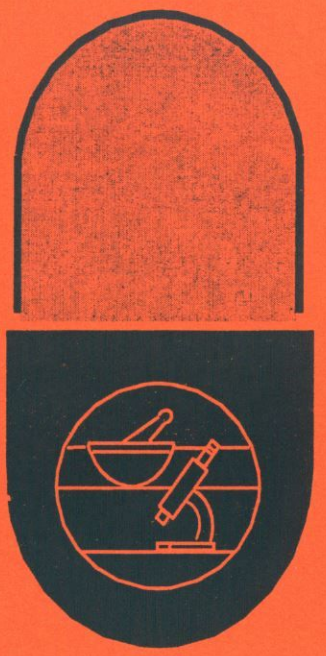
CUMULATIVE
SUPPLEMENT 1
JANUARY 2004



# 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

# APPROVED DRUG PRODUCTS
# with
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## 24th EDITION

## Cumulative Supplement 1

## January 2004

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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 1**
**January 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have never been marketed, are for exportation, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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<br>(FORMER ABBREVIATED NAME) | NEW APPLICANT NAME<br>(NEW ABBREVIATED NAME) |
|---|---|

No applicant name changes for January 2004.

## 1.3 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

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

### DESCRIPTION OF REPORT

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

The baseline column (Dec 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 | JUN 2004 | SEP 2004 | DEC 2004 |
|---|---|---|---|---|
| DRUG PRODUCTS LISTED | 10665 | | | |
| SINGLE SOURCE | 2423 (22.7%) | | | |
| MULTISOURCE | 8134 (76.3%) | | | |
| THERAPEUTICALLY EQUIVALENT | 7856 (73.7%) | | | |
| NOT THERAPEUTICALLY EQUIVALENT | 278 (2.6%) | | | |
| EXCEPTIONS[1] | 108 (1.0%) | | | |
| NEW MOLECULAR ENTITIES APPROVED | 6 | | | |
| NUMBER OF APPLICANTS | 601 | | | |

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

BETAMETHASONE DIPROPIONATE
CREAM, AUGMENTED; TOPICAL
BETAMETHASONE DIPROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | ATRIX | EQ 0.05% BASE | N76603 001 | JAN 23, 2004 | JAN | NEWA |

BUPROPION HYDROCHLORIDE
TABLET, EXTENDED RELEASE; ORAL
BUPROPION HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | IMPAX LABS | 100MG | N75913 001 | JAN 28, 2004 | JAN | NEWA |

CALCITRIOL
INJECTABLE; INJECTION
CALCITRIOL

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

CARBOPLATIN
INJECTABLE; IV (INFUSION)
PARAPLATIN

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

CEFACLOR
CAPSULE; ORAL
CEFACLOR

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

CEFUROXIME SODIUM
INJECTABLE; IM-IV
CEFUROXIME

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

INJECTABLE; INJECTION

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

CROMOLYN SODIUM
AEROSOL, METERED; INHALATION
INTAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | + | AVENTIS | 0.8MG/INH | N18887 001 | DEC 05, 1985 | JAN | CAHN |
| >A> | | + | KING PHARMS | 0.8MG/INH | N18887 001 | DEC 05, 1985 | JAN | CAHN |

SOLUTION; INHALATION

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AN | + | AVENTIS PHARMS | 10MG/ML | N18596 001 | MAY 28, 1982 | JAN | CAHN |
| >A> | AN | + | KING PHARMS | 10MG/ML | N18596 001 | MAY 28, 1982 | JAN | CAHN |

CYTARABINE
INJECTABLE; INJECTION
CYTARABINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | | | | | | | |
| >A> | AP | | AM PHARM | 100MG/ML | N76512 001 | JAN 15, 2004 | JAN | NEWA |
| >D> | | + | MAYNE PHARMA USA | 100MG/ML | N75383 001 | NOV 22, 1999 | JAN | CFTG |
| >A> | AP | + | | 100MG/ML | N75383 001 | NOV 22, 1999 | JAN | CFTG |

DILTIAZEM HYDROCHLORIDE
TABLET, EXTENDED RELEASE; ORAL
CARDIZEM LA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | + | BIOVAIL | 120MG | N21392 001 | FEB 06, 2003 | JAN | CRLD |
| >A> | | | | 120MG | N21392 001 | FEB 06, 2003 | JAN | CRLD |
| >D> | | + | | 180MG | N21392 002 | FEB 06, 2003 | JAN | CRLD |
| >A> | | | | 180MG | N21392 002 | FEB 06, 2003 | JAN | CRLD |
| >D> | | + | | 240MG | N21392 003 | FEB 06, 2003 | JAN | CRLD |
| >A> | | | | 240MG | N21392 003 | FEB 06, 2003 | JAN | CRLD |
| >D> | | + | | 300MG | N21392 004 | FEB 06, 2003 | JAN | CRLD |
| >A> | | | | 300MG | N21392 004 | FEB 06, 2003 | JAN | CRLD |
| >D> | | + | | 360MG | N21392 005 | FEB 06, 2003 | JAN | CRLD |
| >A> | | | | 360MG | N21392 005 | FEB 06, 2003 | JAN | CRLD |

DIVALPROEX SODIUM
TABLET, DELAYED RELEASE; ORAL
DEPAKOTE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | + | ABBOTT | EQ 125MG VALPROIC ACID | N18723 003 | OCT 26, 1984 | JAN | CRLD |
| >A> | | | | EQ 125MG VALPROIC ACID | N18723 003 | OCT 26, 1984 | JAN | CRLD |
| >D> | | + | | EQ 250MG VALPROIC ACID | N18723 001 | MAR 10, 1983 | JAN | CRLD |
| >A> | | | | EQ 250MG VALPROIC ACID | N18723 001 | MAR 10, 1983 | JAN | CRLD |

DOXEPIN HYDROCHLORIDE
CONCENTRATE; ORAL
DOXEPIN HCL

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

ERYTHROMYCIN
CAPSULE, DELAYED REL PELLETS; ORAL
ERYC

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | | @ WARNER CHILCOTT | 250MG | N62338 001 | | JAN | CMFD |
| >A> | AB | | | 250MG | N62338 001 | | JAN | CMFD |

ERYTHROMYCIN ESTOLATE
SUSPENSION; ORAL
ERYTHROMYCIN ESTOLATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | | ALPHARMA | EQ 125MG BASE/5ML | N62353 001 | NOV 18, 1982 | JAN | CTEC |
| >A> | | | | EQ 125MG BASE/5ML | N62353 001 | NOV 18, 1982 | JAN | CTEC |
| >D> | AB | | | EQ 250MG BASE/5ML | N62409 001 | DEC 16, 1982 | JAN | CRLD |
| >A> | | + | | EQ 250MG BASE/5ML | N62409 001 | DEC 16, 1982 | JAN | CRLD |
| >D> | | | ILOSONE | | | | | |
| >D> | AB | | LILLY | EQ 125MG BASE/5ML | N50010 001 | | JAN | DISC |
| >A> | | | @ | EQ 125MG BASE/5ML | N50010 001 | | JAN | DISC |
| >D> | AB | + | | EQ 250MG BASE/5ML | N50010 002 | | JAN | DISC |
| >A> | | | @ | EQ 250MG BASE/5ML | N50010 002 | | JAN | DISC |

ETHINYL ESTRADIOL; NORGESTIMATE
TABLET; ORAL-28
PREVIFEM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | ANDRX PHARMS | 0.035MG;0.25MG | N76334 001 | JAN 09, 2004 | JAN | NEWA |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | FOMIVIRSEN SODIUM | | | | | | |
| | | | INJECTABLE; INJECTION | | | | | | |
| | | | VITRAVENE PRESERVATIVE FREE | | | | | | |
| >D> | | + | NOVARTIS | 6.6MG/ML | N20961 001 | AUG 26, 1998 | JAN | CAHN |
| >A> | | + | NOVARTIS | 6.6MG/ML | N20961 001 | AUG 26, 1998 | JAN | CAHN |
| | | | GENTAMICIN SULFATE | | | | | | |
| >D> | | | SOLUTION; OPHTHALMIC | | | | | | |
| | | | GARAMYCIN | | | | | | |
| >D> | AT | + | SCHERING | EQ 0.3% BASE | N50039 002 | | JAN | CDFR |
| >A> | | | SOLUTION/DROPS; OPHTHALMIC | | | | | | |
| | | | GARAMYCIN | | | | | | |
| >A> | AT | + | | EQ 0.3% BASE | N50039 002 | | JAN | CDFR |
| | | | GENTAMICIN SULFATE | | | | | | |
| >A> | AT | | ALTANA | EQ 0.3% BASE | N65121 001 | JAN 30, 2004 | JAN | NEWA |
| | | | HYDROCORTISONE BUTYRATE | | | | | | |
| | | | SOLUTION; TOPICAL | | | | | | |
| >A> | | | HYDROCORTISONE BUTYRATE | | | | | | |
| >A> | AT | | TARO PHARM INDS | 0.1% | N76364 001 | JAN 14, 2004 | JAN | NEWA |
| | | | LOCOID | | | | | | |
| >D> | | + | FERNDALE LABS | 0.1% | N19116 001 | FEB 25, 1987 | JAN | CFTG |
| >A> | AT | + | | 0.1% | N19116 001 | FEB 25, 1987 | JAN | CFTG |
| | | | KETOCONAZOLE | | | | | | |
| | | | SHAMPOO; TOPICAL | | | | | | |
| >A> | | | KETOCONAZOLE | | | | | | |
| >A> | AB | | CLAY PARK | 2% | N76419 001 | JAN 07, 2004 | JAN | NEWA |
| | | | NIZORAL | | | | | | |
| >D> | | + | MCNEIL CONS SPECLT | 2% | N19927 001 | AUG 31, 1990 | JAN | CFTG |
| >A> | AB | + | | 2% | N19927 001 | AUG 31, 1990 | JAN | CFTG |
| | | | KETOROLAC TROMETHAMINE | | | | | | |
| | | | INJECTABLE; INJECTION | | | | | | |
| | | | KETOROLAC TROMETHAMINE | | | | | | |
| >D> | AP | | BEDFORD | 15MG/ML | N75222 001 | APR 26, 1999 | JAN | CRLD |
| >A> | AP | + | | 15MG/ML | N75222 001 | APR 26, 1999 | JAN | CRLD |
| >D> | AP | | | 30MG/ML | N75222 002 | APR 26, 1999 | JAN | CRLD |
| >A> | AP | + | | 30MG/ML | N75222 002 | APR 26, 1999 | JAN | CRLD |
| >D> | | | TORADOL | | | | | | |
| >D> | AP | + | ROCHE PALO | 15MG/ML | N19698 001 | NOV 30, 1989 | JAN | DISC |
| >A> | | | @ | 15MG/ML | N19698 001 | NOV 30, 1989 | JAN | DISC |
| >D> | AP | + | | 30MG/ML | N19698 002 | NOV 30, 1989 | JAN | DISC |
| >A> | | | @ | 30MG/ML | N19698 002 | NOV 30, 1989 | JAN | DISC |
| | | | LITHIUM CARBONATE | | | | | | |
| | | | TABLET, EXTENDED RELEASE; ORAL | | | | | | |
| | | | LITHIUM CARBONATE | | | | | | |
| >A> | AB | | ROXANE | 450MG | N76691 001 | JAN 05, 2004 | JAN | NEWA |
| | | | MESNA | | | | | | |
| | | | INJECTABLE; INTRAVENOUS | | | | | | |
| | | | MESNA | | | | | | |
| >A> | AP | | BEDFORD | 100MG/ML | N75739 001 | JAN 09, 2004 | JAN | NEWA |

METFORMIN HYDROCHLORIDE
TABLET, EXTENDED RELEASE; ORAL
GLUCOPHAGE XR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | BRISTOL MYERS SQUIBB | 500MG | N21202 001 | OCT 13, 2000 | JAN | CFTG |
| >A> | AB | | 500MG | N21202 001 | OCT 13, 2000 | JAN | CFTG |

METFORMIN HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | IVAX PHARMS | 500MG | N76545 001 | DEC 01, 2003 | JAN | NEWA |

METOLAZONE
TABLET; ORAL
METOLAZONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | TEVA | 2.5MG | N76600 001 | JAN 06, 2004 | JAN | NEWA |

MYKROX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | CELLTECH PHARMS | 0.5MG | N19532 001 | OCT 30, 1987 | JAN | DISC |
| >A> | | @ | 0.5MG | N19532 001 | OCT 30, 1987 | JAN | DISC |

METOPROLOL TARTRATE
TABLET; ORAL
METOPROLOL TARTRATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | CARACO | 25MG | N76670 001 | JAN 15, 2004 | JAN | NEWA |
| >A> | + | MYLAN | 25MG | N76704 001 | JAN 16, 2004 | JAN | NEWA |
| >A> | AB | | 50MG | N76704 002 | JAN 16, 2004 | JAN | NEWA |
| >A> | AB | | 100MG | N76704 003 | JAN 16, 2004 | JAN | NEWA |

METRONIDAZOLE
CAPSULE; ORAL
METRONIDAZOLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | KALI LABS | 375MG | N76522 001 | JAN 29, 2004 | JAN | NEWA |

MINOCYCLINE HYDROCHLORIDE
TABLET; ORAL
MINOCYCLINE HCL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | MEDICIS | EQ 50MG BASE | N65131 001 | APR 16, 2003 | JAN | CFTG |
| >A> | AB | | EQ 50MG BASE | N65131 001 | APR 16, 2003 | JAN | CFTG |
| >D> | | | EQ 75MG BASE | N65131 002 | APR 16, 2003 | JAN | CFTG |
| >A> | AB | | EQ 75MG BASE | N65131 002 | APR 16, 2003 | JAN | CFTG |
| >D> | + | | EQ 100MG BASE | N65131 003 | APR 16, 2003 | JAN | CFTG |
| >A> | AB + | | EQ 100MG BASE | N65131 003 | APR 16, 2003 | JAN | CFTG |
| >A> | AB | RANBAXY | EQ 50MG BASE | N65156 001 | JAN 06, 2004 | JAN | NEWA |
| >A> | AB | | EQ 75MG BASE | N65156 002 | JAN 06, 2004 | JAN | NEWA |
| >A> | AB | | EQ 100MG BASE | N65156 003 | JAN 06, 2004 | JAN | NEWA |

NABILONE
CAPSULE; ORAL
CESAMET

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | @ LILLY | 1MG | N18677 001 | DEC 26, 1985 | JAN | CAHN |
| >A> | | @ VALEANT | 1MG | N18677 001 | DEC 26, 1985 | JAN | CAHN |

NAPROXEN
TABLET; ORAL
NAPROXEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | WESTWARD | 250MG | N76494 001 | JAN 14, 2004 | JAN | NEWA |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | AB | | 375MG | N76494 002 | JAN 14, 2004 | JAN | NEWA |
| >A> | AB | | 500MG | N76494 003 | JAN 14, 2004 | JAN | NEWA |
| | | NEDOCROMIL SODIUM | | | | | |
| | | AEROSOL, METERED; INHALATION | | | | | |
| | | TILADE | | | | | |
| >D> | | + AVENTIS | 1.75MG/INH | N19660 001 | DEC 30, 1992 | JAN | CAHN |
| >A> | | + KING PHARMS | 1.75MG/INH | N19660 001 | DEC 30, 1992 | JAN | CAHN |
| | | PREDNISONE | | | | | |
| | | TABLET; ORAL | | | | | |
| | | PREDNISONE | | | | | |
| >A> | AB | WEST WARD | 2.5MG | N40538 001 | JAN 08, 2004 | JAN | NEWA |
| | | PROPRANOLOL HYDROCHLORIDE | | | | | |
| | | INJECTABLE; INJECTION | | | | | |
| | | PROPRANOLOL | | | | | |
| >A> | AP | AM PHARM PARTNERS | 1MG/ML | N75826 001 | AUG 31, 2001 | JAN | NEWA |
| | | SOMATROPIN RECOMBINANT | | | | | |
| | | INJECTABLE; INJECTION | | | | | |
| | | SEROSTIM | | | | | |
| >D> | | SERONO | 4MG/VIAL | N20604 003 | JUL 25, 1997 | JAN | CTEC |
| >A> | BX | | 4MG/VIAL | N20604 003 | JUL 25, 1997 | JAN | CTEC |
| >D> | | + | 8.8MG/VIAL | N20604 004 | SEP 06, 2001 | JAN | DISC |
| >A> | | @ | 8.8MG/VIAL | N20604 004 | SEP 06, 2001 | JAN | DISC |
| | | TERBINAFINE | | | | | |
| | | GEL; TOPICAL | | | | | |
| | | LAMISIL | | | | | |
| >D> | | @ NOVARTIS | 1% | N20846 001 | APR 29, 1998 | JAN | CMFD |
| >A> | | | 1% | N20846 001 | APR 29, 1998 | JAN | CMFD |
| >A> | | TIOTROPIUM BROMIDE MONOHYDRATE | | | | | |
| >A> | | CAPSULE; INHALATION | | | | | |
| >A> | | SPIRIVA | | | | | |
| >A> | | + BOEHRINGER INGELHEIM | EQ 0.018MG BASE | N21395 001 | JAN 30, 2004 | JAN | NEWA |
| | | TIZANIDINE HYDROCHLORIDE | | | | | |
| | | TABLET; ORAL | | | | | |
| | | TIZANIDINE HCL | | | | | |
| >A> | AB | TORPHARM | EQ 2MG BASE | N76533 001 | JAN 16, 2004 | JAN | NEWA |
| >A> | AB | | EQ 4MG BASE | N76533 002 | JAN 16, 2004 | JAN | NEWA |

IBUPROFEN
SUSPENSION; ORAL
>A> CHILDREN'S ELIXSURE
>A> TARO 100MG/5ML N21604 001 JAN 07, 2004 JAN NEWA
TABLET, CHEWABLE; ORAL
IBUPROFEN
>A> PERRIGO 50MG N76359 001 JAN 16, 2004 JAN NEWA
>A> 100MG N76359 002 JAN 16, 2004 JAN NEWA

LORATADINE; PSEUDOEPHEDRINE SULFATE
TABLET, EXTENDED RELEASE; ORAL
LORATADINE AND PSEUDOEPHEDRINE SULFATE
>A> ANDRX PHARMS 5MG;120MG N76208 001 JAN 28, 2004 JAN NEWA

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

**CUMULATIVE SUPPLEMENT NUMBER 1 JANUARY 2004**

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**NO JANUARY 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
January 2004

| Generic Name/ Trade Name (if present): | Date Designated = DD<br>Date Approved= MA | Indication Designated: | Sponsor and Address |
|---|---|---|---|
| Corporation<br>*Rituxan* | DD: 1/29/2004<br>MA: | Treatment of chronic lymphocytic leukemia | IDEC Pharmaceuticals<br>3030 Callan Road<br>San Diego CA 92121 |
| **(1S)-1-(9-deazahypoxanthin-9-yl)-1,** Pharmaceuticals, Inc.<br>**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 |
| **3-4'aminoisoindoline-1'-one)-1-pipe ridine-2,6-dione (CC-5013)**<br>*REVIMID* | DD: 1/29/2004<br>MA: | Treatment of myelodysplastic syndromes | Celgene Corporation<br>7 Powder Horn Drive<br>Warren NJ 07059 |
| **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 |
| **antivenin crotaline (pit-viper)** Therapeutics, Inc.<br>**equine immune F(ab)2**<br>*Antivipmyn* | DD: 1/29/2004<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 |
| **Miltefosine solution** Corporation<br>*Miltex solution* | DD: 1/29/2004<br>MA: | For use as a topical pallative treatment for cutaneous metastases of breast cancer | Baxter Healthcare<br>One Baxter Parkway<br>One Baxter Parkway<br>Deerfield IL 60015 |
| **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 |
| **Staphylococcus aureus Immune Globulin (Human)**<br>*Altastaph* | DD: 1/29/2004<br>MA: | Prophylaxis against Staphylococcus aureus infections in low birth weight neonates | Nabi Biopharmaceuticals<br>12276 Wilkins Avenue<br>Rockville MD 20852 |
| **tetrahydrobiopterin** Inc. | DD: 1/29/2004<br>MA: | For treatment of hyperphenylalaninemia | Biomarin Pharmaceutical<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 JANUARY 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 |
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| >ADD> | 021320 001 | ABARELIX;PLENAXIS | 5968895 | DEC 11, 2016 | DP | | |
| >ADD> | | | 6180608 | DEC 11, 2016 | DP U549 | | |
| >ADD> | | | 6423686 | JUN 07, 2015 | DS | | |
| >ADD> | | | 6455499 | JUN 07, 2015 | U549 | | |
| >ADD> | | | 5843901 | DEC 01, 2015 | DS DP | | |
| >ADD> | 021540 001 | AMLODIPINE BESYLATE;CADUET | | | | NC | JAN 30, 2007 |
| >ADD> | 021540 002 | AMLODIPINE BESYLATE;CADUET | | | | NC | JAN 30, 2007 |
| >ADD> | 021540 003 | AMLODIPINE BESYLATE;CADUET | | | | NC | JAN 30, 2007 |
| >ADD> | 021540 004 | AMLODIPINE BESYLATE;CADUET | | | | NC | JAN 30, 2007 |
| >ADD> | 021540 005 | AMLODIPINE BESYLATE;CADUET | | | | NC | JAN 30, 2007 |
| >ADD> | 021540 006 | AMLODIPINE BESYLATE;CADUET | | | | NC | JAN 30, 2007 |
| >ADD> | 021540 007 | AMLODIPINE BESYLATE;CADUET | | | | NC | JAN 30, 2007 |
| >ADD> | 021540 008 | AMLODIPINE BESYLATE;CADUET | | | | NC | JAN 30, 2007 |
| >ADD> | 020114 001 | AZELASTINE HYDROCHLORIDE;ASTELIN | 5164194 | NOV 01, 2010 | U207 | | |
| >ADD> | | | 5164194*PED | MAY 01, 2011 | | | |
| >ADD> | 020452 001 | CARBOPLATIN;PARAPLATIN | 4657927 | APR 14, 2004 | DP U175 | | |
| >ADD> | 020452 002 | CARBOPLATIN;PARAPLATIN | 4657927 | APR 14, 2004 | DP U175 | | |
| >ADD> | 020452 003 | CARBOPLATIN;PARAPLATIN | 4657927 | APR 14, 2004 | DP U175 | | |
| >ADD> | 019858 001 | CIPROFLOXACIN;CIPRO IN SODIUM CHLO | 4670444 | DEC 09, 2003 | | | |
| >ADD> | | | 4705789 | NOV 10, 2004 | | | |
| >ADD> | | | 4957922 | SEP 18, 2007 | | | |
| >ADD> | | | 4808583 | FEB 28, 2006 | | | |
| >ADD> | | | 4670444*PED | JUN 09, 2004 | | | |
| >ADD> | | | 4705789*PED | MAY 10, 2005 | | | |
| >ADD> | | | 4808583*PED | AUG 28, 2006 | | | |
| >ADD> | | | 4957922*PED | MAR 18, 2008 | | | |
| >ADD> | 021644 001 | CLOBETASOL PROPIONATE;CLOBEX | | | | NDF | FEB 05, 2007 |
| >ADD> | 021166 001 | ESTRADIOL;ESTROGEL | | | | NDF | FEB 09, 2007 |
| >ADD> | 020992 006 | ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN | | | | NS | FEB 05, 2007 |
| >ADD> | | | | | | D-85 | FEB 05, 2007 |
| >ADD> | 021490 001 | ETHINYL ESTRADIOL;OVCON-35 | 6667050 | JUN 12, 2021 | DP U1 | | |
| >ADD> | 019949 001 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| >ADD> | | | 4404216*PED | JUL 29, 2004 | | | |
| >ADD> | 019949 002 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| >ADD> | | | 4404216*PED | JUL 29, 2004 | | | |
| >ADD> | 019949 003 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| >ADD> | | | 4404216*PED | JUL 29, 2004 | | | |
| >ADD> | 019949 004 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| >ADD> | | | 4404216*PED | JUL 29, 2004 | | | |
| >ADD> | 020090 001 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| >ADD> | | | 4404216*PED | JUL 29, 2004 | | | |
| >ADD> | 020090 002 | FLUCONAZOLE;DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| >ADD> | | | 4404216*PED | JUL 29, 2004 | | | |
| >ADD> | 019950 003 | FLUCONAZOLE;DIFLUCAN IN DEXTROSE | 4404216 | JAN 29, 2004 | | | |
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| >ADD> | | | 4404216*PED | JUL 29, 2004 | | | |
| >ADD> | 019950 002 | FLUCONAZOLE;DIFLUCAN IN SODIUM C | 4404216 | JAN 29, 2004 | | | |
| >ADD> | | | 4404216*PED | JUL 29, 2004 | | | |
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PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | PATENT CODE(S) | EXCLUS CODE | EXCLUS EXPIRES |
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| >ADD> | 020985 001 | FLUOROURACIL;CARAC | 6670335 | JUN 02, 2021 | DP U68 | | |
| >ADD> | 021235 001 | FLUOXETINE HYDROCHLORIDE;PROZAC WEEKLY | 5910319 | MAY 29, 2017 | U396 | | |
| >ADD> | | | 5985322 | MAY 29, 2017 | U397 | | |
| >ADD> | 021249 001 | LOVASTATIN;ADVICOR | 6676967 | SEP 20, 2013 | U548 | | |
| >ADD> | 021249 002 | LOVASTATIN;ADVICOR | 6676967 | SEP 20, 2013 | U548 | | |
| >ADD> | 021249 003 | LOVASTATIN;ADVICOR | 6676967 | SEP 20, 2013 | U548 | | |
| >ADD> | 013217 001 | METAXALONE;SKELAXIN | 6683102 | DEC 03, 2021 | U189 | | |
| >ADD> | 013217 002 | METAXALONE;SKELAXIN | 6683102 | DEC 03, 2021 | U189 | | |
| >ADD> | 076545 001 | METFORMIN HYDROCHLORIDE;METFORMIN HCL | | | | PC | MAY 29, 2004 |
| >ADD> | 021308 001 | MICONAZOLE NITRATE;MONISTAT 1 COMBINATI | | | | RTO | JUN 29, 2004 |
| >ADD> | 076307 001 | MIRTAZAPINE;MIRTAZAPINE | | | | PC | JUN 14, 2004 |
| >ADD> | 076307 002 | MIRTAZAPINE;MIRTAZAPINE | | | | PC | JUN 14, 2004 |
| >ADD> | 021598 001 | MOXIFLOXACIN HYDROCHLORIDE;VIGAMOX | | | | NCE | DEC 10, 2004 |
| >ADD> | | | | | | PED | JUN 10, 2005 |
| >ADD> | 020381 002 | NIACIN;NIASPAN | 6676967 | SEP 20, 2013 | U548 | | |
| >ADD> | 020381 003 | NIACIN;NIASPAN | 6676967 | SEP 20, 2013 | U548 | | |
| >ADD> | 020381 004 | NIACIN;NIASPAN | 6676967 | SEP 20, 2013 | U548 | | |
| >ADD> | 020592 001 | OLANZAPINE;ZYPREXA | 5229382 | APR 23, 2011 | DS DP U149 | I-417 | JAN 14, 2007 |
| >ADD> | | | 5229382 | APR 23, 2001 | U547 | | |
| >ADD> | 020592 002 | OLANZAPINE;ZYPREXA | 5229382 | APR 23, 2011 | DS DP U149 | I-417 | JAN 14, 2007 |
| >ADD> | | | 5229382 | APR 23, 2011 | U547 | | |
| >ADD> | 020592 003 | OLANZAPINE;ZYPREXA | 5229382 | APR 23, 2011 | DS DP U149 | I-417 | JAN 14, 2007 |
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| >ADD> | 020592 004 | OLANZAPINE;ZYPREXA | 5229382 | APR 23, 2011 | DS DP U149 | I-417 | JAN 14, 2007 |
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| >ADD> | 021462 001 | PEMETREXED DISODIUM;ALIMTA | | | | NCE | FEB 04, 2009 |
| >ADD> | 020639 001 | QUETIAPINE FUMARATE;SEROQUEL | 4879288 | SEP 26, 2011 | DS DP U550 | I-419 | JAN 12, 2007 |
| >ADD> | | | | | | I-418 | JAN 12, 2007 |
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| >ADD> | 020741 003 | REPAGLINIDE;PRANDIN | 6677358 | JUN 12, 2018 | DS DP U546 | | |
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| >ADD> | | | 5691374 | MAY 18, 2015 | | I-353 | APR 11, 2005 |
| >ADD> | | | 6063811 | MAY 06, 2017 | U266 | M-27 | AUG 06, 2006 |
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| >ADD> | | | 6063811 | MAY 06, 2017 | U266 | M-27 | AUG 06, 2006 |
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| >ADD> | | | 5474995*PED | DEC 24, 2013 | | PED | OCT 11, 2005 |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | PATENT CODE(S) | EXCLUS CODE | EXCLUS EXPIRES |
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PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | PATENT CODE(S) | EXCLUS CODE | EXCLUS EXPIRES |
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| >ADD> | | | 5307953 | DEC 02, 2012 | | | |
| >ADD> | | | 5554639 | SEP 10, 2013 | U232 | | |
| >ADD> | | | 5705520 | DEC 10, 2011 | U232 | | |
| >ADD> | | | 5554639*PED | MAR 10, 2014 | | | |
| >ADD> | | | 5705520*PED | JUN 10, 2012 | | | |
| >ADD> | | | 4816470*PED | JUN 28, 2007 | | | |
| >ADD> | | | 5037845*PED | FEB 06, 2009 | | | |
| >ADD> | | | 5307953*PED | JUN 02, 2013 | | | |
| >ADD> | 021395 001 | TIOTROPIUM BROMIDE;SPIRIVA | | | | NCE | JAN 30, 2009 |
| >ADD> | 020771 002 | TOLTERODINE TARTRATE;DETROL | 5559269 | NOV 05, 2013 | U318 | | |
| >ADD> | | | 5559269*PED | MAY 05, 2014 | | | |
| >ADD> | 021630 001 | VORICONAZOLE;VFEND | 5116844 | AUG 11, 2009 | DP U540 | NCE | MAY 24, 2007 |
| >ADD> | | | 5364938 | NOV 15, 2011 | DS | I-409 | NOV 14, 2006 |
| >ADD> | | | 5567817 | OCT 22, 2013 | DS DP U540 | | |
| >ADD> | | | 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.

## 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 |

## 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 |

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