABLET; ORAL
PREDNISONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | WEST WARD | 2.5MG | N40538 | 001 | Jan 08, 2004 | Jan | NEWA |

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AP | BEDFORD LABS | 25MG/ML | N40524 | 001 | Mar 17, 2004 | Mar | NEWA |
| >A> | AP | | 50MG/ML | N40524 | 002 | Mar 17, 2004 | Mar | NEWA |

SYRUP; ORAL
PROMETH PLAIN
@ ALPHARMA 6.25MG/5ML N85953 001 Feb DISC
PROMETHAZINE HCL
AA + HI TECH PHARMA 6.25MG/5ML N40026 001 Sep 25, 1998 Feb CRLD

PROPRANOLOL HYDROCHLORIDE
INJECTABLE; INJECTION
PROPRANOLOL
AP AM PHARM PARTNERS 1MG/ML N75826 001 Aug 31, 2001 Jan NEWA

PROTAMINE SULFATE
INJECTABLE; INJECTION
PROTAMINE SULFATE
>D> AP AM PHARM PARTNERS 10MG/ML N89454 001 Apr 07, 1987 Mar CRLD
>A> + 10MG/ML N89454 001 Apr 07, 1987 Mar CRLD
>D> AP + LILLY 10MG/ML N06460 002 Mar DISC
>A> @ 10MG/ML N06460 002 Mar DISC

SIROLIMUS
TABLET; ORAL
RAPAMUNE
WYETH PHARMS INC 2MG N21110 002 Aug 22, 2002 Feb CRLD
+ 5MG N21110 003 Feb 23, 2004 Feb NEWA

SODIUM FERRIC GLUCONATE COMPLEX
INJECTABLE; INJECTION
FERRLECIT
+ WATSON PHARMS 62.5MG/5ML N20955 001 Feb 18, 1999 Feb CAHN

SOMATROPIN RECOMBINANT
INJECTABLE; INJECTION
SEROSTIM
BX SERONO 4MG/VIAL N20604 003 Jul 25, 1997 Jan CTEC
@ 8.8MG/VIAL N20604 004 Sep 06, 2001 Jan DISC

>D> SPARFLOXACIN
>D> TABLET; ORAL
>D> ZAGAM
>D> + MYLAN 200MG N20677 001 Dec 19, 1996 Mar DISC
>A> @ 200MG N20677 001 Dec 19, 1996 Mar DISC

SUCRALFATE
TABLET; ORAL
CARAFATE
AB + AXCAN SCANDIPHARM 1GM N18333 001 Feb CAHN

SULFACETAMIDE SODIUM
SOLUTION/DROPS; OPHTHALMIC
SULF-10
>D> @ NOVARTIS 10% N80025 001 Mar CMFD
>A> AT 10% N80025 001 Mar CMFD

TERBINAFINE

GEL; TOPICAL

LAMISIL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | NOVARTIS | 1% | N20846 | 001 | Apr 29, 1998 | Jan | CMFD |

TIOTROPIUM BROMIDE MONOHYDRATE

CAPSULE; INHALATION

SPIRIVA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | | BOEHRINGER INGELHEIM | EQ 0.018MG BASE | N21395 | 001 | Jan 30, 2004 | Jan | NEWA |

TIZANIDINE HYDROCHLORIDE

TABLET; ORAL

TIZANIDINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | TORPHARM | EQ 2MG BASE | N76533 | 001 | Jan 16, 2004 | Jan | NEWA |
| AB | | | EQ 4MG BASE | N76533 | 002 | Jan 16, 2004 | Jan | NEWA |

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL

VALTREX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | | GLAXOSMITHKLINE | EQ 1GM BASE | N20487 | 002 | Jun 23, 1995 | Feb | CRLD |

VINCRISTINE SULFATE

INJECTABLE; INJECTION

ONCOVIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | | | | | | | |
| >D> | AP | + LILLY | 1MG/ML | N14103 | 003 | Mar 07, 1984 | Mar | DISC |
| >A> | | @ | 1MG/ML | N14103 | 003 | Mar 07, 1984 | Mar | DISC |

TERBINAFINE HYDROCHLORIDE

SPRAY; TOPICAL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | LAMISIL AT | | | | | | |
| + | NOVARTIS | 1% | N21124 | 002 | Mar 17, 2000 | Feb | NEWA |

ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

VASOCON-A

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | NOVARTIS | 0.5%;0.05% | N18746 | 002 | Jul 11, 1994 | Feb | CAHN |

CHLORPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL

EFIDAC 24 CHLORPHENIRAMINE MALEATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | ALZA | 16MG | N19746 | 002 | Nov 18, 1994 | Mar | CRLD |
| >A> | + | 16MG | N19746 | 002 | Nov 18, 1994 | Mar | CRLD |

CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

SUSPENSION; ORAL

CHILDREN'S ADVIL ALLERGY SINUS

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | WYETH CONS | 1MG/5ML;100MG/5ML;15MG/5ML | N21587 | 001 | Feb 24, 2004 | Feb | NEWA |

IBUPROFEN

SUSPENSION; ORAL

CHILDREN'S ELIXSURE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | TARO | 100MG/5ML | N21604 | 001 | Jan 07, 2004 | Jan | NEWA |

TABLET, CHEWABLE; ORAL

IBUPROFEN

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | PERRIGO | 50MG | N76359 | 001 | Jan 16, 2004 | Jan | NEWA |
| | | 100MG | N76359 | 002 | Jan 16, 2004 | Jan | NEWA |

>A> IBUPROFEN POTASSIUM; PSEUDOEPHEDRINE HYDROCHLORIDE

>A> CAPSULE; ORAL

>A> ADVIL COLD AND SINUS

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> + | WYETH CONS | 200MG;30MG | N21374 | 001 | May 30, 2002 | Mar | CAIN |

>D> IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

>D> CAPSULE; ORAL

>D> ADVIL COLD AND SINUS

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | WYETH CONS | 200MG;30MG | N21374 | 001 | May 30, 2002 | Mar | CAIN |

LORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

LORATADINE AND PSEUDOEPHEDRINE SULFATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | ANDRX PHARMS | 5MG;120MG | N76208 | 001 | Jan 28, 2004 | Jan | NEWA |
| >A> | IMPAX LABS | 10MG;240MG | N75989 | 001 | Mar 04, 2004 | Mar | NEWA |

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL

>A> MICONAZOLE 7 COMBINATION PACK

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | G AND W LABS | 2%,100MG | N76585 | 001 | Mar 26, 2004 | Mar | NEWA |

CREAM; TOPICAL, VAGINAL

>A> MICONAZOLE 3 COMBINATION PACK

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | PERRIGO | 2%,4% | N76357 | 001 | Mar 30, 2004 | Mar | NEWA |

NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

NAPROXEN SODIUM AND PSEUDOEPHEDRINE HCL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | PERRIGO | EQ 200MG BASE;120MG | N76518 | 001 | Mar 17, 2004 | Mar | NEWA |

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

## CUMULATIVE SUPPLEMENT NUMBER 3 MARCH 2004

---

**NO MARCH 2004 APPROVALS**

**This data is provided to the Office of Generic Drugs from the Office of Orphan Products Development and it is not edited prior to publication.**

Orphan Products Designations and Approvals List
March 2004

| Generic Name/ Trade Name (if present): | Date Designated = DD Date Approved= MA | Indication Designated: | Sponsor and Address |
|---|---|---|---|
| Rituxan | DD: 1/29/2004<br>MA: | Treatment of chronic lymphocytic leukemia | Biogen IDEC, Inc.<br>3030 Callan Road<br>San Diego CA 92121 |
| Biopharmaceuticals, Ltd. | DD: 3/17/2004 | Treatment of the West Nile virus infection | q<br>OMRIX |
| Institute | MA: | | Plasma Fractionation<br>Sheba Hospital<br>Ramat Gan 52621 |
| (1S)-1-(9-deazahypoxanthin-9-yl)-1, 4-dideoxy-1,4-imino-D-ribitol-hydr ochloride | DD: 1/29/2004<br>MA: | Treatment of T-cell non-Hodgkin's lymphoma | BioCryst<br>2190 Parkway Lake Drive<br>Birmingham AL 35244 |
| 1-Deoxygalactonojirimycin | DD: 2/25/2004 | Treatment of Fabry Disease | Amicus Therapeutics, Inc. |
| 08902 | MA: | | 675 US Route 1<br>North Brunswick NJ |
| 3-4'aminoisoindoline-1'-one)-1-pipe ridine-2,6-dione (CC-5013)<br>REVIMID | DD: 1/29/2004<br>MA:<br>MA: | Treatment of myelodysplastic syndromes | Celgene Corporation<br>7 Powder Horn Drive<br>Warren NJ 07059 |
| 5-methyl-1-phenyl-2-(1H)-pyridone( CAS 53179-13-8)<br>Pirfenidone | DD: 3/5/2004<br>MA:<br>MA: | Treatment of idiopathic pulmonary fibrosis | InterMune, Inc.<br>3280 Bayshore Blvd<br>Brisbane CA 94005 |
| 90Y-hPAMA4<br>PAN-Cide | DD: 1/29/2004<br>MA: | Treatment of pancreatic cancer | Immunomedics, Inc.<br>300 American Road<br>Morris Plains NJ 07950 |
| Alpha-1-acid glycoprotein | DD: 3/17/2004<br>MA: | Treatment of tricyclic antidepressant poisoning | Bio Products Laboratory<br>Dagger Lane<br>Elstree, Hertfordshire |

# Orphan Products Designations and Approvals List

March 2004

| | | | |
|---|---|---|---|
| alpha-1-acid glycoprotein | DD: 3/5/2004<br>MA: | Treatment of cocaine overdose | Bio Products Laboratory<br>Dagger Lane, Elstree<br>Hertfordshire |
| antivenin crotaline (pit-viper) Therapeutics, Inc.<br>equine immune F(ab)2)<br>Antivipmyn | DD: 1/29/2004<br>MA:<br>MA: | Treatment of envenomation by Crotaline snakes | Rare Disease<br>1101 Kermit Drive,<br>Suite 608<br>Nashville TN 37217 |
| chenodeoxycholic acid<br>Chenofalk | DD: 1/29/2004<br>MA: | Treatment of cerebrotendinous xanthomatosis | Dr. Falk Pharma GmbH<br>Leinenweberstrasse 5<br>Leinenweberstrasse 5<br>Postfach 6529 |
| DEAE-rebeccamycin<br>94083-0511 | DD: 3/1/2004<br>MA: | Treatment of bile duct tumors | Exelixis, Inc.<br>170 Harbor Way<br>South San Francisco CA |
| Dexrazoxane<br>Copenhagen | DD: 3/25/2004<br>MA: | Treatment of anthracycline extravasation during chemotherapy | Topo Target A/S<br>Fruebjergvej 3, 2100 |
| Idebenone (INN) | DD: 3/25/2004<br>MA: | Treatment of cardiomyopathy associated with Friedreich's ataxia | MyoContract Ltd.<br>Hammerstrasse 25<br>CH-4410 Liestal |
| multi-vitiam infusion without vitamin K<br>ParkDrive<br>M.V.I.-12 | DD: 3/8/2004<br>MA: | Prevention of vitamin deficiency and thromboembolic complications in people receiving home parenteral nutrition and warfarin-type anticoagulant therapy | aaiPharma, Inc.<br>2320 Scientific<br>Wilmington NC 28405 |
| oral unfractionated heparin<br>94019 | DD: 1/29/2004<br>MA: | Treatment of sickle cell disease | TRF Technologies, Inc.<br>108 Eagle Trace Drive<br>Half Moon Bay CA |
| Recombinant Porcine Factor VIII, B-domain Deleted | DD: 3/16/2004<br>MA: | Treatment and prevention of episodic bleeding in patients with inhibitor antibodies to human coagulation factor VIII | Ipsen Limited<br>190 Bath Road<br>Berkshire S11 3XE |

# Orphan Products Designations and Approvals List

March 2004

| | | | |
|---|---|---|---|
| rh-microplasmin<br><br>Office Park | DD: 3/16/2004<br><br>MA: | Adjunct to surgery in cases of pediatric vitrectomy | ThromboGenics Ltd<br>Unit 14, Bridgecourt<br><br>Dublin 12 |
| rofecoxib<br>VIOXX | DD: 3/16/2004<br><br>MA: | Treatment of juvenile rheumatoid arthritis | MERCK & Co., Inc.<br>126 East Lincoln Ave.<br>Rahway NJ 07065 |
| SGN-30 (anti-CD30 antibody)<br><br>Southeast | DD: 2/18/2004<br><br>MA: | For the treatment of CD30 positive T-cell lymphomas | Seattle Genetics, Inc.<br>21823 30th Drive<br><br>Bothell WA 98021 |
| sodium thiosulfate<br>Inc.<br><br>Crescent | DD: 3/17/2004<br><br>MA: | Prevention of platinum-induced ototoxicity in pediatric patients | Adherex Technologies,<br><br>600 Peter Morand<br><br>Ottawa, Ontario |
| somatropin<br><br>Serostim | DD: 3/16/2004<br><br>MA: | Treatment of patients with HIV-associated adipose redistribution syndrome | Serono, Inc.<br>One Technology Place<br>One Technology Place<br>Rockland MA 02370 |
| Staphylococcus aureus Immune Globulin (Human)<br>Altastaph | DD: 1/29/2004<br>MA:<br>MA: | Prophylaxis against Staphylococcus aureus infections in low birth weight neonates | Nabi Biopharmaceuticals<br>12276 Wilkins Avenue<br><br>Rockville MD 20852 |
| Suberoylanilide Hydroxamic Acid<br><br>Road<br><br>6717 | DD: 3/17/2004<br><br>MA: | Treatment of mesothelioma | Aton Pharma, Inc.<br>777 Old Saw Mill River<br><br>Tarrytown NY 10591- |
| Suberoylanilide Hydroxamic Acid (SAHA)<br>Road<br><br>6717 | DD: 3/16/2004<br><br>MA: | Treatment of T-cell non-Hodgkin's lymphoma | Aton Pharma, Inc.<br>777 Old Saw Mill River<br><br>Tarrytown NY 10591- |
| tetrahydrobiopterin<br>Pharmaceutical Inc. | DD: 1/29/2004<br><br>MA: | For treatment of hyperphenylalaninemia | Biomarin<br><br>371 Bel Marin Blvd.<br>Novato CA 94949 |

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

NO MARCH 2004 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnotes 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> | 021320 001 | ABARELIX;PLENAXIS | 6699833 | DEC 11, 2016 | DP | | |
| | | | 5968895 | DEC 11, 2016 | DP | | |
| | | | 6180608 | DEC 11, 2016 | DP U549 | | |
| | | | 6423686 | JUN 07, 2015 | DS | | |
| | | | 6455499 | JUN 07, 2015 | U549 | | |
| | | | 5843901 | DEC 01, 2015 | DS DP | | |
| >ADD> | 021539 001 | ACETYLCYSTEINE;ACETADOTE | | | | ODE | JAN 23, 2011 |
| | 020949 001 | ALBUTEROL SULFATE;ACCUNEB | 6702997 | DEC 28, 2021 | U558 | | |
| | 020949 002 | ALBUTEROL SULFATE;ACCUNEB | 6702997 | DEC 28, 2021 | U558 | | |
| >ADD> | 020886 001 | ALITRETINOIN;PANRETIN | 5932622 | AUG 03, 2016 | U562 | | |
| | 021540 001 | AMLODIPINE BESYLATE;CADUET | 5273995 | DEC 28, 2010 | DS DP U162 | NC | JAN 30, 2007 |
| | | | 5273995*PED | JUN 28, 2011 | | | |
| | | | 6455574 | AUG 11, 2018 | U552 | | |
| | | | 5969156 | JUL 08, 2016 | DS | | |
| | | | 5969156*PED | JAN 08, 2017 | | | |
| | | | 5686104 | NOV 11, 2014 | DP U213 | | |
| | | | 5686104*PED | MAY 11, 2015 | | | |
| | | | 6126971 | JAN 19, 2013 | DP | | |
| | | | 6126971*PED | JUL 19, 2013 | | | |
| | | | 4681893 | SEP 24, 2009 | DS DP U161 | | |
| | | | 4681893*PED | MAR 24, 2010 | | | |
| | | | 4879303 | MAR 25, 2007 | DS DP | | |
| | | | 4879303*PED | SEP 25, 2007 | | | |
| | | | 4572909 | JUL 31, 2006 | DS DP U3 | | |
| | | | 4572909*PED | JAN 31, 2007 | | | |
| | 021540 002 | AMLODIPINE BESYLATE;CADUET | 4681893 | SEP 24, 2009 | DS DP U161 | NC | JAN 30, 2007 |
| | | | 4681893*PED | MAR 24, 2010 | | | |
| | | | 4879303 | MAR 25, 2007 | DS DP | | |
| | | | 4879303*PED | SEP 25, 2007 | | | |
| | | | 4572909 | JUL 31, 2006 | DS DP U3 | | |
| | | | 4572909*PED | JAN 31, 2007 | | | |
| | | | 5273995 | DEC 28, 2010 | DS DP U162 | | |
| | | | 5273995*PED | JUN 28, 2011 | | | |
| | | | 6455574 | AUG 11, 2018 | U552 | | |
| | | | 5969156 | JUL 08, 2016 | DS | | |
| | | | 5969156*PED | JAN 08, 2017 | | | |
| | | | 5686104 | NOV 11, 2014 | DP U213 | | |
| | | | 5686104*PED | MAY 11, 2015 | | | |
| | | | 6126971 | JAN 19, 2013 | DP | | |
| | | | 6126971*PED | JUL 19, 2013 | | | |
| | 021540 003 | AMLODIPINE BESYLATE;CADUET | 4681893 | SEP 24, 2009 | DS DP U161 | NC | JAN 30, 2007 |
| | | | 4681893*PED | MAR 24, 2010 | | | |
| | | | 4879303 | MAR 25, 2007 | DS DP | | |
| | | | 4879303*PED | SEP 25, 2007 | | | |
| | | | 4572909 | JUL 31, 2006 | DS DP U3 | | |
| | | | 4572909*PED | JAN 31, 2007 | | | |
| | | | 5273995 | DEC 28, 2010 | DS DP U162 | | |
| | | | 5273995*PED | JUN 28, 2011 | | | |
| | | | 6455574 | AUG 11, 2018 | U552 | | |
| | | | 5969156 | JUL 08, 2016 | DS | | |
| | | | 5969156*PED | JAN 08, 2017 | | | |
| | | | 5686104 | NOV 11, 2014 | DP U213 | | |
| | | | 5686104*PED | MAY 11, 2015 | | | |
| | | | 6126971 | JAN 19, 2013 | DP | | |
| | | | 6126971*PED | JUL 19, 2013 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnotes 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 |
|---|---|---|---|---|---|---|
| 021540 004 | AMLODIPINE BESYLATE;CADUET | 4681893 | SEP 24, 2009 | DS DP U161 | NC | JAN 30, 2007 |
| | | 4681893*PED | MAR 24, 2010 | | | |
| | | 4879303 | MAR 25, 2007 | DS DP | | |
| | | 4879303*PED | SEP 25, 2007 | | | |
| | | 4572909 | JUL 31, 2006 | DS DP U3 | | |
| | | 4572909*PED | JAN 31, 2007 | | | |
| | | 5273995 | DEC 28, 2010 | DS DP U162 | | |
| | | 5273995*PED | JUN 28, 2011 | | | |
| | | 6455574 | AUG 11, 2018 | U552 | | |
| | | 5969156 | JUL 08, 2016 | DS | | |
| | | 5969156*PED | JAN 08, 2017 | | | |
| | | 5686104 | NOV 11, 2014 | DP U213 | | |
| | | 5686104*PED | MAY 11, 2015 | | | |
| | | 6126971 | JAN 19, 2013 | DP | | |
| | | 6126971*PED | JUL 19, 2013 | | | |
| 021540 005 | AMLODIPINE BESYLATE;CADUET | 4681893 | SEP 24, 2009 | DS DP U161 | NC | JAN 30, 2007 |
| | | 4681893*PED | MAR 24, 2010 | | | |
| | | 4879303 | MAR 25, 2007 | DS DP | | |
| | | 4879303*PED | SEP 25, 2007 | | | |
| | | 4572909 | JUL 31, 2006 | DS DP U3 | | |
| | | 4572909*PED | JAN 31, 2007 | | | |
| | | 5273995 | DEC 28, 2010 | DS DP U162 | | |
| | | 5273995*PED | JUN 28, 2011 | | | |
| | | 6455574 | AUG 11, 2018 | U552 | | |
| | | 5969156 | JUL 08, 2016 | DS | | |
| | | 5969156*PED | JAN 08, 2017 | | | |
| | | 5686104 | NOV 11, 2014 | DP U213 | | |
| | | 5686104*PED | MAY 11, 2015 | | | |
| | | 6126971 | JAN 19, 2013 | DP | | |
| | | 6126971*PED | JUL 19, 2013 | | | |
| 021540 006 | AMLODIPINE BESYLATE;CADUET | 4681893 | SEP 24, 2009 | DS DP U161 | NC | JAN 30, 2007 |
| | | 4681893*PED | MAR 24, 2010 | | | |
| | | 4879303 | MAR 25, 2007 | DS DP | | |
| | | 4879303*PED | SEP 25, 2007 | | | |
| | | 4572909 | JUL 31, 2006 | DS DP U3 | | |
| | | 4572909*PED | JAN 31, 2007 | | | |
| | | 5273995 | DEC 28, 2010 | DS DP U162 | | |
| | | 5273995*PED | JUN 28, 2011 | | | |
| | | 6455574 | AUG 11, 2018 | U552 | | |
| | | 5969156 | JUL 08, 2016 | DS | | |
| | | 5969156*PED | JAN 08, 2017 | | | |
| | | 5686104 | NOV 11, 2014 | DP U213 | | |
| | | 5686104*PED | MAY 11, 2015 | | | |
| | | 6126971 | JAN 19, 2013 | DP | | |
| | | 6126971*PED | JUL 19, 2013 | | | |
| 021540 007 | AMLODIPINE BESYLATE;CADUET | 4681893 | SEP 24, 2009 | DS DP U161 | NC | JAN 30, 2007 |
| | | 4681893*PED | MAR 24, 2010 | | | |
| | | 4879303 | MAR 25, 2007 | DS DP | | |
| | | 4879303*PED | SEP 25, 2007 | | | |
| | | 4572909 | JUL 31, 2006 | DS DP U3 | | |
| | | 4572909*PED | JAN 31, 2007 | | | |
| | | 5273995 | DEC 28, 2010 | DS DP U162 | | |
| | | 5273995*PED | JUN 28, 2011 | | | |
| | | 6455574 | AUG 11, 2018 | U552 | | |
| | | 5969156 | JUL 08, 2016 | DS | | |
| | | 5969156*PED | JAN 08, 2017 | | | |

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 |
|---|---|---|---|---|---|---|---|
| | | | 5686104 | NOV 11, 2014 | DP U213 | | |
| | | | 5686104*PED | MAY 11, 2015 | | | |
| | | | 6126971 | JAN 19, 2013 | DP | | |
| | | | 6126971*PED | JUL 19, 2013 | | | |
| | 021540 008 | AMLODIPINE BESYLATE;CADUET | 4681893 | SEP 24, 2009 | DS DP U161 | NC | JAN 30, 2007 |
| | | | 4681893*PED | MAR 24, 2010 | | | |
| | | | 4879303 | MAR 25, 2007 | DS DP | | |
| | | | 4879303*PED | SEP 25, 2007 | | | |
| | | | 4572909 | JUL 31, 2006 | DS DP U3 | | |
| | | | 4572909*PED | JAN 31, 2007 | | | |
| | | | 5273995 | DEC 28, 2010 | DS DP U162 | | |
| | | | 5273995*PED | JUN 28, 2011 | | | |
| | | | 6455574 | AUG 11, 2018 | U552 | | |
| | | | 5969156 | JUL 08, 2016 | DS | | |
| | | | 5969156*PED | JAN 08, 2017 | | | |
| | | | 5686104 | NOV 11, 2014 | DP U213 | | |
| | | | 5686104*PED | MAY 11, 2015 | | | |
| | | | 6126971 | JAN 19, 2013 | DP | | |
| | | | 6126971*PED | JUL 19, 2013 | | | |
| | 020114 001 | AZELASTINE HYDROCHLORIDE;ASTELIN | 5164194 | NOV 01, 2010 | U207 | | |
| | | | 5164194*PED | MAY 01, 2011 | | | |
| | 019851 001 | BENAZEPRIL HYDROCHLORIDE;LOTENSIN | | | | M-30 | MAR 02, 2007 |
| | | | | | | PED | SEP 02, 2007 |
| | 019851 002 | BENAZEPRIL HYDROCHLORIDE;LOTENSIN | | | | M-30 | MAR 02, 2007 |
| | | | | | | PED | SEP 02, 2007 |
| | 019851 003 | BENAZEPRIL HYDROCHLORIDE;LOTENSIN | | | | M-30 | MAR 02, 2007 |
| | | | | | | PED | SEP 02, 2007 |
| | 019851 004 | BENAZEPRIL HYDROCHLORIDE;LOTENSIN | | | | M-30 | MAR 02, 2007 |
| | | | | | | PED | SEP 02, 2007 |
| >ADD> | 021602 001 | BORTEZOMIB;VELCADE | 6713446 | JAN 25, 2022 | DP | | |
| | 020746 001 | BUDESONIDE;RHINOCORT | 6686346 | APR 29, 2017 | DP U557 | | |
| | 020746 002 | BUDESONIDE;RHINOCORT | 6686346 | APR 29, 2017 | DP U557 | | |
| | 020452 001 | CARBOPLATIN;PARAPLATIN | 4657927 | APR 14, 2004 | DP U175 | | |
| | 020452 002 | CARBOPLATIN;PARAPLATIN | 4657927 | APR 14, 2004 | DP U175 | | |
| | 020452 003 | CARBOPLATIN;PARAPLATIN | 4657927 | APR 14, 2004 | DP U175 | | |
| >ADD> | 021621 001 | CETIRIZINE HYDROCHLORIDE;ZYRTEC | 4525358 | JUN 25, 2007 | DS DP U565 | | |
| >ADD> | | | 4525358*PED | DEC 25, 2007 | | | |
| >ADD> | | | 6455533 | JUL 02, 2018 | DP | | |
| >ADD> | 021621 002 | CETIRIZINE HYDROCHLORIDE;ZYRTEC | 4525358 | JUN 25, 2007 | DS DP U565 | | |
| >ADD> | | | 4525358*PED | DEC 25, 2007 | | | |
| >ADD> | | | 6455533 | JUL 02, 2018 | DP | | |
| | 021587 001 | CHLORPHENIRAMINE MALEATE;CHILDREN'S ADVIL ALL | | | | NP | FEB 24, 2007 |
| >ADD> | 021688 001 | CINACALCET HYDROCHLORIDE;SENSIPAR | 6031003 | DEC 14, 2016 | U559 | ODE | MAR 08, 2011 |
| >ADD> | | | 6211244 | OCT 23, 2015 | DS DP U560 | NCE | MAR 08, 2009 |
| >ADD> | | | 6313146 | DEC 14, 2016 | DS DP | | |
| >ADD> | | | 6011068 | DEC 14, 2016 | DS DP | | |
| >ADD> | 021688 002 | CINACALCET HYDROCHLORIDE;SENSIPAR | 6031003 | DEC 14, 2016 | | ODE | MAR 08, 2011 |
| >ADD> | | | 6211244 | OCT 23, 2015 | DS DP U560 | NCE | MAR 08, 2009 |
| >ADD> | | | 6313146 | DEC 14, 2016 | DS DP | | |
| >ADD> | | | 6011068 | DEC 14, 2016 | DS DP | | |
| >ADD> | 021688 003 | CINACALCET HYDROCHLORIDE;SENSIPAR | 6031003 | DEC 14, 2016 | U559 | ODE | MAR 08, 2011 |
| >ADD> | | | 6211244 | OCT 23, 2015 | DS DP U560 | NCE | MAR 08, 2009 |
| >ADD> | | | 6313146 | DEC 14, 2016 | DS DP | | |
| >ADD> | | | 6011068 | DEC 14, 2016 | DS DP | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnotes 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> | 019537 001 | CIPROFLOXACIN HYDROCHLORIDE;CIPRO | | | | I-421 | MAR 25, 2007 |
| >ADD> | | | | | | PED | SEP 25, 2007 |
| >ADD> | 019537 002 | CIPROFLOXACIN HYDROCHLORIDE;CIPRO | | | | I-421 | MAR 25, 2007 |
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| | 019858 001 | CIPROFLOXACIN;CIPRO IN SODIUM CHLO | 4670444 | DEC 09, 2003 | | | |
| | | | 4705789 | NOV 10, 2004 | | | |
| | | | 4957922 | SEP 18, 2007 | | | |
| | | | 4808583 | FEB 28, 2006 | | | |
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| | | | 4705789*PED | MAY 10, 2005 | | | |
| | | | 4808583*PED | AUG 28, 2006 | | | |
| | | | 4957922*PED | MAR 18, 2008 | | | |
| | 021473 002 | CIPROFLOXACIN;CIPRO XR | 4670444 | DEC 09, 2003 | DS DP U555 | | |
| | | | 4670444*PED | JUN 09, 2004 | | | |
| | 021644 001 | CLOBETASOL PROPIONATE;CLOBEX | | | | NDF | FEB 05, 2007 |
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| >ADD> | 021392 003 | DILTIAZEM HYDROCHLORIDE;CARDIZEM LA | | | | I-133 | APR 09, 2007 |
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| >ADD> | 020931 003 | DOFETILIDE;TIKOSYN | 4959366 | SEP 25, 2007 | | | |
| >ADD> | 020869 001 | DORZOLAMIDE HYDROCHLORIDE;COSOPT | 6316443 | APR 17, 2011 | DP U561 | | |
| >ADD> | 018651 001 | DRONABINOL;MARINOL | 6703418 | FEB 26, 2011 | U563 | | |
| >ADD> | 018651 002 | DRONABINOL;MARINOL | 6703418 | FEB 26, 2011 | U563 | | |
| >ADD> | 018651 003 | DRONABINOL;MARINOL | 6703418 | FEB 26, 2011 | U563 | | |
| >ADD> | 021500 001 | EMTRICITABINE;EMTRIVA | 6703396 | MAR 09, 2021 | DS DP | | |
| | 021371 001 | ESTRADIOL HEMIHYDRATE;ESTRASORB | | | | NDF | OCT 09, 2006 |
| | 021166 001 | ESTRADIOL;ESTROGEL | | | | NDF | FEB 09, 2007 |
| | 020992 002 | ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN | | | | D-85 | FEB 05, 2007 |
| | 020992 003 | ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN | | | | D-85 | FEB 05, 2007 |
| | 020992 004 | ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN | | | | D-85 | FEB 05, 2007 |
| | 020992 006 | ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN | | | | NS | FEB 05, 2007 |
| | | | | | | D-85 | FEB 05, 2007 |
| | 021490 001 | ETHINYL ESTRADIOL;OVCON-35 | 6667050 | JUN 12, 2021 | DP U1 | | |

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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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| >ADD> | 019922 001 | FENOLDOPAM MESYLATE;CORLOPAM | | | | I-422 | APR 01, 2007 |
| | 019949 001 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 019949 002 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 019949 003 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 019949 004 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 020090 001 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 020090 002 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 019950 003 | FLUCONAZOLE;DIFLUCAN IN DEXTROSE | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 019950 005 | FLUCONAZOLE;DIFLUCAN IN DEXTROSE | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 019950 001 | FLUCONAZOLE;DIFLUCAN IN SODIUM C | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 019950 002 | FLUCONAZOLE;DIFLUCAN IN SODIUM C | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 019950 004 | FLUCONAZOLE;DIFLUCAN IN SODIUM C | 4404216 | JAN 29, 2004 | | | |
| | | | 4404216*PED | JUL 29, 2004 | | | |
| | 020985 001 | FLUOROURACIL;CARAC | 6670335 | JUN 02, 2021 | DP U68 | | |
| | 021235 001 | FLUOXETINE HYDROCHLORIDE;PROZAC WEEKLY | 5910319 | MAY 29, 2017 | U396 | | |
| | | | 5985322 | MAY 29, 2017 | U397 | | |
| >ADD> | 021493 001 | GATIFLOXACIN;ZYMAR | 6333045 | AUG 20, 2019 | DP | | |
| | 021604 001 | IBUPROFEN;CHILDREN'S ELIXSURE | | | | NP | JAN 07, 2007 |
| >ADD> | 076478 001 | IBUPROFEN;IBUPROFEN AND PSEUDO | | | | PC | JUL 29, 2004 |
| | 020723 001 | IMIQUIMOD;ALDARA | | | | I-420 | MAR 02, 2007 |
| | 020685 001 | INDINAVIR SULFATE;CRIXIVAN | 6689761 | FEB 10, 2021 | U554 | | |
| | 020685 003 | INDINAVIR SULFATE;CRIXIVAN | 6689761 | FEB 10, 2021 | U554 | | |
| | 020685 005 | INDINAVIR SULFATE;CRIXIVAN | 6689761 | FEB 10, 2021 | U554 | | |
| | 020685 006 | INDINAVIR SULFATE;CRIXIVAN | 6689761 | FEB 10, 2021 | U554 | | |
| | 020571 001 | IRINOTECAN HYDROCHLORIDE;CAMPTOSAR | 4604463 | AUG 20, 2007 | | | |
| | | | 6403569 | APR 28, 2020 | U449 | | |
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| | | | 6403569*PED | OCT 28, 2020 | | | |
| >ADD> | 020182 001 | LEVOCARNITINE;CARNITOR | 6696493 | JAN 18, 2021 | U433 | | |
| | 021571 001 | LEVOFLOXACIN;IQUIX | | | | NP | MAR 01, 2007 |
| | 021451 001 | LIDOCAINE;ORAQIX | 6031007 | APR 01, 2017 | DP U553 | | |
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| | 075505 001 | LORATADINE;LORATADINE | | | | PC | AUG 20, 2004 |
| | 021249 001 | LOVASTATIN;ADVICOR | 6676967 | SEP 20, 2013 | U548 | | |
| | 021249 002 | LOVASTATIN;ADVICOR | 6676967 | SEP 20, 2013 | U548 | | |
| | 021249 003 | LOVASTATIN;ADVICOR | 6676967 | SEP 20, 2013 | U548 | | |
| | 013217 001 | METAXALONE;SKELAXIN | 6683102 | DEC 03, 2021 | U189 | | |
| | 013217 002 | METAXALONE;SKELAXIN | 6683102 | DEC 03, 2021 | U189 | | |
| | 076545 001 | METFORMIN HYDROCHLORIDE;METFORMIN HCL | | | | PC | MAY 29, 2004 |
| | 021308 001 | MICONAZOLE NITRATE;MONISTAT 1 COMBINATI | | | | RTO | JUN 29, 2004 |
| | 076307 001 | MIRTAZAPINE;MIRTAZAPINE | | | | PC | JUN 14, 2004 |

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| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | PATENT CODE(S) | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 076307 002 | MIRTAZAPINE;MIRTAZAPINE | | | | PC | JUN 14, 2004 |
| | 021598 001 | MOXIFLOXACIN HYDROCHLORIDE;VIGAMOX | | | | NCE | DEC 10, 2004 |
| | | | | | | PED | JUN 10, 2005 |
| | 020381 002 | NIACIN;NIASPAN | 6676967 | SEP 20, 2013 | U548 | | |
| | 020381 003 | NIACIN;NIASPAN | 6676967 | SEP 20, 2013 | U548 | | |
| | 020381 004 | NIACIN;NIASPAN | 6676967 | SEP 20, 2013 | U548 | | |
| | 020592 001 | OLANZAPINE;ZYPREXA | 5229382 | APR 23, 2011 | DS DP U149 | I-417 | JAN 14, 2007 |
| | | | 5229382 | APR 23, 2001 | U547 | | |
| | 020592 002 | OLANZAPINE;ZYPREXA | 5229382 | APR 23, 2011 | DS DP U149 | I-417 | JAN 14, 2007 |
| | | | 5229382 | APR 23, 2011 | U547 | | |
| | 020592 003 | OLANZAPINE;ZYPREXA | 5229382 | APR 23, 2011 | DS DP U149 | I-417 | JAN 14, 2007 |
| | | | 5229382 | APR 23, 2011 | U547 | | |
| | 020592 004 | OLANZAPINE;ZYPREXA | 5229382 | APR 23, 2011 | DS DP U149 | I-417 | JAN 14, 2007 |
| | | | 5229382 | APR 23, 2011 | U547 | | |
| | 020592 005 | OLANZAPINE;ZYPREXA | 5229382 | APR 23, 2011 | DS DP U149 | I-417 | JAN 14, 2007 |
| | | | 5229382 | APR 23, 2011 | U547 | | |
| | 020592 006 | OLANZAPINE;ZYPREXA | 5229382 | APR 23, 2011 | DS DP U149 | I-417 | JAN 14, 2007 |
| | | | 5229382 | APR 23, 2011 | DS DP U547 | | |
| >ADD> | 021253 001 | OLANZAPINE;ZYPREXA | | | | NDF | MAR 29, 2007 |
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| >ADD> | 021086 001 | OLANZAPINE;ZYPREXA ZYDIS | | | | I-417 | JAN 14, 2007 |
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| >ADD> | 021086 002 | OLANZAPINE;ZYPREXA ZYDIS | | | | I-417 | JAN 14, 2007 |
| >ADD> | | | | | | I-400 | JUL 10, 2006 |
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| >ADD> | | | | | | I-400 | JUL 10, 2006 |
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|---|---|---|---|---|---|---|---|
| | 020639 001 | QUETIAPINE FUMARATE;SEROQUEL | 4879288 | SEP 26, 2011 | DS DP U550 | I-419 | JAN 12, 2007 |
| | | | | | | I-418 | JAN 12, 2007 |
| | 020639 002 | QUETIAPINE FUMARATE;SEROQUEL | 4879288 | SEP 26, 2011 | DS DP U550 | I-419 | JAN 12, 2007 |
| | | | | | | I-418 | JAN 12, 2007 |
| | 020639 003 | QUETIAPINE FUMARATE;SEROQUEL | 4879288 | SEP 26, 2011 | DS DP U550 | I-419 | JAN 12, 2007 |
| | | | | | | I-418 | JAN 12, 2007 |
| | 020639 004 | QUETIAPINE FUMARATE;SEROQUEL | 4879288 | SEP 26, 2011 | DS DP U550 | I-419 | JAN 12, 2007 |
| | | | | | | I-418 | JAN 12, 2007 |
| | 020639 005 | QUETIAPINE FUMARATE;SEROQUEL | 4879288 | SEP 26, 2011 | DS DP U550 | I-419 | JAN 12, 2007 |
| | | | | | | I-418 | JAN 12, 2007 |
| | 020741 001 | REPAGLINIDE;PRANDIN | 6677358 | JUN 12, 2018 | DS DP U546 | | |
| | 020741 002 | REPAGLINIDE;PRANDIN | 6677358 | JUN 12, 2018 | DS DP U546 | | |
| | 020741 003 | REPAGLINIDE;PRANDIN | 6677358 | JUN 12, 2018 | DS DP U546 | | |
| >ADD> | 020903 002 | RIBAVIRIN;REBETOL | 6177074 | NOV 01, 2016 | U454 | | |
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| >ADD> | 020945 001 | RITONAVIR;NORVIR | 6703403 | JUN 26, 2016 | U564 | | |
| | 021042 001 | ROFECOXIB;VIOXX | 5474995 | JUN 24, 2013 | U266 | NCE | MAY 20, 2004 |
| | | | 5691374 | MAY 18, 2015 | | I-353 | APR 11, 2005 |
| | | | 6063811 | MAY 06, 2017 | U266 | M-27 | AUG 06, 2006 |
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| | | | 6239173*PED | DEC 24, 2013 | | | |
| | 021052 001 | ROFECOXIB;VIOXX | 5474995 | JUN 24, 2013 | U266 | NCE | MAY 20, 2004 |
| | | | 5691374 | MAY 18, 2015 | | I-353 | APR 11, 2005 |
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| | | | 6239173 | JUN 24, 2013 | | PED | NOV 20, 2004 |
| | | | 5474995*PED | DEC 24, 2013 | | PED | FEB 06, 2007 |
| | | | 5691374*PED | NOV 18, 2015 | | PED | OCT 11, 2005 |
| | | | 6063811*PED | NOV 06, 2017 | | | |

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| | | | 5691374 | MAY 18, 2015 | | I-353 | APR 11, 2005 |
| | | | 6063811 | MAY 06, 2017 | U266 | M-27 | AUG 06, 2006 |
| | | | 6239173 | JUN 24, 2013 | | PED | NOV 20, 2004 |
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| | 020926 001 | SEVELAMER HYDROCHLORIDE;RENAGEL | 6509013 | AUG 11, 2013 | | | |
| | 021179 001 | SEVELAMER HYDROCHLORIDE;RENAGEL | 6509013 | AUG 11, 2013 | | | |
| | 021110 003 | SIROLIMUS;RAPAMUNE | | | | NCE | SEP 15, 2004 |
| | | | | | | I-386 | APR 11, 2006 |
| | 020080 001 | SUMATRIPTAN SUCCINATE;IMITREX | 4816470 | DEC 28, 2006 | U72 | | |
| | | | 5037845 | AUG 06, 2008 | U72 | | |
| | | | 4816470*PED | JUN 28, 2007 | | | |
| | | | 5037845*PED | FEB 06, 2009 | | | |
| | 020132 001 | SUMATRIPTAN SUCCINATE;IMITREX | 4816470 | DEC 28, 2006 | U72 | | |
| | | | 5037845 | AUG 06, 2008 | U72 | | |
| | | | 6368627 | MAR 02, 2012 | U444 | | |
| | | | 5863559 | JAN 26, 2016 | U72 | | |
| | | | 6020001 | MAR 02, 2012 | U444 | | |
| | | | 6020001*PED | SEP 02, 2012 | | | |
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| | 020132 002 | SUMATRIPTAN SUCCINATE;IMITREX | 4816470 | DEC 28, 2006 | U72 | | |
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| | | | 5863559 | JAN 26, 2016 | U72 | | |
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| | | | 6020001 | MAR 02, 2012 | U444 | | |
| | | | 6020001*PED | SEP 02, 2012 | | | |
| | | | 6368627*PED | SEP 02, 2012 | | | |
| | | | 4816470*PED | JUN 28, 2007 | | | |
| | | | 5037845*PED | FEB 06, 2009 | | | |
| | | | 5863559*PED | JUL 26, 2016 | | | |
| | 020626 001 | SUMATRIPTAN;IMITREX | 4816470 | DEC 28, 2006 | U72 | | |
| | | | 5037845 | AUG 06, 2008 | | | |
| | | | 5307953 | DEC 02, 2012 | | | |
| | | | 5554639 | SEP 10, 2013 | U232 | | |
| | | | 5705520 | DEC 10, 2011 | U232 | | |
| | | | 5554639*PED | MAR 10, 2014 | | | |
| | | | 5705520*PED | JUN 10, 2012 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnotes 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 |
|---|---|---|---|---|---|---|---|
| | 020626 002 | SUMATRIPTAN;IMITREX | 4816470*PED | JUN 28, 2007 | | | |
| | | | 5037845*PED | FEB 06, 2009 | | | |
| | | | 5307953*PED | JUN 02, 2013 | | | |
| | | | 4816470 | DEC 28, 2006 | U72 | | |
| | | | 5037845 | AUG 06, 2008 | | | |
| | | | 5307953 | DEC 02, 2012 | | | |
| | | | 5554639 | SEP 10, 2013 | U232 | | |
| | | | 5705520 | DEC 10, 2011 | U232 | | |
| | | | 5554639*PED | MAR 10, 2014 | | | |
| | | | 5705520*PED | JUN 10, 2012 | | | |
| | | | 4816470*PED | JUN 28, 2007 | | | |
| | | | 5037845*PED | FEB 06, 2009 | | | |
| | | | 5307953*PED | JUN 02, 2013 | | | |
| | 020626 003 | SUMATRIPTAN;IMITREX | 4816470 | DEC 28, 2006 | U72 | | |
| | | | 5037845 | AUG 06, 2008 | | | |
| | | | 5307953 | DEC 02, 2012 | | | |
| | | | 5554639 | SEP 10, 2013 | U232 | | |
| | | | 5705520 | DEC 10, 2011 | U232 | | |
| | | | 5554639*PED | MAR 10, 2014 | | | |
| | | | 5705520*PED | JUN 10, 2012 | | | |
| | | | 4816470*PED | JUN 28, 2007 | | | |
| | | | 5037845*PED | FEB 06, 2009 | | | |
| | | | 5307953*PED | JUN 02, 2013 | | | |
| | 021368 001 | TADALAFIL;CIALIS | 5859006 | JAN 12, 2016 | DS DP | | |
| | | | 6140329 | JUL 11, 2016 | DP U155 | | |
| | 021368 002 | TADALAFIL;CIALIS | 5859006 | JAN 12, 2016 | DS DP | | |
| | | | 6140329 | JUL 11, 2016 | DP U155 | | |
| | 021368 003 | TADALAFIL;CIALIS | 5859006 | JAN 12, 2016 | DS DP | | |
| | | | 6140329 | JUL 11, 2016 | DP U155 | | |
| | 021388 001 | TALC;TALC | | | | ODE | DEC 24, 2004 |
| >ADD> | 021124 002 | TERBINAFINE HYDROCHLORIDE;LAMISIL AT | 5681849 | OCT 28, 2014 | | | |
| >ADD> | | | 4755534 | DEC 30, 2006 | U73 | | |
| >ADD> | | | 4680291 | JUL 14, 2004 | U73 | | |
| >ADD> | | | 6121314 | MAY 18, 2012 | U504 | | |
| | 020846 001 | TERBINAFINE;LAMISIL | 5681849 | OCT 28, 2014 | DP | | |
| | | | 6121314 | MAY 18, 2012 | DP U504 | | |
| | | | 6121314 | MAY 18, 2012 | DP U540 | | |
| | | | 6121314 | MAY 18, 2012 | DP U502 | | |
| | 020898 001 | THYROTROPIN ALFA;THYROGEN | | | | | |
| >ADD> | 021395 001 | TIOTROPIUM BROMIDE MONOHYDRATE;SPIRIVA | 6365127 | NOV 24, 2015 | DS DP U556 | | |
| | 020771 002 | TOLTERODINE TARTRATE;DETROL | 5610163 | MAR 11, 2014 | DS DP U566 | NCE | JAN 30, 2009 |
| | | | 5559269 | NOV 05, 2013 | U318 | | |
| >ADD> | 021257 001 | TRAVOPROST;TRAVATAN | 5559269*PED | MAY 05, 2014 | | | |
| >ADD> | | | 6011062 | DEC 22, 2014 | DP | | |
| >ADD> | | | 5849792 | DEC 22, 2014 | DP U383 | | |
| >ADD> | | | 5889052 | DEC 02, 2014 | DP U383 | | |
| | 021630 001 | VORICONAZOLE;VFEND | 5510383 | AUG 03, 2013 | DP U383 | | |
| | | | 5116844 | AUG 11, 2009 | DP U540 | NCE | MAY 24, 2007 |
| | | | 5364938 | NOV 15, 2011 | DS | I-409 | NOV 14, 2006 |
| | | | 5567817 | OCT 22, 2013 | DS DP U540 | | |
| | | | 5773443 | JAN 25, 2011 | DS DP U540 | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnotes 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 |
|---|---|---|---|---|---|---|

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(c)(3)(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. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 24TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION. THE MOST CURRENT COMPLETE LIST OF ALL PATENT AND EXCLUSIVITY TERMS IS AVAILABLE AT HTTP://WWW.FDA.GOV/CDER/ORANGE/PATEX.HTM.

## PATENT & EXCLUSIVITY ABBREVIATIONS

| | |
|---|---|
| W | EXCLUSIVITY ON THIS APPLICATION EXPIRING ON THIS DATE HAS BEEN WAIVED BY SPONSOR - SEE SECTION 1.8 OF ORANGE BOOK PREFACE WAIVED EXCLUSIVITY |

## EXCLUSIVITY DOSING SCHEDULE

| | |
|---|---|
| D-85 | LOWER RECOMMENDED STARTING DOSE GUIDELINES FOR TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS ASSOCIATED WITH THE MENOPAUSE |

## EXCLUSIVITY INDICATION

| | |
|---|---|
| I-417 | USE IN THE LONG TERM TREATMENT OF BIPOLAR I DISORDER |
| I-418 | ADJUNCTIVE THERAPY W/ MOOD STABILIZERS (LITHIUM OR DIVALPROEX) IN THE TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDERS |
| I-419 | MONOTHERAPY IN THE TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER |
| I-420 | TOPICAL TREATMENT OF CLINICALLY TYPICAL, NONHYPERKERATOTIC, NONHYPERTROPHIC ACTINIC KERATOSES ON THE FACE OR SCALP IN IMMUNOCOMPETENT ADULTS |
| I-421 | TREATMENT OF COMPLICATED URINARY TRACT INFECTIONS AND PYELONEPHRITIS DUE TO E.COLI FOR PED PATIENTS (1-17) NOT AS FIRST CHOICE |
| I-422 | INDICATED FOR THE IN-HOSPITAL SHORT-TERM (UP TO 4 HOURS) REDUCTIN IN BLOOD PRESSURE IN PEDIATRIC PATIENTS |

## EXCLUSIVITY MISCELLANEOUS

| | |
|---|---|
| M-30 | CHANGES TO CLINICAL PHARMACOLOGY, PRECAUTIONS, AND DOSAGE AND ADMINISTRATION SECTIONS OF LABELING CONCERNING USE OF LOTENSIN IN PEDIATRIC PATIENTS WITH HYPERTENSION |

## PATENT USE

| | |
|---|---|
| U-546 | USE OF REPAGLINIDE IN COMBINATION WITH METFORMIN TO LOWER BLOOD GLUCOSE |
| U-547 | MAINTENANCE MONOTHERAPY FOR BIPOLAR DISORDER |
| U-548 | A METHOD OF REDUCING FLUSH IN AN INDIVIDUAL BEING TREATED FOR A LIPIDEMIC DISORDER AND EFFECTIVELY TREATING THE LIPIDEMIC DISORDER |
| U-549 | USE IN THE TREATMENT OF MEN WITH ADVANCED SYMPTOMATIC PROSTATE CANCER |
| U-550 | TREATMENT OF BIPOLAR MANIA AND SCHIZOPHRENIA |
| U-551 | METHOD FOR REDUCING TOXICITY OF ALIMTA TREATED PATIENTS BY ADMINISTERING FOLIC ACID |
| U-552 | TREATMENT OF HYPERTENSION AND HYPERLIPIDEMIA WITH A SINGLE COMPOSITION |
| U-553 | MANAGEMENT OF PAIN AND DISCOMFORT ASSOCIATED WITH PERIDONTAL SCALING AND ROOT PLANNING PROCEDURES BY APPLICATION OF AN EUTECTIC MIXTURE OF LOCAL ANESTHETICS TO PERIDONTAL POCKETS |

| | |
|---|---|
| U-554 | TREATING HIV INFECTION WITH INDINAVIR SULFATE IN COMBINATION WITH ANTIRETROVIRAL AGENTS |
| U-555 | TREATMENT OF COMPLICATED URINARY TRACT INFECTIONS AND ACUTE UNCOMPLICATED PYELONEPHRITIS |
| U-556 | USE AS ADJUNCT DIAGNOSTIC FOR SERUM THYROGLOBULIN (TG) TESTING |
| U-557 | NASAL TREATMENT OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS SYMPTOMS |
| U-558 | INDICATED FOR THE RELIEF OF BRONCHOSPASM IN PATIENTS 2-12 YEARS OF AGE WITH ASTHMA REVERSIBLE OBSTRUCTIVE AIRWAY DISEASE) |
| U-559 | METHOD OF DECREASING OR REDUCING PARATHYROID HORMONE LEVEL; METHOD OF MODULATING PARATHYROID HORMONE SECRETION; METHOD OF TREATING HYPERPARATHYROIDISM; METHOD OF REDUCING SERUM IONIZED CALCIUM LEVEL |
| U-560 | METHOD OF DECREASING PARATHYROID HORMONE LEVEL; METHOD OF TREATING HYPERPARATHYROIDISM |
| U-561 | COSOPT IS INDICATED FOR THE REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN-ANGLE GLAUCOMA OR OCULAR HYPERTENSION WHO ARE INSUFFICIENTLY RESPONSIVE TO BETA BLOCKERS |
| U-562 | TOPICAL TREATMENT OF CUTANEOUS LESIONS IN PATIENTS WITH AIDS-RELATED KAPOSI'S SARCOMA |
| U-563 | MARINOL IS INDICATED FOR, INTER ALIA, ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS |
| U-564 | TREATMENT OF HIV IN CONCOMITANT THERAPY |
| U-565 | TREATMENT OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS SYMPTOMS, AND CHRONIC URTICARIA |
| U-566 | FOR THE LONG-TERM, ONCE-DAILY, MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA |

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