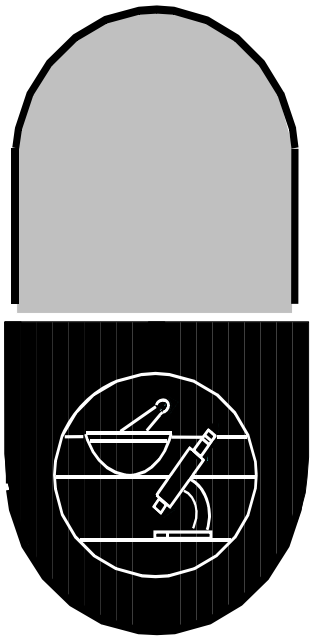
**CUMULATIVE SUPPLEMENT 1**
**JANUARY 2014**



# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

## 34th EDITION

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

**2014**

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

**APPROVED DRUG PRODUCTS**
**with**
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**Cumulative Supplement 1**

**January 2014**

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## 34th EDITION

## CUMULATIVE SUPPLEMENT 1
## January 2014

## 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, 34th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of this Edition List will then be added to the "Discontinued Drug Product List" appearing in the next Edition. The current Annual Edition Section 2.1, How To Use The Drug Product Lists, describes the layout and usage of the List.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol **>A>**. The Patent and Exclusivity List new additions are indicated by the symbol **>A>** to the left of Patent Number or Exclusivity Code. The **>A>** symbol is then dropped in subsequent Cumulative Supplements for that item.

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

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

## 1.2 CUMULATIVE SUPPLEMENT CONTENT

Since February 2005, we have been providing daily Electronic Orange Book (EOB) product information for new generic drug approvals. Daily generic updates provide the consumer with the current list of approved generic products which is important for substitution purposes. Previously, a first-time-generic product approved early in the month would not be published in the Cumulative Supplement (CS) for several weeks.

The CS monthly update publish goal is by the end of the following month’s second work week (e.g., November’s supplement will be updated by the end of the second full work week in December).

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.

- All product changes received and processed as of the date of publication.
  - Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
  - Discontinued products will be processed as of the date of publication. There will be circumstances where a product is discontinued in one month, however, it will be reported in a different month's CS. For example, the Orange Book Staff received a letter November 7 that the product has been discontinued from manufacturing and marketing. The Orange Book subsequently publishes the October CS on November 14. The product will show in the October CS that it is discontinued even though the date of discontinuance is the day that the Orange Book Staff receives notification (November 7).

- New Drug Application (NDA) approvals appear in the CS month they were approved.

- Patent information, also updated daily in the EOB, is current to the date of publication.

- Exclusivity information is updated monthly and current to the date of publication.

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at drugproducts@fda.hhs.gov. Send Changes by FAX: 240-276-8974; mail to:

FDA/CDER Orange Book Staff
Office of Generic Drugs, HFD-610
7620 Standish Place
Rockville, MD 20855-2773

## 1.3 APPLICANT NAME CHANGES

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

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

| FORMER APPLICANT NAME (FORMER ABBREVIATED NAME) | NEW APPLICANT NAME (NEW ABBREVIATED NAME) |
|---|---|

## 1.4 LEVOTHYROXINE SODIUM

Because there are multiple reference listed drugs of levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character TE codes may be potentially confusing and inadequate for these drug products. Accordingly, FDA provides the following explanation and chart of therapeutic equivalence evaluations for levothyroxine sodium drug products.

Levothyroxine Sodium (Mylan ANDA 76187) and Levo-T (Alara NDA 21342) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets. Levo-T (Alara NDA 021342), Levothyroxine Sodium (Mylan ANDA 76187), Unithroid (Jerome Stevens NDA 021210), and Levothyroxine Sodium (Merck KGAA ANDA 76752)tablets have been determined to be therapeutically

equivalent to corresponding strengths of Synthroid (Abbott NDA 021402) tablets.

Levo-T (Alara NDA 021342), Unithroid (Jerome Stevens NDA 021210), Levothyroxine Sodium (Mylan ANDA 076187), and Levothyroxine Sodium (Merck KGAA ANDA 76752) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King Pharms NDA 021301) tablets.

Levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levothroid (Lloyd NDA 021116) tablets.

The chart outlines TE codes for all 0.025mg products. Other product strengths may be similar. Therapeutic equivalence has been established between products that have the same AB+number TE code. More than one TE code may apply to some products. One common TE code indicates therapeutic equivalence between products.

| Trade Name | Applicant | Potency | TE Code | Appl No | Product No |
|---|---|---|---|---|---|
| UNITHROID | STEVENS J | 0.025MG | AB1 | 21210 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB1 | 76187 | 001 |
| LEVOXYL | KING PHARMS | 0.025MG | AB1 | 21301 | 001 |
| SYNTHROID | ABBOTT | 0.025MG | AB1 | 21402 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB1 | 21342 | 001 |
| | | | | | |
| SYNTHROID | ABBOTT | 0.025MG | AB2 | 21402 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB2 | 76187 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB2 | 21342 | 001 |
| UNITHROID | STEVENS J | 0.025MG | AB2 | 21210 | 001 |
| | | | | | |
| LEVOXYL | KUNG PHARMS | 0.025MG | AB3 | 21301 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB3 | 21342 | 001 |
| UNITHROID | STEVENS J | 0.025MG | AB3 | 21210 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB3 | 76187 | 001 |
| | | | | | |
| LEVOTHROID | LLOYD | 0.025MG | AB4 | 21116 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB4 | 76187 | 001 |
| | | | | | |

## 1.5 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm, has been available on the internet and has become the updated-every-month Orange Book. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder, applicant number or patent number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product.

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Publications. The PDF annual and cumulative supplements duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The downloaded Annual Edition and Cumulative Supplements are also available in a paper version (Approved Drug Products with Therapeutic

Equivalence Evaluations, ADP) from the U.S. Government Printing Office: http://bookstore.gpo.gov; toll free 866-512-1800.

There are historical lists of Orange Book cumulative supplement product monthly changes at http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm. There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at http://www.fda.gov/Drugs/InformationOnDrugs/ucm129689.htm. The drug product text files are provided in eobzip.zip format. The files are updated concurrently with the monthly cumulative supplements. The annual Orange Book Edition Appendices A, B, and C in PDF format are updated quarterly.

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

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

## 1.6 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 2012) 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 2013 | MAR 2014 | JUN 2014 | SEPT 2014 | DEC 2014 |
|---|---|---|---|---|---|
| DRUG PRODUCTS LISTED | 15711 | | | | |
| SINGLE SOURCE | 2517 (16.0%) | | | | |
| MULTISOURCE | 13194 (84.0%) | | | | |
| THERAPEUTICALLY EQUIVALENT | 13055 (83.1%) | | | | |
| NOT THERAPEUTICALLY EQUIVALENT | 139 (0.9%) | | | | |
| EXCEPTIONS[1] | 78 (0.5%) | | | | |
| NEW MOLECULAR ENTITIES APPROVED | 20 | | | | |
| NUMBER OF APPLICANTS | 866 | | | | |

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

## 1.7 CUMULATIVE SUPPLEMENT LEGEND

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

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The application number preceded by “N” is a New Drug Application (NDA or innovator). The application number preceded by an “A” is an Abbreviated New Drug Application (ANDA or generic). The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

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

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

The change code and description:

| | |
|---|---|
| NEWA | New drug product approval usually in the supplement month. |
| CAHN | Applicant holder firm name has changed. |
| CAIN | Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name. |
| CDFR | Change. Dosage Form; Route of Administration. |
| CFTG | Change. A first time generic for the innovator product. A TE Code is added. |
| CMFD | Change. The product is moved from the Discontinued Section due to a change in marketing status. |
| CMS1 | Change. Miscellaneous addition to list. |
| CMS2 | Change. Miscellaneous deletion from list. |
| CPOT | Change. Potency amount/unit. |

| | |
|---|---|
| CRLD | Change. Reference Listed Drug. |
| CTEC | Change. Therapeutic Equivalence Code. |
| CTNA | Change. Trade Name. |
| DISC | Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition. |

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET;ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | | WATSON LABS | 500MG;50MG;40MG | A040267 | 001 | Jul 30, 1998 | Jan DISC |
| >A> | | @ | | 500MG;50MG;40MG | A040267 | 001 | Jul 30, 1998 | Jan DISC |

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION;ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | | MALLINCKRODT | 500MG/15ML;7.5MG/15ML | A040418 | 001 | Jun 27, 2001 | Jan DISC |
| >A> | | @ | | 500MG/15ML;7.5MG/15ML | A040418 | 001 | Jun 27, 2001 | Jan DISC |

TABLET;ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | | ANEXSIA | | | | | |
| >D> | AA | | MALLINCKRODT | 500MG;5MG | A089160 | 001 | Apr 23, 1987 | Jan DISC |
| >A> | | @ | | 500MG;5MG | A089160 | 001 | Apr 23, 1987 | Jan DISC |
| >D> | AA | | | 750MG;10MG | A040468 | 001 | Oct 31, 2002 | Jan DISC |
| >A> | | @ | | 750MG;10MG | A040468 | 001 | Oct 31, 2002 | Jan DISC |

ANEXSIA 7.5/650

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | | MALLINCKRODT | 650MG;7.5MG | A089725 | 001 | Sep 30, 1987 | Jan DISC |
| >A> | | @ | | 650MG;7.5MG | A089725 | 001 | Sep 30, 1987 | Jan DISC |

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | | MALLINCKRODT | 500MG;5MG | A040084 | 002 | Jun 01, 1995 | Jan DISC |
| >A> | | @ | | 500MG;5MG | A040084 | 002 | Jun 01, 1995 | Jan DISC |
| >D> | AA | | | 500MG;7.5MG | A040201 | 001 | Feb 27, 1998 | Jan DISC |
| >A> | | @ | | 500MG;7.5MG | A040201 | 001 | Feb 27, 1998 | Jan DISC |
| >D> | AA | | | 500MG;10MG | A040201 | 002 | Feb 27, 1998 | Jan DISC |
| >A> | | @ | | 500MG;10MG | A040201 | 002 | Feb 27, 1998 | Jan DISC |
| >D> | AA | | | 650MG;10MG | A040084 | 004 | Oct 16, 1996 | Jan DISC |
| >A> | | @ | | 650MG;10MG | A040084 | 004 | Oct 16, 1996 | Jan DISC |
| >D> | AA | + | | 660MG;10MG | A040084 | 003 | Jul 29, 1996 | Jan DISC |
| >A> | | @ | | 660MG;10MG | A040084 | 003 | Jul 29, 1996 | Jan DISC |
| >D> | AA | | | 750MG;7.5MG | A040084 | 001 | Jun 01, 1995 | Jan DISC |
| >A> | | @ | | 750MG;7.5MG | A040084 | 001 | Jun 01, 1995 | Jan DISC |
| >D> | AA | | VINTAGE PHARMS | 650MG;7.5MG | A040155 | 001 | Apr 14, 1997 | Jan DISC |
| >A> | | @ | | 650MG;7.5MG | A040155 | 001 | Apr 14, 1997 | Jan DISC |
| >D> | AA | | | 750MG;7.5MG | A040157 | 001 | Apr 12, 1996 | Jan DISC |
| >A> | | @ | | 750MG;7.5MG | A040157 | 001 | Apr 12, 1996 | Jan DISC |
| >D> | AA | | WATSON LABS | 500MG;7.5MG | A081080 | 001 | Aug 30, 1991 | Jan DISC |
| >A> | | @ | | 500MG;7.5MG | A081080 | 001 | Aug 30, 1991 | Jan DISC |
| >D> | AA | | | 750MG;7.5MG | A081083 | 001 | Aug 30, 1991 | Jan DISC |
| >A> | | @ | | 750MG;7.5MG | A081083 | 001 | Aug 30, 1991 | Jan DISC |

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE;ORAL

OXYCODONE AND ACETAMINOPHEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | | MALLINCKRODT | 500MG;5MG | A040257 | 001 | Aug 04, 1998 | Jan DISC |
| >A> | | @ | | 500MG;5MG | A040257 | 001 | Aug 04, 1998 | Jan DISC |
| >D> | AA | | WATSON LABS | 500MG;5MG | A040234 | 001 | Oct 30, 1997 | Jan DISC |
| >A> | | @ | | 500MG;5MG | A040234 | 001 | Oct 30, 1997 | Jan DISC |

TABLET;ORAL

OXYCODONE AND ACETAMINOPHEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | | WATSON LABS | 500MG;7.5MG | A040371 | 001 | Dec 29, 2000 | Jan DISC |
| >A> | | @ | | 500MG;7.5MG | A040371 | 001 | Dec 29, 2000 | Jan DISC |
| >D> | AA | | | 650MG;10MG | A040371 | 002 | Dec 29, 2000 | Jan DISC |
| >A> | | @ | | 650MG;10MG | A040371 | 002 | Dec 29, 2000 | Jan DISC |
| >D> | | | PERCOCET | | | | | |
| >D> | AA | + | VINTAGE PHARMS LLC | 500MG;7.5MG | A040341 | 001 | Jul 26, 1999 | Jan DISC |
| >A> | | @ | | 500MG;7.5MG | A040341 | 001 | Jul 26, 1999 | Jan DISC |
| >D> | AA | + | | 650MG;10MG | A040341 | 002 | Jul 26, 1999 | Jan DISC |
| >A> | | @ | | 650MG;10MG | A040341 | 002 | Jul 26, 1999 | Jan DISC |

ALPRAZOLAM

TABLET, EXTENDED RELEASE;ORAL

ALPRAZOLAM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | ANI PHARMS INC | 0.5MG | A077725 | 001 | Jul 31, 2006 | Jan CAHN |
| >A> | | @ | | 0.5MG | A077979 | 001 | Feb 28, 2007 | Jan CAHN |
| >A> | AB | | | 1MG | A077725 | 002 | Jul 31, 2006 | Jan CAHN |
| >A> | | @ | | 1MG | A077979 | 002 | Feb 28, 2007 | Jan CAHN |
| >A> | AB | | | 2MG | A077725 | 004 | Jul 31, 2006 | Jan CAHN |
| >A> | | @ | | 2MG | A077979 | 003 | Feb 28, 2007 | Jan CAHN |

TABLET, EXTENDED RELEASE;ORAL
ALPRAZOLAM

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AB | | 3MG | A077725 | 003 | Jul 31, 2006 | Jan | CAHN |
| >A> | @ | 3MG | A077979 | 004 | Feb 28, 2007 | Jan | CAHN |
| >D> AB | BARR | 0.5MG | A077725 | 001 | Jul 31, 2006 | Jan | CAHN |
| >D> AB | | 1MG | A077725 | 002 | Jul 31, 2006 | Jan | CAHN |
| >D> AB | | 2MG | A077725 | 004 | Jul 31, 2006 | Jan | CAHN |
| >D> AB | | 3MG | A077725 | 003 | Jul 31, 2006 | Jan | CAHN |
| >D> | @ TEVA PHARMS USA | 0.5MG | A077979 | 001 | Feb 28, 2007 | Jan | CAHN |
| >D> | @ | 1MG | A077979 | 002 | Feb 28, 2007 | Jan | CAHN |
| >D> | @ | 2MG | A077979 | 003 | Feb 28, 2007 | Jan | CAHN |
| >D> | @ | 3MG | A077979 | 004 | Feb 28, 2007 | Jan | CAHN |

AMMONIA N-13

INJECTABLE;INTRAVENOUS
AMMONIA N 13

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AP | WA UNIV SCH MED | 30mCi-300mCi/8ML (3.75-37.5mCi/ML) | A204506 | 001 | Feb 07, 2014 | Jan | NEWA |

AMPICILLIN SODIUM

INJECTABLE;INJECTION
AMPICILLIN SODIUM

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> AP | ISTITUTO BIO ITA SPA | EQ 10MG BASE/VIAL | A201404 | 001 | Dec 20, 2013 | Jan | CPOT |
| >A> AP | | EQ 10GM BASE/VIAL | A201404 | 001 | Dec 20, 2013 | Jan | CPOT |

BENDROFLUMETHIAZIDE; NADOLOL

TABLET;ORAL
NADOLOL AND BENDROFLUMETHAZIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> AB | MYLAN | 5MG;40MG | A078688 | 001 | Feb 15, 2008 | Jan | CTNA |
| >D> AB | | 5MG;80MG | A078688 | 002 | Feb 15, 2008 | Jan | CTNA |

NADOLOL AND BENDROFLUMETHIAZIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AB | MYLAN | 5MG;40MG | A078688 | 001 | Feb 15, 2008 | Jan | CTNA |
| >A> AB | | 5MG;80MG | A078688 | 002 | Feb 15, 2008 | Jan | CTNA |

BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE

LOTION;TOPICAL
LOTRISONE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AB + | MERCK SHARP DOHME | EQ 0.05% BASE;1% | N020010 | 001 | Dec 08, 2000 | Jan | CAHN |
| >D> AB + | SCHERING CORP | EQ 0.05% BASE;1% | N020010 | 001 | Dec 08, 2000 | Jan | CAHN |

BROMFENAC SODIUM

SOLUTION/DROPS;OPHTHALMIC
BROMDAY

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> + | ISTA PHARMS INC | EQ 0.09% ACID | N021664 | 002 | Oct 16, 2010 | Jan | CFTG |
| >A> AT + | | EQ 0.09% ACID | N021664 | 002 | Oct 16, 2010 | Jan | CFTG |

BROMFENAC SODIUM

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> AT | COASTAL PHARMS | EQ 0.09% ACID | A201211 | 001 | May 11, 2011 | Jan | CTEC |
| >A> AT1 | | EQ 0.09% ACID | A201211 | 001 | May 11, 2011 | Jan | CTEC |
| >A> AT | HI-TECH PHARMACAL | EQ 0.09% ACID | A203395 | 001 | Jan 22, 2014 | Jan | NEWA |
| >D> AT | LUITPOLD | EQ 0.09% ACID | A202030 | 001 | Jan 09, 2013 | Jan | CTEC |
| >A> AT1 | | EQ 0.09% ACID | A202030 | 001 | Jan 09, 2013 | Jan | CTEC |

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
BUPROPION HYDROCHLORIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AB3 | ZYDUS PHARMS USA INC | 300MG | A201567 | 001 | Jan 17, 2014 | Jan | NEWA |

BUSPIRONE HYDROCHLORIDE

TABLET;ORAL
BUSPIRONE HYDROCHLORIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AB | ZYDUS PHARMS USA INC | 5MG | A078888 | 001 | Feb 07, 2014 | Jan | NEWA |
| >A> AB | | 10MG | A078888 | 002 | Feb 07, 2014 | Jan | NEWA |
| >A> AB | | 15MG | A078888 | 003 | Feb 07, 2014 | Jan | NEWA |
| >A> AB | | 30MG | A078888 | 004 | Feb 07, 2014 | Jan | NEWA |

CARISOPRODOL

TABLET;ORAL
CARISOPRODOL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AA | SCIEGEN PHARMS INC | 350MG | A203374 | 001 | Jan 27, 2014 | Jan | NEWA |

CEFACLOR

FOR SUSPENSION;ORAL

CEFACLOR

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> AB | YUNG SHIN PHARM | EQ 375MG BASE/5ML | A065412 | 004 | Feb 17, 2012 | Jan CRLD |
| >A> AB | + | EQ 375MG BASE/5ML | A065412 | 004 | Feb 17, 2012 | Jan CRLD |

CEFADROXIL/CEFADROXIL HEMIHYDRATE

FOR SUSPENSION;ORAL

CEFADROXIL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | @ ANI PHARMS INC | EQ 125MG BASE/5ML | A062698 | 001 | Mar 01, 1989 | Jan CAHN |
| >A> | @ | EQ 250MG BASE/5ML | A062698 | 002 | Mar 01, 1989 | Jan CAHN |
| >A> | @ | EQ 250MG BASE/5ML | A065278 | 001 | Jan 20, 2006 | Jan CAHN |
| >A> | @ | EQ 500MG BASE/5ML | A062698 | 003 | Mar 01, 1989 | Jan CAHN |
| >A> | @ | EQ 500MG BASE/5ML | A065278 | 002 | Jan 20, 2006 | Jan CAHN |
| >D> | @ TEVA | EQ 125MG BASE/5ML | A062698 | 001 | Mar 01, 1989 | Jan CAHN |
| >D> | @ | EQ 250MG BASE/5ML | A062698 | 002 | Mar 01, 1989 | Jan CAHN |
| >D> | @ | EQ 500MG BASE/5ML | A062698 | 003 | Mar 01, 1989 | Jan CAHN |
| >D> | @ TEVA PHARMS USA | EQ 250MG BASE/5ML | A065278 | 001 | Jan 20, 2006 | Jan CAHN |
| >D> | @ | EQ 500MG BASE/5ML | A065278 | 002 | Jan 20, 2006 | Jan CAHN |

CHLORPROPAMIDE

TABLET;ORAL

CHLORPROPAMIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | @ ANI PHARMS INC | 100MG | A088768 | 001 | Oct 11, 1984 | Jan CAHN |
| >A> | @ | 100MG | A088812 | 001 | Oct 19, 1984 | Jan CAHN |
| >A> | @ | 100MG | A088918 | 001 | Oct 16, 1984 | Jan CAHN |
| >A> AB | | 100MG | A088921 | 001 | Apr 12, 1985 | Jan CAHN |
| >A> | @ | 100MG | A089446 | 001 | Nov 17, 1986 | Jan CAHN |
| >A> | @ | 250MG | A088813 | 001 | Oct 19, 1984 | Jan CAHN |
| >A> | @ | 250MG | A088919 | 001 | Oct 16, 1984 | Jan CAHN |
| >A> AB | | 250MG | A088922 | 001 | Apr 12, 1985 | Jan CAHN |
| >A> | @ | 250MG | A089447 | 001 | Nov 17, 1986 | Jan CAHN |
| >D> | @ BARR | 100MG | A088812 | 001 | Oct 19, 1984 | Jan CAHN |
| >D> | @ | 100MG | A089446 | 001 | Nov 17, 1986 | Jan CAHN |
| >D> | @ | 250MG | A088813 | 001 | Oct 19, 1984 | Jan CAHN |
| >D> | @ | 250MG | A089447 | 001 | Nov 17, 1986 | Jan CAHN |
| >D> | @ DURAMED PHARMS BARR | 100MG | A088918 | 001 | Oct 16, 1984 | Jan CAHN |
| >D> | @ | 250MG | A088919 | 001 | Oct 16, 1984 | Jan CAHN |
| >D> AB | PLIVA | 100MG | A088921 | 001 | Apr 12, 1985 | Jan CAHN |
| >D> AB | | 250MG | A088922 | 001 | Apr 12, 1985 | Jan CAHN |
| >D> | @ TEVA | 100MG | A088768 | 001 | Oct 11, 1984 | Jan CAHN |

GLUCAMIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | @ ANI PHARMS INC | 250MG | A088641 | 001 | Oct 11, 1984 | Jan CAHN |
| >D> | @ TEVA | 250MG | A088641 | 001 | Oct 11, 1984 | Jan CAHN |

CIMETIDINE HYDROCHLORIDE

SOLUTION;ORAL

CIMETIDINE HYDROCHLORIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AA | ANI PHARMS INC | EQ 300MG BASE/5ML | A074610 | 001 | Sep 26, 1996 | Jan CAHN |
| >A> | @ | EQ 300MG BASE/5ML | A075110 | 001 | Jun 18, 1998 | Jan CAHN |
| >D> | @ DURAMED PHARMS BARR | EQ 300MG BASE/5ML | A075110 | 001 | Jun 18, 1998 | Jan CAHN |
| >D> AA | TEVA | EQ 300MG BASE/5ML | A074610 | 001 | Sep 26, 1996 | Jan CAHN |

CLOPIDOGREL BISULFATE

TABLET;ORAL

CLOPIDOGREL BISULFATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AB | MACLEODS PHARMS LTD | EQ 75MG BASE | A202928 | 001 | Feb 10, 2014 | Jan NEWA |

>A> DAPAGLIFLOZIN

>A> TABLET;ORAL

>A> FARXIGA

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | BRISTOL MYERS SQUIBB | 5MG | N202293 | 001 | Jan 08, 2014 | Jan NEWA |
| >A> | + | 10MG | N202293 | 002 | Jan 08, 2014 | Jan NEWA |

DECITABINE

POWDER;INTRAVENOUS

DECITABINE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | + SUN PHARMA GLOBAL | 50MG/VIAL | N205582 | 001 | Jan 28, 2014 | Jan NEWA |

DESIPRAMINE HYDROCHLORIDE

TABLET;ORAL

DESIPRAMINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | @ ANI PHARMS INC | 25MG | A071800 | 001 | Dec 08, 1987 | Jan CAHN |
| >A> | | @ | 50MG | A071801 | 001 | Dec 08, 1987 | Jan CAHN |
| >A> | | @ | 75MG | A071802 | 001 | Dec 08, 1987 | Jan CAHN |
| >D> | | @ PLIVA | 25MG | A071800 | 001 | Dec 08, 1987 | Jan CAHN |
| >D> | | @ | 50MG | A071801 | 001 | Dec 08, 1987 | Jan CAHN |
| >D> | | @ | 75MG | A071802 | 001 | Dec 08, 1987 | Jan CAHN |

DESMOPRESSIN ACETATE

SOLUTION;NASAL

DESMOPRESSIN ACETATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | | SUN PHARMA GLOBAL | 0.01% | A078271 | 001 | Dec 23, 2013 | Jan CMS2 |

SPRAY, METERED;NASAL

DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | SUN PHARMA GLOBAL | 0.01MG/SPRAY | A078271 | 001 | Dec 23, 2013 | Jan CMS2 |

DESVENLAFAXINE

TABLET, EXTENDED RELEASE;ORAL

DESVENLAFAXINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | BC | | SUN PHARMA GLOBAL | 50MG | N205583 | 001 | Jan 28, 2014 | Jan NEWA |
| >A> | BC | + | | 100MG | N205583 | 002 | Jan 28, 2014 | Jan NEWA |

DEXCHLORPHENIRAMINE MALEATE

TABLET;ORAL

DEXCHLORPHENIRAMINE MALEATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | @ ANI PHARMS INC | 2MG | A088682 | 001 | Jan 17, 1986 | Jan CAHN |
| >D> | | @ PLIVA | 2MG | A088682 | 001 | Jan 17, 1986 | Jan CAHN |

DICLOFENAC POTASSIUM

FOR SOLUTION;ORAL

CAMBIA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | + DEPOMED INC | 50MG | N022165 | 001 | Jun 17, 2009 | Jan CAHN |
| >D> | | + NAUTILUS NEUROSCIENC | 50MG | N022165 | 001 | Jun 17, 2009 | Jan CAHN |

DICLOFENAC SODIUM

SOLUTION;TOPICAL

PENNSAID

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | + MALLINCKRODT INC | 2% | N204623 | 001 | Jan 16, 2014 | Jan NEWA |

DIGOXIN

TABLET;ORAL

LANOXIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | @ COVIS PHARMA | 0.0625MG | N020405 | 001 | Sep 30, 1997 | Jan CMFD |
| >A> | | | 0.0625MG | N020405 | 001 | Sep 30, 1997 | Jan CMFD |
| >D> | | @ | 0.1875MG | N020405 | 003 | Sep 30, 1997 | Jan CMFD |
| >A> | | | 0.1875MG | N020405 | 003 | Sep 30, 1997 | Jan CMFD |

DISULFIRAM

TABLET;ORAL

DISULFIRAM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | ROXANE | 250MG | A202652 | 001 | Feb 05, 2014 | Jan NEWA |
| >A> | AB | | | 500MG | A202652 | 002 | Feb 05, 2014 | Jan NEWA |

DONEPEZIL HYDROCHLORIDE

TABLET;ORAL

DONEPEZIL HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | MACLEODS PHARMS LTD | 23MG | A202631 | 001 | Jan 22, 2014 | Jan NEWA |

DOXERCALCIFEROL

INJECTABLE;INJECTION

DOXERCALCIFEROL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AP | | SANDOZ | 4MCG/2ML (2MCG/ML) | A200926 | 001 | Feb 04, 2014 | Jan NEWA |

ECONAZOLE NITRATE

CREAM;TOPICAL

SPECTAZOLE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | @ MERZ PHARMS LLC | 1% | N018751 | 001 | Dec 23, 1982 | Jan CAHN |
| >D> | @ ORTHO JANSSEN | 1% | N018751 | 001 | Dec 23, 1982 | Jan CAHN |

ERYTHROMYCIN STEARATE

TABLET;ORAL

ERYTHROMYCIN STEARATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | @ ANI PHARMS INC | EQ 250MG BASE | A061591 | 001 | | Jan CAHN |
| >D> | @ BARR | EQ 250MG BASE | A061591 | 001 | | Jan CAHN |

ESZOPICLONE

TABLET;ORAL

ESZOPICLONE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | @ TEVA | 1MG | A091169 | 001 | May 23, 2011 | Jan CMFD |
| >A> AB | | 1MG | A091169 | 001 | May 23, 2011 | Jan CMFD |
| >D> | @ | 2MG | A091169 | 002 | May 23, 2011 | Jan CMFD |
| >A> AB | | 2MG | A091169 | 002 | May 23, 2011 | Jan CMFD |
| >D> | @ | 3MG | A091169 | 003 | May 23, 2011 | Jan CMFD |
| >A> AB | | 3MG | A091169 | 003 | May 23, 2011 | Jan CMFD |

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET;ORAL-28

LEVONORGESTREL AND ETHINYL ESTRADIOL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AB1 | HAUPT PHARMA | 0.02MG;0.1MG | A201108 | 001 | Feb 05, 2014 | Jan NEWA |

ETODOLAC

CAPSULE;ORAL

ETODOLAC

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | @ ANI PHARMS INC | 200MG | A075126 | 001 | Sep 16, 1999 | Jan CAHN |
| >A> AB | | 300MG | A075126 | 002 | Sep 16, 1999 | Jan CAHN |
| >D> | @ TEVA | 200MG | A075126 | 001 | Sep 16, 1999 | Jan CAHN |
| >D> AB | | 300MG | A075126 | 002 | Sep 16, 1999 | Jan CAHN |

FLUDEOXYGLUCOSE F-18

INJECTABLE;INTRAVENOUS

FLUDEOXYGLUCOSE F18

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AP | ESSENTIAL ISOTOPES | 20-300mCi/ML | A203946 | 001 | Feb 05, 2014 | Jan NEWA |
| >A> AP | LANTHEUS MEDICAL | 20-200mCi/ML | A203664 | 001 | Feb 04, 2014 | Jan NEWA |
| >A> AP | WUSM CYCLOTRON | 20-300mCi/ML | A203935 | 001 | Feb 05, 2014 | Jan NEWA |

FLUOXETINE HYDROCHLORIDE

CAPSULE;ORAL

FLUOXETINE HYDROCHLORIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AB2 | ANI PHARMS INC | EQ 10MG BASE | A076287 | 001 | May 20, 2008 | Jan CAHN |
| >A> AB2 | | EQ 20MG BASE | A076287 | 002 | May 20, 2008 | Jan CAHN |
| >D> AB2 | TEVA | EQ 10MG BASE | A076287 | 001 | May 20, 2008 | Jan CAHN |
| >D> AB2 | | EQ 20MG BASE | A076287 | 002 | May 20, 2008 | Jan CAHN |

TABLET;ORAL

SARAFEM

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | WARNER CHILCOTT LLC | EQ 10MG BASE | N021860 | 001 | May 19, 2006 | Jan CFTG |
| >A> AB1 | | EQ 10MG BASE | N021860 | 001 | May 19, 2006 | Jan CFTG |
| >D> | | EQ 15MG BASE | N021860 | 002 | May 19, 2006 | Jan CFTG |
| >A> AB1 | | EQ 15MG BASE | N021860 | 002 | May 19, 2006 | Jan CFTG |
| >D> + | | EQ 20MG BASE | N021860 | 003 | May 19, 2006 | Jan CFTG |
| >A> AB1 + | | EQ 20MG BASE | N021860 | 003 | May 19, 2006 | Jan CFTG |

>A> SELFEMRA

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AB1 | TEVA PHARMS USA | EQ 10MG BASE | A200151 | 001 | Feb 03, 2014 | Jan NEWA |
| >A> AB1 | | EQ 15MG BASE | A200151 | 002 | Feb 03, 2014 | Jan NEWA |
| >A> AB1 | | EQ 20MG BASE | A200151 | 003 | Feb 03, 2014 | Jan NEWA |

FOLIC ACID

TABLET;ORAL

FOLIC ACID

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> AA | CADILA PHARMS LTD | 1 MG | A202437 | 001 | Jan 27, 2014 | Jan NEWA |

FOSINOPRIL; HYDROCHLOROTHIAZIDE

TABLET;ORAL

FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | | EMCURE PHARMS INDIA | 20MG;12.5MG | A079025 | 002 | Sep 17, 2010 | Jan CRLD |
| >A> | AB | + | | 20MG;12.5MG | A079025 | 002 | Sep 17, 2010 | Jan CRLD |

FUROSEMIDE

INJECTABLE;INJECTION

FUROSEMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AP | | CLARIS LIFESCIENCES | 10MG/ML | A202747 | 001 | Jan 27, 2014 | Jan NEWA |

GLATIRAMER ACETATE

INJECTABLE;SUBCUTANEOUS

COPAXONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | + | TEVA PHARMS USA | 40MG/ML | N020622 | 003 | Jan 28, 2014 | Jan NEWA |

GLYCOPYRROLATE

TABLET;ORAL

GLYCOPYRROLATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AA | | STASON PHARMS | 1MG | A091182 | 001 | Feb 03, 2014 | Jan NEWA |
| >A> | AA | | | 2MG | A091182 | 002 | Feb 03, 2014 | Jan NEWA |

GUANABENZ ACETATE

TABLET;ORAL

GUANABENZ ACETATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | | ANI PHARMS INC | EQ 4MG BASE | A074149 | 001 | Apr 07, 1995 | Jan CAHN |
| >A> | | + | | EQ 8MG BASE | A074149 | 002 | Apr 07, 1995 | Jan CAHN |
| >D> | | | IVAX SUB TEVA PHARMS | EQ 4MG BASE | A074149 | 001 | Apr 07, 1995 | Jan CAHN |
| >D> | | + | | EQ 8MG BASE | A074149 | 002 | Apr 07, 1995 | Jan CAHN |

ISOSORBIDE MONONITRATE

TABLET;ORAL

ISOSORBIDE MONONITRATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | ANI PHARMS INC | 20MG | A075147 | 001 | Nov 27, 1998 | Jan CAHN |
| >D> | AB | | TEVA | 20MG | A075147 | 001 | Nov 27, 1998 | Jan CAHN |

KETOROLAC TROMETHAMINE

SOLUTION/DROPS;OPHTHALMIC

ACUVAIL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | + | ALLERGAN | 0.45% | N022427 | 001 | Jul 22, 2009 | Jan CFTG |
| >A> | AT | + | | 0.45% | N022427 | 001 | Jul 22, 2009 | Jan CFTG |

KETOROLAC TROMETHAMINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AT | | AKORN | 0.45% | A203376 | 001 | Feb 10, 2014 | Jan NEWA |

LAMIVUDINE; ZIDOVUDINE

TABLET;ORAL

LAMIVUDINE AND ZIDOVUDINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | HETERO LABS LTD V | 150MG;300MG | A203259 | 001 | Feb 03, 2014 | Jan NEWA |

LANSOPRAZOLE

TABLET, DELAYED RELEASE, ORALLY DISINTEGRATING;ORAL

LANSOPRAZOLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | @ | ANI PHARMS INC | 15MG | A078730 | 001 | Oct 15, 2010 | Jan CAHN |
| >A> | | @ | | 30MG | A078730 | 002 | Oct 15, 2010 | Jan CAHN |
| >D> | | @ | TEVA PHARMS | 15MG | A078730 | 001 | Oct 15, 2010 | Jan CAHN |
| >D> | | @ | | 30MG | A078730 | 002 | Oct 15, 2010 | Jan CAHN |

LEVOCETIRIZINE DIHYDROCHLORIDE

SOLUTION;ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AA | | L PERRIGO CO | 2.5MG/5ML | A091263 | 001 | Nov 07, 2011 | Jan CAHN |
| >D> | AA | | SYNTHON PHARMS | 2.5MG/5ML | A091263 | 001 | Nov 07, 2011 | Jan CAHN |

LIDOCAINE HYDROCHLORIDE

JELLY;TOPICAL

ANESTACON

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | @ | DSM PHARMS INC | 2% | A080429 | 001 | | Jan CAHN |
| >D> | | @ | POLYMEDICA | 2% | A080429 | 001 | | Jan CAHN |

LULICONAZOLE

CREAM;TOPICAL

LUZU

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | | MEDICIS | 1% | N204153 | 001 | Nov 14, 2013 | Jan CRLD |
| >A> | + | | 1% | N204153 | 001 | Nov 14, 2013 | Jan CRLD |

METHAZOLAMIDE

TABLET;ORAL

METHAZOLAMIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | AB | ANI PHARMS INC | 25MG | A040001 | 001 | Jun 30, 1993 | Jan CAHN |
| >A> | AB | | 50MG | A040001 | 002 | Jun 30, 1993 | Jan CAHN |
| >D> | AB | TEVA PHARMS | 25MG | A040001 | 001 | Jun 30, 1993 | Jan CAHN |
| >D> | AB | | 50MG | A040001 | 002 | Jun 30, 1993 | Jan CAHN |

METRONIDAZOLE

TABLET;ORAL

METRONIDAZOLE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | AB | UNICHEM LABS LTD | 250MG | A203458 | 001 | Jan 22, 2014 | Jan NEWA |
| >A> | AB | | 500MG | A203458 | 002 | Jan 22, 2014 | Jan NEWA |

MODAFINIL

TABLET;ORAL

MODAFINIL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | AB | APOTEX INC | 100MG | A077667 | 001 | Feb 03, 2014 | Jan NEWA |
| >A> | AB | | 200MG | A077667 | 002 | Feb 03, 2014 | Jan NEWA |

MORPHINE SULFATE

SOLUTION;ORAL

MORPHINE SULFATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | AA | CARACO | 10MG/5ML | A201011 | 001 | Feb 05, 2014 | Jan NEWA |
| >A> | AA | | 20MG/5ML | A201011 | 002 | Feb 05, 2014 | Jan NEWA |

NAFCILLIN SODIUM

INJECTABLE;INJECTION

NAFCILLIN SODIUM

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | AP | ANTIBIOTICE | EQ 1GM BASE | A090560 | 001 | Oct 03, 2011 | Jan CPOT |
| >A> | AP | | EQ 1GM BASE/VIAL | A090560 | 001 | Oct 03, 2011 | Jan CPOT |
| >D> | AP | | EQ 2GM BASE | A090560 | 002 | Oct 03, 2011 | Jan CPOT |
| >A> | AP | | EQ 2GM BASE/VIAL | A090560 | 002 | Oct 03, 2011 | Jan CPOT |

NARATRIPTAN

TABLET;ORAL

NARATRIPTAN

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | AB | APOTEX CORP | EQ 1MG BASE | A091373 | 001 | Apr 22, 2011 | Jan CAIN |
| >D> | AB | | EQ 2.5MG BASE | A091373 | 002 | Apr 22, 2011 | Jan CAIN |
| >D> | AB | SUN PHARM INDS LTD | EQ 2.5MG BASE | A091552 | 001 | Feb 14, 2011 | Jan CAIN |

NARATRIPTAN HYDROCHLORIDE

TABLET;ORAL

NARATRIPTAN

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | AB | APOTEX CORP | EQ 1MG BASE | A091373 | 001 | Apr 22, 2011 | Jan CAIN |
| >A> | AB | | EQ 2.5MG BASE | A091373 | 002 | Apr 22, 2011 | Jan CAIN |
| >A> | AB | SUN PHARM INDS LTD | EQ 2.5MG BASE | A091552 | 001 | Feb 14, 2011 | Jan CAIN |

NEVIRAPINE

TABLET;ORAL

NEVIRAPINE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | AB | STRIDES | 200MG | A078195 | 001 | May 22, 2012 | Jan CAHN |
| >A> | AB | STRIDES ARCOLAB LTD | 200MG | A078195 | 001 | May 22, 2012 | Jan CAHN |

NICARDIPINE HYDROCHLORIDE

CAPSULE;ORAL

NICARDIPINE HYDROCHLORIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | AB | ANI PHARMS INC | 20MG | A074439 | 001 | Dec 10, 1996 | Jan CAHN |
| >A> | AB | | 20MG | A074540 | 001 | Oct 28, 1996 | Jan CAHN |
| >A> | AB | | 30MG | A074439 | 002 | Dec 10, 1996 | Jan CAHN |
| >A> | AB | | 30MG | A074540 | 002 | Oct 28, 1996 | Jan CAHN |
| >D> | AB | BARR | 20MG | A074439 | 001 | Dec 10, 1996 | Jan CAHN |
| >D> | AB | | 30MG | A074439 | 002 | Dec 10, 1996 | Jan CAHN |
| >D> | AB | TEVA | 20MG | A074540 | 001 | Oct 28, 1996 | Jan CAHN |
| >D> | AB | | 30MG | A074540 | 002 | Oct 28, 1996 | Jan CAHN |

INJECTABLE;INJECTION
NICARDIPINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AP | | LUITPOLD | 25MG/10ML (2.5MG/ML) | A090534 | 001 | Nov 17, 2009 | Jan CAHN |
| >D> | AP | | PHARMAFORCE | 25MG/10ML (2.5MG/ML) | A090534 | 001 | Nov 17, 2009 | Jan CAHN |

NIZATIDINE

CAPSULE;ORAL
NIZATIDINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | @ | ANI PHARMS INC | 150MG | A075461 | 001 | Jul 08, 2002 | Jan CAHN |
| >A> | AB | | | 150MG | A075668 | 001 | Sep 12, 2002 | Jan CAHN |
| >A> | | @ | | 300MG | A075461 | 002 | Jul 08, 2002 | Jan CAHN |
| >A> | AB | | | 300MG | A075668 | 002 | Sep 12, 2002 | Jan CAHN |
| >D> | | @ | IVAX SUB TEVA PHARMS | 150MG | A075461 | 001 | Jul 08, 2002 | Jan CAHN |
| >D> | | @ | | 300MG | A075461 | 002 | Jul 08, 2002 | Jan CAHN |
| >D> | AB | | TEVA | 150MG | A075668 | 001 | Sep 12, 2002 | Jan CAHN |
| >D> | AB | | | 300MG | A075668 | 002 | Sep 12, 2002 | Jan CAHN |

ONDANSETRON HYDROCHLORIDE

INJECTABLE;INJECTION
ONDANSETRON HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | | LANNETT | EQ 2MG BASE/ML | A090116 | 001 | Apr 14, 2010 | Jan DISC |
| >A> | | @ | | EQ 2MG BASE/ML | A090116 | 001 | Apr 14, 2010 | Jan DISC |

TABLET;ORAL
ONDANSETRON HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | IPCA LABS LTD | EQ 4MG BASE | A203761 | 001 | Jan 23, 2014 | Jan NEWA |
| >A> | AB | | | EQ 8MG BASE | A203761 | 002 | Jan 23, 2014 | Jan NEWA |

OXANDROLONE

TABLET;ORAL
OXANDRIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | CREALTA PHARMS LLC | 2.5MG | N013718 | 001 | | Jan CAHN |
| >A> | AB | + | | 10MG | N013718 | 002 | Nov 05, 2001 | Jan CAHN |
| >D> | AB | | SAVIENT PHARMS | 2.5MG | N013718 | 001 | | Jan CAHN |
| >D> | AB | + | | 10MG | N013718 | 002 | Nov 05, 2001 | Jan CAHN |

OXCARBAZEPINE

TABLET;ORAL
OXCARBAZEPINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | @ | ANI PHARMS INC | 150MG | A078005 | 001 | Dec 11, 2007 | Jan CAHN |
| >A> | | @ | | 300MG | A078005 | 002 | Dec 11, 2007 | Jan CAHN |
| >A> | | @ | | 600MG | A078005 | 003 | Dec 11, 2007 | Jan CAHN |
| >D> | | @ | TEVA PHARMS USA | 150MG | A078005 | 001 | Dec 11, 2007 | Jan CAHN |
| >D> | | @ | | 300MG | A078005 | 002 | Dec 11, 2007 | Jan CAHN |
| >D> | | @ | | 600MG | A078005 | 003 | Dec 11, 2007 | Jan CAHN |

PAMIDRONATE DISODIUM

INJECTABLE;INJECTION
PAMIDRONATE DISODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | | MN PHARMS | 30MG/VIAL | A078300 | 001 | Mar 10, 2009 | Jan DISC |
| >A> | | @ | | 30MG/VIAL | A078300 | 001 | Mar 10, 2009 | Jan DISC |
| >D> | AP | | | 90MG/VIAL | A078300 | 002 | Mar 10, 2009 | Jan DISC |
| >A> | | @ | | 90MG/VIAL | A078300 | 002 | Mar 10, 2009 | Jan DISC |

PAROXETINE HYDROCHLORIDE

TABLET;ORAL
PAXIL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | | APOTEX TECNOLOGIES | EQ 10MG BASE | N020031 | 001 | Dec 29, 1992 | Jan CAHN |
| >A> | AB | | | EQ 20MG BASE | N020031 | 002 | Dec 29, 1992 | Jan CAHN |
| >A> | AB | | | EQ 30MG BASE | N020031 | 003 | Dec 29, 1992 | Jan CAHN |
| >A> | AB | + | | EQ 40MG BASE | N020031 | 005 | Dec 29, 1992 | Jan CAHN |
| >A> | | @ | | EQ 50MG BASE | N020031 | 004 | Dec 29, 1992 | Jan CAHN |
| >D> | AB | | GLAXOSMITHKLINE | EQ 10MG BASE | N020031 | 001 | Dec 29, 1992 | Jan CAHN |
| >D> | AB | | | EQ 20MG BASE | N020031 | 002 | Dec 29, 1992 | Jan CAHN |
| >D> | AB | | | EQ 30MG BASE | N020031 | 003 | Dec 29, 1992 | Jan CAHN |
| >D> | AB | + | | EQ 40MG BASE | N020031 | 005 | Dec 29, 1992 | Jan CAHN |
| >D> | | @ | | EQ 50MG BASE | N020031 | 004 | Dec 29, 1992 | Jan CAHN |

PERINDOPRIL ERBUMINE

TABLET;ORAL

PERINDOPRIL ERBUMINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | ANI PHARMS INC | 2MG | A | 078138 | 001 | Nov 10, 2009 | Jan CAHN |
| >A> | AB | | 4MG | A | 078138 | 002 | Nov 10, 2009 | Jan CAHN |
| >A> | AB | | 8MG | A | 078138 | 003 | Nov 10, 2009 | Jan CAHN |
| >D> | AB | IVAX PHARMS | 2MG | A | 078138 | 001 | Nov 10, 2009 | Jan CAHN |
| >D> | AB | | 4MG | A | 078138 | 002 | Nov 10, 2009 | Jan CAHN |
| >D> | AB | | 8MG | A | 078138 | 003 | Nov 10, 2009 | Jan CAHN |

PHENTERMINE HYDROCHLORIDE

CAPSULE;ORAL

PHENTERMINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AA | INVAGEN PHARMS | 37.5MG | A | 202846 | 001 | Feb 05, 2014 | Jan NEWA |

TABLET;ORAL

PHENTERMINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AA | INVAGEN PHARMS | 37.5MG | A | 202942 | 001 | Feb 05, 2014 | Jan NEWA |

PHENYTOIN SODIUM

CAPSULE;ORAL

EXTENDED PHENYTOIN SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | @ ANI PHARMS INC | 100MG EXTENDED | A | 089441 | 001 | Dec 18, 1986 | Jan CAHN |
| >D> | | @ PLIVA | 100MG EXTENDED | A | 089441 | 001 | Dec 18, 1986 | Jan CAHN |

PROMPT PHENYTOIN SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | @ ANI PHARMS INC | 100MG PROMPT | A | 080259 | 001 | | Jan CAHN |
| >D> | | @ IVAX SUB TEVA PHARMS | 100MG PROMPT | A | 080259 | 001 | | Jan CAHN |

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

MIRAPEX ER

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | BOEHRINGER INGELHEIM | 0.375MG | N | 022421 | 001 | Feb 19, 2010 | Jan CFTG |
| >A> | AB + | | 0.375MG | N | 022421 | 001 | Feb 19, 2010 | Jan CFTG |
| >D> | | | 0.75MG | N | 022421 | 002 | Feb 19, 2010 | Jan CFTG |
| >A> | AB | | 0.75MG | N | 022421 | 002 | Feb 19, 2010 | Jan CFTG |
| >D> | | | 1.5MG | N | 022421 | 003 | Feb 19, 2010 | Jan CFTG |
| >A> | AB | | 1.5MG | N | 022421 | 003 | Feb 19, 2010 | Jan CFTG |
| >D> | | | 2.25MG | N | 022421 | 006 | Jun 17, 2011 | Jan CFTG |
| >A> | AB | | 2.25MG | N | 022421 | 006 | Jun 17, 2011 | Jan CFTG |
| >D> | | | 3MG | N | 022421 | 004 | Feb 19, 2010 | Jan CFTG |
| >A> | AB | | 3MG | N | 022421 | 004 | Feb 19, 2010 | Jan CFTG |
| >D> | | | 3.75MG | N | 022421 | 007 | Jun 17, 2011 | Jan CFTG |
| >A> | AB | | 3.75MG | N | 022421 | 007 | Jun 17, 2011 | Jan CFTG |
| >D> | | | 4.5MG | N | 022421 | 005 | Feb 19, 2010 | Jan CFTG |
| >A> | AB | | 4.5MG | N | 022421 | 005 | Feb 19, 2010 | Jan CFTG |

>A> PRAMIPEXOLE DIHYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | ANCHEN PHARMS | 0.375MG | A | 202206 | 001 | Feb 06, 2014 | Jan NEWA |
| >A> | AB | | 0.75MG | A | 202206 | 002 | Feb 06, 2014 | Jan NEWA |
| >A> | AB | | 1.5MG | A | 202206 | 003 | Feb 06, 2014 | Jan NEWA |
| >A> | AB | | 2.25MG | A | 202206 | 004 | Feb 06, 2014 | Jan NEWA |
| >A> | AB | | 3MG | A | 202206 | 005 | Feb 06, 2014 | Jan NEWA |
| >A> | AB | | 3.75MG | A | 202206 | 006 | Feb 06, 2014 | Jan NEWA |
| >A> | AB | | 4.5MG | A | 202206 | 007 | Feb 06, 2014 | Jan NEWA |

PRIMAQUINE PHOSPHATE

TABLET;ORAL

PRIMAQUINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | SANOFI AVENTIS US | EQ 15MG BASE | N | 008316 | 001 | | Jan CFTG |
| >A> | AB + | | EQ 15MG BASE | N | 008316 | 001 | | Jan CFTG |

>A> PRIMAQUINE PHOSPHATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | ALVOGEN INC | EQ 15MG BASE | A | 203924 | 001 | Feb 03, 2014 | Jan NEWA |

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

PROCAINAMIDE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | @ ANI PHARMS INC | 1GM | A | 040111 | 001 | Dec 13, 1996 | Jan CAHN |
| >A> | | @ | 250MG | A | 088958 | 001 | Dec 02, 1985 | Jan CAHN |
| >A> | | @ | 500MG | A | 088959 | 001 | Dec 02, 1985 | Jan CAHN |
| >A> | | @ | 750MG | A | 089438 | 001 | Mar 23, 1987 | Jan CAHN |
| >D> | | @ COPLEY PHARM | 1GM | A | 040111 | 001 | Dec 13, 1996 | Jan CAHN |
| >D> | | @ | 750MG | A | 089438 | 001 | Mar 23, 1987 | Jan CAHN |
| >D> | | @ PLIVA | 250MG | A | 088958 | 001 | Dec 02, 1985 | Jan CAHN |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | TABLET, EXTENDED RELEASE;ORAL | | | | | | |
| | | PROCAINAMIDE HYDROCHLORIDE | | | | | | |
| >D> | | @ | 500MG | A088959 | 001 | Dec 02, 1985 | Jan CAHN | |
| | | PROPAFENONE HYDROCHLORIDE | | | | | | |
| | | TABLET;ORAL | | | | | | |
| | | PROPAFENONE HYDROCHLORIDE | | | | | | |
| >A> | AB | ANI PHARMS INC | 150MG | A076550 | 001 | Apr 23, 2004 | Jan CAHN | |
| >A> | AB | | 225MG | A076550 | 002 | Apr 23, 2004 | Jan CAHN | |
| >A> | AB | | 300MG | A076550 | 003 | Apr 23, 2004 | Jan CAHN | |
| >D> | AB | PLIVA | 150MG | A076550 | 001 | Apr 23, 2004 | Jan CAHN | |
| >D> | AB | | 225MG | A076550 | 002 | Apr 23, 2004 | Jan CAHN | |
| >D> | AB | | 300MG | A076550 | 003 | Apr 23, 2004 | Jan CAHN | |
| | | PROPRANOLOL HYDROCHLORIDE | | | | | | |
| | | TABLET;ORAL | | | | | | |
| >D> | | INDERAL | | | | | | |
| >D> | AB | WYETH PHARMS INC | 40MG | N016418 | 002 | | Jan DISC | |
| >A> | | @ | 40MG | N016418 | 002 | | Jan DISC | |
| >D> | AB | | 60MG | N016418 | 009 | Oct 18, 1982 | Jan DISC | |
| >A> | | @ | 60MG | N016418 | 009 | Oct 18, 1982 | Jan DISC | |
| >D> | AB | + | 80MG | N016418 | 004 | | Jan DISC | |
| >A> | | @ | 80MG | N016418 | 004 | | Jan DISC | |
| | | PROPRANOLOL HYDROCHLORIDE | | | | | | |
| >A> | | @ ANI PHARMS INC | 90MG | A071977 | 001 | Apr 06, 1988 | Jan CAHN | |
| >D> | | @ PLIVA | 90MG | A071977 | 001 | Apr 06, 1988 | Jan CAHN | |
| | | PROPYLTHIOURACIL | | | | | | |
| | | TABLET;ORAL | | | | | | |
| | | PROPYLTHIOURACIL | | | | | | |
| >A> | | @ ANI PHARMS INC | 50MG | A080215 | 001 | | Jan CAHN | |
| >D> | | @ IVAX SUB TEVA PHARMS | 50MG | A080215 | 001 | | Jan CAHN | |
| | | REPAGLINIDE | | | | | | |
| | | TABLET;ORAL | | | | | | |
| | | REPAGLINIDE | | | | | | |
| >A> | AB | ACTAVIS TOTOWA | 0.5MG | A090008 | 001 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | | 1MG | A090008 | 002 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | | 2MG | A090008 | 003 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | AUROBINDO PHARMA LTD | 0.5MG | A203820 | 001 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | | 1MG | A203820 | 002 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | | 2MG | A203820 | 003 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | MYLAN PHARMS INC | 1MG | A090252 | 002 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | | 2MG | A090252 | 003 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | PADDOCK LLC | 1MG | A201189 | 002 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | | 2MG | A201189 | 003 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | SANDOZ | 1MG | A078555 | 002 | Jan 22, 2014 | Jan NEWA | |
| >A> | AB | | 2MG | A078555 | 003 | Jan 22, 2014 | Jan NEWA | |
| | | RISPERIDONE | | | | | | |
| | | SOLUTION;ORAL | | | | | | |
| | | RISPERIDONE | | | | | | |
| >A> | AA | ANI PHARMS INC | 1MG/ML | A076440 | 001 | Jan 30, 2009 | Jan CAHN | |
| >D> | AA | TEVA | 1MG/ML | A076440 | 001 | Jan 30, 2009 | Jan CAHN | |
| | | RIZATRIPTAN BENZOATE | | | | | | |
| | | TABLET;ORAL | | | | | | |
| | | RIZATRIPTAN BENZOATE | | | | | | |
| >A> | AB | MACLEODS PHARMS LTD | EQ 5MG BASE | A203147 | 001 | Feb 11, 2014 | Jan NEWA | |
| >A> | AB | | EQ 10MG BASE | A203147 | 002 | Feb 11, 2014 | Jan NEWA | |
| | | SUMATRIPTAN SUCCINATE | | | | | | |
| | | INJECTABLE;SUBCUTANEOUS | | | | | | |
| | | SUMATRIPTAN SUCCINATE | | | | | | |
| >A> | AB | DR REDDYS LABS INC | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | A090495 | 001 | Jan 29, 2014 | Jan NEWA | |

SUNITINIB MALATE

CAPSULE;ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | | SUNITINIB MALATE | | | | | |
| >A> | AB | | MYLAN PHARMS INC | EQ 12.5MG BASE | A201275 | 001 | Jan 30, 2014 | Jan NEWA |
| >A> | AB | | | EQ 25MG BASE | A201275 | 002 | Jan 30, 2014 | Jan NEWA |
| >A> | AB | | | EQ 37.5MG BASE | A201275 | 003 | Jan 30, 2014 | Jan NEWA |
| >A> | AB | | | EQ 50MG BASE | A201275 | 004 | Jan 30, 2014 | Jan NEWA |
| | | | SUTENT | | | | | |
| >D> | | | CPPI CV | EQ 12.5MG BASE | N021938 | 001 | Jan 26, 2006 | Jan CFTG |
| >A> | AB | | | EQ 12.5MG BASE | N021938 | 001 | Jan 26, 2006 | Jan CFTG |
| >D> | | | | EQ 25MG BASE | N021938 | 002 | Jan 26, 2006 | Jan CFTG |
| >A> | AB | | | EQ 25MG BASE | N021938 | 002 | Jan 26, 2006 | Jan CFTG |
| >D> | | | | EQ 37.5MG BASE | N021938 | 004 | Mar 31, 2009 | Jan CFTG |
| >A> | AB | | | EQ 37.5MG BASE | N021938 | 004 | Mar 31, 2009 | Jan CFTG |
| >D> | | + | | EQ 50MG BASE | N021938 | 003 | Jan 26, 2006 | Jan CFTG |
| >A> | AB | + | | EQ 50MG BASE | N021938 | 003 | Jan 26, 2006 | Jan CFTG |

TASIMELTEON

CAPSULE;ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | | HETLIOZ | | | | | |
| >A> | | + | VANDA PHARMS INC | 20MG | N205677 | 001 | Jan 31, 2014 | Jan NEWA |

THEOPHYLLINE

TABLET, EXTENDED RELEASE;ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | THEOCHRON | | | | | |
| >D> | AB | | CARACO | 300MG | A087400 | 002 | Jan 11, 1983 | Jan DISC |
| >A> | | @ | | 300MG | A087400 | 002 | Jan 11, 1983 | Jan DISC |

TRANEXAMIC ACID

TABLET;ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | TRANEXAMIC ACID | | | | | |
| >A> | AB | | APOTEX INC | 650 MG | A202286 | 001 | Jan 27, 2014 | Jan NEWA |

TRETINOIN

GEL;TOPICAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | RETIN-A-MICRO | | | | | |
| >A> | | + | VALEANT INTL | 0.08% | N020475 | 003 | Jan 28, 2014 | Jan NEWA |

VALACYCLOVIR HYDROCHLORIDE

TABLET;ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | VALACYCLOVIR HYDROCHLORIDE | | | | | |
| >A> | AB | | CIPLA LTD | EQ 1GM BASE | A077135 | 002 | May 24, 2010 | Jan CAHN |
| >A> | AB | | | EQ 500MG BASE | A077135 | 001 | May 24, 2010 | Jan CAHN |
| >D> | AB | | WATSON LABS | EQ 1GM BASE | A077135 | 002 | May 24, 2010 | Jan CAHN |
| >D> | AB | | | EQ 500MG BASE | A077135 | 001 | May 24, 2010 | Jan CAHN |

VALPROIC ACID

SYRUP;ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | VALPROIC ACID | | | | | |
| >A> | AA | | ANI PHARMS INC | 250MG/5ML | A073178 | 001 | Aug 25, 1992 | Jan CAHN |
| >D> | AA | | TEVA PHARMS | 250MG/5ML | A073178 | 001 | Aug 25, 1992 | Jan CAHN |

ZONISAMIDE

CAPSULE;ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | ZONISAMIDE | | | | | |
| >A> | AB | | ANI PHARMS INC | 25MG | A077639 | 001 | Dec 22, 2005 | Jan CAHN |
| >A> | | @ | | 25MG | A077641 | 003 | Dec 22, 2005 | Jan CAHN |
| >A> | AB | | | 50MG | A077639 | 002 | Dec 22, 2005 | Jan CAHN |
| >A> | | @ | | 50MG | A077641 | 002 | Dec 22, 2005 | Jan CAHN |
| >A> | AB | | | 100MG | A077639 | 003 | Dec 22, 2005 | Jan CAHN |
| >A> | | @ | | 100MG | A077641 | 001 | Dec 22, 2005 | Jan CAHN |
| >D> | AB | | BARR | 25MG | A077639 | 001 | Dec 22, 2005 | Jan CAHN |
| >D> | AB | | | 50MG | A077639 | 002 | Dec 22, 2005 | Jan CAHN |
| >D> | AB | | | 100MG | A077639 | 003 | Dec 22, 2005 | Jan CAHN |
| >D> | | @ | TEVA PHARMS | 25MG | A077641 | 003 | Dec 22, 2005 | Jan CAHN |
| >D> | | @ | | 50MG | A077641 | 002 | Dec 22, 2005 | Jan CAHN |
| >D> | | @ | | 100MG | A077641 | 001 | Dec 22, 2005 | Jan CAHN |

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE;ORAL

DEXBROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | AVANTHI INC | 6MG;120MG | A078648 | 001 | Feb 27, 2013 | Jan | CRLD |
| >A> | + | | 6MG;120MG | A078648 | 001 | Feb 27, 2013 | Jan | CRLD |
| | | DISOPHROL | | | | | | |
| >D> | | SCHERING PLOUGH | 6MG;120MG | N013483 | 004 | Sep 13, 1982 | Jan | DISC |
| >A> | @ | | 6MG;120MG | N013483 | 004 | Sep 13, 1982 | Jan | DISC |
| | | DRIXORAL | | | | | | |
| >D> | + | SCHERING PLOUGH | 6MG;120MG | N013483 | 003 | Sep 13, 1982 | Jan | DISC |
| >A> | @ | | 6MG;120MG | N013483 | 003 | Sep 13, 1982 | Jan | DISC |

DIPHENHYDRAMINE HYDROCHLORIDE; NAPROXEN SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | TABLET;ORAL | | | | | | |
| >A> | | ALEVE PM | | | | | | |
| >A> | + | BAYER HLTHCARE | 25MG;220MG | N205352 | 001 | Jan 17, 2014 | 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 2014**

NO JANUARY 2014 APPROVALS

# ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

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

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

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

NO JANUARY 2014 ADDITIONS

# PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2014

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|---|---|---|---|---|---|
| ACYCLOVIR; HYDROCORTISONE - XERESE | | | | | | |
| N 022436 001 | | | | | >A> NPP | Jan 22, 2017 |
| ALISKIREN HEMIFUMARATE - TEKTURNA | | | | | | |
| N 021985 001 | >A> 8617595 | Feb 19, 2026 | DP | | | |
| ALISKIREN HEMIFUMARATE - TEKTURNA | | | | | | |
| N 021985 002 | >A> 8617595 | Feb 19, 2026 | DP | | | |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO | | | | | | |
| N 022545 001 | >A> 8613949 | Dec 21, 2029 | DP | | | |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO | | | | | | |
| N 022545 002 | >A> 8613949 | Dec 21, 2029 | DP | | | |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO | | | | | | |
| N 022545 003 | >A> 8613949 | Dec 21, 2029 | DP | | | |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO | | | | | | |
| N 022545 004 | >A> 8613949 | Dec 21, 2029 | DP | | | |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE | | | | | | |
| N 200045 001 | >A> 8618174 | Nov 15, 2021 | DP | | | |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE | | | | | | |
| N 200045 002 | >A> 8618174 | Nov 15, 2021 | DP | | | |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE | | | | | | |
| N 200045 003 | >A> 8618174 | Nov 15, 2021 | DP | | | |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE | | | | | | |
| N 200045 004 | >A> 8618174 | Nov 15, 2021 | DP | | | |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE | | | | | | |
| N 200045 005 | >A> 8618174 | Nov 15, 2021 | DP | | | |
| ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT | | | | | | |
| N 022107 001 | >A> 8618172 | Jul 13, 2028 | DP | | | |
| ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT | | | | | | |
| N 022107 002 | >A> 8618172 | Jul 13, 2028 | DP | | | |
| ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT | | | | | | |
| N 022107 003 | >A> 8618172 | Jul 13, 2028 | DP | | | |
| ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT | | | | | | |
| N 022107 004 | >A> 8618172 | Jul 13, 2028 | DP | | | |
| BROMOCRIPTINE MESYLATE - CYCLOSET | | | | | | |
| N 020866 001 | >A> 8613947 | Apr 30, 2032 | DP U-976 | | | |
| BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT | | | | | | |
| N 021929 001 | >A> 8616196 | Apr 07, 2029 | DP | | | |
| BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT | | | | | | |
| N 021929 002 | >A> 8616196 | Apr 07, 2029 | DP | | | |
| COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - STRIBILD | | | | | | |
| N 203100 001 | >A> 8633219 | Oct 11, 2031 | DP U-257 | | | |
| CYCLOSPORINE - RESTASIS | | | | | | |
| N 050790 001 | >A> 8633162 | Aug 27, 2024 | U-1479 | | | |
| | >A> 8642556 | Aug 27, 2024 | DP | | | |
| | >A> 8648048 | Aug 27, 2024 | U-1483 | | | |
| DABRAFENIB MESYLATE - TAFINLAR | | | | | | |
| N 202806 001 | | | | | >A> I-678 | Jan 08, 2017 |
| | | | | | >A> ODE | Jan 09, 2021 |
| DABRAFENIB MESYLATE - TAFINLAR | | | | | | |
| N 202806 002 | | | | | >A> I-678 | Jan 08, 2017 |
| | | | | | >A> ODE | Jan 09, 2021 |
| DAPAGLIFLOZIN - FARXIGA | | | | | | |
| N 202293 001 | | | | | >A> NCE | Jan 08, 2019 |
| DAPAGLIFLOZIN - FARXIGA | | | | | | |
| N 202293 002 | | | | | >A> NCE | Jan 08, 2019 |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|---|---|---|---|---|---|
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N 021976 001 | >A> 8597876 | Jun 23, 2019 | U-1305 | | | |
| | >A> 8597876*PED | Dec 23, 2019 | | | | |
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N 021976 002 | >A> 8597876 | Jun 23, 2019 | U-1305 | | | |
| | >A> 8597876*PED | Dec 23, 2019 | | | | |
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N 021976 003 | >A> 8597876 | Jun 23, 2019 | U-1305 | | | |
| | >A> 8597876*PED | Dec 23, 2019 | | | | |
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N 021976 004 | >A> 8597876 | Jun 23, 2019 | U-1305 | | | |
| | >A> 8597876*PED | Dec 23, 2019 | | | | |
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N 021976 005 | >A> 8597876 | Jun 23, 2019 | U-1305 | | | |
| | >A> 8597876*PED | Dec 23, 2019 | | | | |
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N 021976 006 | >A> 8597876 | Jun 23, 2019 | U-1305 | | | |
| | >A> 8597876*PED | Dec 23, 2019 | | | | |
| DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX | | | | | | |
| N 021038 001 | | | | | >A> M-61 | Jun 17, 2016 |
| | | | | | >A> PED | Dec 17, 2016 |
| DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX | | | | | | |
| N 021038 002 | | | | | >A> M-61 | Jun 17, 2016 |
| | | | | | >A> PED | Dec 17, 2016 |
| DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX | | | | | | |
| N 021038 003 | | | | | >A> M-61 | Jun 17, 2016 |
| | | | | | >A> PED | Dec 17, 2016 |
| DICLOFENAC POTASSIUM - ZIPSOR | | | | | | |
| N 022202 001 | >A> 6287594 | Jan 15, 2019 | DP | | | |
| | >A> 8623920 | Feb 24, 2029 | U-1482 | | | |
| DICLOFENAC SODIUM - PENNSAID | | | | | | |
| N 204623 001 | | | | | >A> NP | Jan 16, 2017 |
| DIPHENHYDRAMINE HYDROCHLORIDE; NAPROXEN SODIUM - ALEVE PM | | | | | | |
| N 205352 001 | | | | | >A> NC | Jan 17, 2017 |
| DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - BEYAZ | | | | | | |
| N 022532 001 | >A> 8617597 | Feb 08, 2030 | DP | | | |
| DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - SAFYRAL | | | | | | |
| N 022574 001 | >A> 8617597 | Feb 08, 2030 | DP | | | |
| FLUOCINONIDE - FLUOCINONIDE | | | | | | |
| A 090256 001 | | | | | >A> PC | Jul 13, 2014 |
| GABAPENTIN ENACARBIL - HORIZANT | | | | | | |
| N 022399 001 | | | | | >A> ODE | Jun 06, 2019 |
| GABAPENTIN ENACARBIL - HORIZANT | | | | | | |
| N 022399 002 | | | | | >A> ODE | Jun 06, 2019 |
| IMATINIB MESYLATE - GLEEVEC | | | | | | |
| N 021335 001 | >A> RE43932 | Jan 16, 2019 | DS DP | | | |
| | >A> RE43932*PED | Jul 16, 2019 | | | | |
| IMATINIB MESYLATE - GLEEVEC | | | | | | |
| N 021335 002 | >A> RE43932 | Jan 16, 2019 | DS DP | | | |
| | >A> RE43932*PED | Jul 16, 2019 | | | | |
| LENALIDOMIDE - REVLIMID | | | | | | |
| N 021880 001 | >A> 8626531 | Oct 23, 2020 | U-1210 | | | |
| LENALIDOMIDE - REVLIMID | | | | | | |
| N 021880 002 | >A> 8626531 | Oct 23, 2020 | U-1210 | | | |
| LENALIDOMIDE - REVLIMID | | | | | | |
| N 021880 003 | >A> 8626531 | Oct 23, 2020 | U-1210 | | | |
| LENALIDOMIDE - REVLIMID | | | | | | |
| N 021880 004 | >A> 8626531 | Oct 23, 2020 | U-1210 | | | |

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| APPL/PROD NO | | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
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| LENALIDOMIDE - REVLIMID | | | | | | | |
| N 021880 | 006 | >A> 8626531 | Oct 23, 2020 | U-1210 | | | |
| LOMITAPIDE MESYLATE - JUXTAPID | | | | | | | |
| N 203858 | 001 | >A> 8618135 | Mar 07, 2025 | U-1316 | | | |
| LOMITAPIDE MESYLATE - JUXTAPID | | | | | | | |
| N 203858 | 002 | >A> 8618135 | Mar 07, 2025 | U-1316 | | | |
| LOMITAPIDE MESYLATE - JUXTAPID | | | | | | | |
| N 203858 | 003 | >A> 8618135 | Mar 07, 2025 | U-1316 | | | |
| LOXAPINE - ADASUVE | | | | | | | |
| N 022549 | 001 | >A> 7052679 | Oct 26, 2021 | DP | | | |
| | | >A> 7537009 | Oct 28, 2024 | DP | | | |
| | | >A> 8074644 | Jul 25, 2022 | DP | | | |
| METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE - KOMBIGLYZE XR | | | | | | | |
| N 200678 | 001 | >A> 8628799 | Jul 13, 2025 | DP | | | |
| METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE - KOMBIGLYZE XR | | | | | | | |
| N 200678 | 002 | >A> 8628799 | Jul 13, 2025 | DP | | | |
| METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE - KOMBIGLYZE XR | | | | | | | |
| N 200678 | 003 | >A> 8628799 | Jul 13, 2025 | DP | | | |
| METHYLPHENIDATE - DAYTRANA | | | | | | | |
| N 021514 | 001 | >A> 8632802 | Oct 07, 2025 | DP | | | |
| METHYLPHENIDATE - DAYTRANA | | | | | | | |
| N 021514 | 002 | >A> 8632802 | Oct 07, 2025 | DP | | | |
| METHYLPHENIDATE - DAYTRANA | | | | | | | |
| N 021514 | 003 | >A> 8632802 | Oct 07, 2025 | DP | | | |
| METHYLPHENIDATE - DAYTRANA | | | | | | | |
| N 021514 | 004 | >A> 8632802 | Oct 07, 2025 | DP | | | |
| METHYLPHENIDATE HYDROCHLORIDE - CONCERTA | | | | | | | |
| N 021121 | 001 | >A> 8629179 | Jul 31, 2017 | DP | | | |
| | | >A> 8629179*PED | Jan 31, 2018 | | | | |
| METHYLPHENIDATE HYDROCHLORIDE - CONCERTA | | | | | | | |
| N 021121 | 002 | >A> 8629179 | Jul 31, 2017 | DP | | | |
| | | >A> 8629179*PED | Jan 31, 2018 | | | | |
| METHYLPHENIDATE HYDROCHLORIDE - CONCERTA | | | | | | | |
| N 021121 | 003 | >A> 8629179 | Jul 31, 2017 | DP | | | |
| | | >A> 8629179*PED | Jan 31, 2018 | | | | |
| METHYLPHENIDATE HYDROCHLORIDE - CONCERTA | | | | | | | |
| N 021121 | 004 | >A> 8629179 | Jul 31, 2017 | DP | | | |
| | | >A> 8629179*PED | Jan 31, 2018 | | | | |
| MYCOPHENOLIC ACID - MYCOPHENOLIC ACID | | | | | | | |
| A 091248 | 001 | | | | | >A> PC | Jul 07, 2014 |
| NIACIN - NIACIN | | | | | | | |
| A 076250 | 001 | | | | | >A> PC | Mar 19, 2014 |
| NIACIN - NIACIN | | | | | | | |
| A 076378 | 001 | | | | | >A> PC | Mar 19, 2014 |
| NIACIN - NIACIN | | | | | | | |
| A 076378 | 002 | | | | | >A> PC | Mar 19, 2014 |
| NITRIC OXIDE - INOMAX | | | | | | | |
| N 020845 | 002 | | | | | >A> M-132 | Dec 21, 2013 |
| | | | | | | >A> PED | Jun 21, 2014 |
| NITRIC OXIDE - INOMAX | | | | | | | |
| N 020845 | 003 | | | | | >A> M-132 | Dec 21, 2013 |
| | | | | | | >A> PED | Jun 21, 2014 |
| POMALIDOMIDE - POMALYST | | | | | | | |
| N 204026 | 001 | >A> 8626531 | Oct 23, 2020 | U-1361 | | | |
| POMALIDOMIDE - POMALYST | | | | | | | |
| N 204026 | 002 | >A> 8626531 | Oct 23, 2020 | U-1361 | | | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
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| POMALIDOMIDE - POMALYST | | | | | | |
| N 204026 003 | >A> 8626531 | Oct 23, 2020 | U-1361 | | | |
| POMALIDOMIDE - POMALYST | | | | | | |
| N 204026 004 | >A> 8626531 | Oct 23, 2020 | U-1361 | | | |
| RALTEGRAVIR POTASSIUM - ISENTRESS | | | | | | |
| N 205786 001 | >A> 7169780 | Oct 03, 2023 | DS DP | | | |
| | >A> 7217713 | Oct 21, 2022 | U-257 | | | |
| | >A> 7435734 | Oct 21, 2022 | U-257 | | | |
| | >A> 7754731 | Mar 11, 2029 | DS DP U-257 | | | |
| RIFAXIMIN - XIFAXAN | | | | | | |
| N 021361 001 | >A> 8642573 | Oct 02, 2029 | U-1481 | | | |
| RIFAXIMIN - XIFAXAN | | | | | | |
| N 022554 001 | >A> 8642573 | Oct 02, 2029 | U-1481 | | | |
| ROFLUMILAST - DALIRESP | | | | | | |
| N 022522 001 | >A> 8618142 | Mar 08, 2024 | DP | | | |
| SIROLIMUS - SIROLIMUS | | | | | | |
| A 201676 003 | | | | | >A> PC | Jul 15, 2014 |
| SOFOSBUVIR - SOVALDI | | | | | | |
| N 204671 001 | >A> 8618076 | Dec 11, 2030 | DS DP U-1470 | | | |
| | >A> 8633309 | Mar 26, 2029 | DS DP U-1470 | | | |
| SORAFENIB TOSYLATE - NEXAVAR | | | | | | |
| N 021923 001 | >A> 8618141 | Feb 11, 2023 | U-1480 | | | |
| TASIMELTEON - HETLIOZ | | | | | | |
| N 205677 001 | | | | | >A> NCE | Jan 31, 2019 |
| TEMOZOLOMIDE - TEMODAR | | | | | | |
| N 022277 001 | >A> 8623868 | Feb 21, 2023 | DP | | | |
| THALIDOMIDE - THALOMID | | | | | | |
| N 020785 001 | >A> 8626531 | Oct 23, 2020 | U-1465 | | | |
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| N 020785 002 | >A> 8626531 | Oct 23, 2020 | U-1465 | | | |
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| N 020785 003 | >A> 8626531 | Oct 23, 2020 | U-1465 | | | |
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| N 020785 004 | >A> 8626531 | Oct 23, 2020 | U-1465 | | | |
| TRAMETINIB DIMETHYL SULFOXIDE - MEKINIST | | | | | | |
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| | | | | | >A> ODE | Jan 08, 2021 |
| TRAMETINIB DIMETHYL SULFOXIDE - MEKINIST | | | | | | |
| N 204114 002 | | | | | >A> I-678 | Jan 08, 2017 |
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| N 204114 003 | | | | | >A> I-678 | Jan 08, 2017 |
| | | | | | >A> ODE | Jan 08, 2021 |
| VARDENAFIL HYDROCHLORIDE - STAXYN | | | | | | |
| N 200179 001 | >A> 8613950 | Dec 23, 2028 | DP | | | |

Footnote:

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

2. Patents 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.

# PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 34th Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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

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