

# **APPROVED DRUG PRODUCTS**

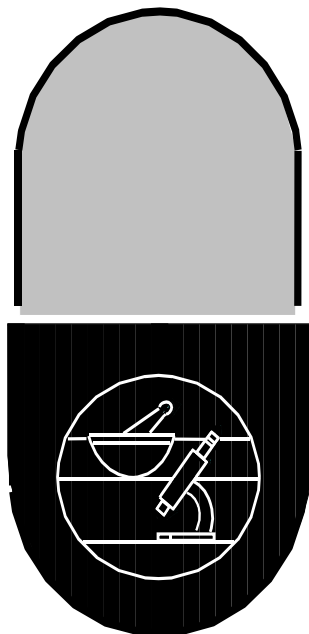
## **With Therapeutic Equivalence Evaluations**



**The "Orange Book"**

**FDA data supplied by [DrugPatentWatch.com](https://www.drugpatentwatch.com)**

**CUMULATIVE  
SUPPLEMENT 4  
APRIL 2013**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**33rd EDITION**

**Department of Health and Human Services**

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

**2013**

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

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**33<sup>rd</sup> EDITION**

**Cumulative Supplement 4**

**April 2013**

**CONTENTS**

|                                                                            | <i>PAGE</i> |
|----------------------------------------------------------------------------|-------------|
| 1.0 INTRODUCTION.....                                                      | iii         |
| 1.1 How to use the Cumulative Supplement .....                             | iii         |
| 1.2 Cumulative Supplement Content .....                                    | iv          |
| 1.3 Applicant Name Changes .....                                           | v           |
| 1.4 Levothyroxine Sodium.....                                              | v           |
| 1.5 Availability of the Edition.....                                       | vi          |
| 1.6 Report of Counts for the Prescription Drug Product List.....           | vii         |
| 1.7 Cumulative Supplement Legend .....                                     | viii        |
| <br>DRUG PRODUCT LISTS                                                     |             |
| Prescription Drug Product List .....                                       | 1-1         |
| OTC Drug Product List .....                                                | 2-1         |
| Drug Products with Approval under Section 505 of the Act                   |             |
| Administered by the Center for Biologics Evaluation and Research List..... | 3-1         |
| Orphan Product Designations and Approvals List .....                       | 4-1         |
| Drug Products Which Must Demonstrate in vivo Bioavailability               |             |
| Only if Product Fails to Achieve Adequate Dissolution .....                | 5-1         |
| <br>PATENT AND EXCLUSIVITY INFORMATION ADDENDUM                            |             |
| A. Patent and Exclusivity Lists .....                                      | A-1         |
| B. Patent and Exclusivity Terms .....                                      | B-1         |

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**33<sup>rd</sup> EDITION**

**CUMULATIVE SUPPLEMENT 4  
April 2013**

**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, 30th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 32nd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 33rd Edition. The current Edition Section 2., How To Use The Drug Product Lists, describes the layout and usage of the List.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. The Patent and Exclusivity 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.
  - o Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
  - o 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](mailto: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)

BIONICHE PHARMA USA LLC  
(BIONICHE PHARMA USA)

MYLAN INSTITUTIONAL LLC  
(MYLAN LLC)

### 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 Levotheroid (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        |
| LEVOTHYROXINE SODIUM | MERCK KGAA  | 0.025MG | AB2     | 76752   | 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        |
| LEVOTHYROXINE SODIUM | MERCK KGAA  | 0.025MG | AB3     | 76752   | 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 2011) 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

| <u>CATEGORIES COUNTED</u>          | <u>DEC 2012</u>  | <u>MAR 2013</u>  | <u>JUN 2013</u> | <u>SEPT 2013</u> | <u>DEC 2013</u> |
|------------------------------------|------------------|------------------|-----------------|------------------|-----------------|
| DRUG PRODUCTS LISTED               | 15343            | 15445            |                 |                  |                 |
| SINGLE SOURCE                      | 2400<br>(15.9%)  | 2467<br>(16.0%)  |                 |                  |                 |
| MULTISOURCE                        | 12825<br>(83.6%) | 12900<br>(83.5)  |                 |                  |                 |
| THERAPEUTICALLY<br>EQUIVALENT      | 12683<br>(82.7%) | 12758<br>(82.6%) |                 |                  |                 |
| NOT THERAPEUTICALLY<br>EQUIVALENT  | 142<br>(0.9%)    | 142<br>(0.9%)    |                 |                  |                 |
| EXCEPTIONS <sup>1</sup>            | 78<br>(0.5%)     | 78<br>(0.5%)     |                 |                  |                 |
| NEW MOLECULAR ENTITIES<br>APPROVED | 17               | 9                |                 |                  |                 |
| NUMBER OF APPLICANTS               | 835              | 844              |                 |                  |                 |

<sup>1</sup>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 preceded 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. |

PRESCRIPTION DRUG PRODUCT LIST - 33RD EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

1-1

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

@ MIRROR PHARMS LLC 500MG;50MG;40MG

A040883 001 Dec 23, 2008 Feb DISC

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

@ MIKART 356.4MG;30MG;16MG

A040109 001 Aug 26, 1997 Feb DISC

TABLET; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

@ MIKART 712.8MG;60MG;32MG

A040316 001 Apr 28, 1999 Feb DISC

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>A> AA AUROLIFE PHARMA LLC 300MG;15MG

A202800 001 Apr 15, 2013 Apr NEWA

>A> AA 300MG;30MG

A202800 002 Apr 15, 2013 Apr NEWA

>A> AA 300MG;60MG

A202800 003 Apr 15, 2013 Apr NEWA

@ MIKART 650MG;30MG

A089231 001 Mar 03, 1986 Feb DISC

@ 650MG;60MG

A089363 001 Sep 09, 1991 Feb DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

@ MIKART 500MG;5MG

A081067 001 Nov 30, 1989 Feb DISC

SOLUTION; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>A> AA PAI 325MG/15ML;7.5MG/15ML

A040838 001 May 10, 2013 Apr NEWA

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

@ MIKART 500MG;2.5MG

A089698 001 Aug 25, 1989 Feb DISC

@ 650MG;5MG

A040849 001 Jun 09, 2010 Feb DISC

AA TRIS PHARMA INC 325MG;5MG

A202214 001 Mar 27, 2013 Mar NEWA

AA 325MG;7.5MG

A202214 002 Mar 27, 2013 Mar NEWA

AA 325MG;10MG

A202214 003 Mar 27, 2013 Mar NEWA

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

OXYCODONE AND ACETAMINOPHEN

>A> AA ACTAVIS ELIZABETH 325MG;2.5MG

A201447 001 Apr 12, 2013 Apr NEWA

>A> AA 325MG;5MG

A201447 002 Apr 12, 2013 Apr NEWA

>A> AA 325MG;7.5MG

A201447 003 Apr 12, 2013 Apr NEWA

>A> AA 325MG;10MG

A201447 004 Apr 12, 2013 Apr NEWA

ACETAZOLAMIDE

TABLET; ORAL

ACETAZOLAMIDE

@ WATSON LABS 250MG

A088882 001 Oct 22, 1985 Jan DISC

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION  
ACETAZOLAMIDE SODIUM

|    |              |                    |             |              |     |      |
|----|--------------|--------------------|-------------|--------------|-----|------|
| AP | SAGENT AGILA | EQ 500MG BASE/VIAL | A200880 001 | May 09, 2012 | Jan | CAHN |
|----|--------------|--------------------|-------------|--------------|-----|------|

ACITRETIN

CAPSULE; ORAL

ACITRETIN

|    |                 |        |             |              |     |      |
|----|-----------------|--------|-------------|--------------|-----|------|
| AB | BARR LABS INC   | 10MG   | A091455 001 | Apr 04, 2013 | Mar | NEWA |
| AB |                 | 25MG   | A091455 002 | Apr 04, 2013 | Mar | NEWA |
| AB | TEVA PHARMS USA | 17.5MG | A202897 001 | Apr 04, 2013 | Mar | NEWA |
| AB |                 | 22.5MG | A202897 002 | Apr 04, 2013 | Mar | NEWA |

SORIATANE

|    |                  |        |             |              |     |      |
|----|------------------|--------|-------------|--------------|-----|------|
| AB | STIEFEL LABS INC | 10MG   | N019821 001 | Oct 28, 1996 | Mar | CFTG |
| AB |                  | 17.5MG | N019821 003 | Aug 06, 2009 | Mar | CFTG |
| AB |                  | 22.5MG | N019821 004 | Aug 06, 2009 | Mar | CFTG |
| AB | +                | 25MG   | N019821 002 | Oct 28, 1996 | Mar | CFTG |

ACYCLOVIR

OINTMENT; TOPICAL

ACYCLOVIR

|    |                  |    |             |              |     |      |
|----|------------------|----|-------------|--------------|-----|------|
| AB | MYLAN PHARMS INC | 5% | A202459 001 | Apr 03, 2013 | Mar | NEWA |
|----|------------------|----|-------------|--------------|-----|------|

ZOVIRAX

|    |   |              |    |             |              |     |      |
|----|---|--------------|----|-------------|--------------|-----|------|
| AB | + | VALEANT INTL | 5% | N018604 001 | Mar 29, 1982 | Mar | CFTG |
|----|---|--------------|----|-------------|--------------|-----|------|

>A> TABLET; BUCCAL

>A> SITAVIG

|     |   |                    |      |             |              |     |      |
|-----|---|--------------------|------|-------------|--------------|-----|------|
| >A> | + | BIOALLIANCE PHARMA | 50MG | N203791 001 | Apr 12, 2013 | Apr | NEWA |
|-----|---|--------------------|------|-------------|--------------|-----|------|

ACYCLOVIR; HYDROCORTISONE

CREAM; TOPICAL

XERESE

|     |   |                 |       |             |              |     |      |
|-----|---|-----------------|-------|-------------|--------------|-----|------|
| >A> | + | VALEANT BERMUDA | 5%;1% | N022436 001 | Jul 31, 2009 | Apr | CAHN |
|-----|---|-----------------|-------|-------------|--------------|-----|------|

|     |   |              |       |             |              |     |      |
|-----|---|--------------|-------|-------------|--------------|-----|------|
| >D> | + | VALEANT INTL | 5%;1% | N022436 001 | Jul 31, 2009 | Apr | CAHN |
|-----|---|--------------|-------|-------------|--------------|-----|------|

ADENOSINE

INJECTABLE; INJECTION

ADENOSINE

|     |   |                 |        |             |              |     |      |
|-----|---|-----------------|--------|-------------|--------------|-----|------|
| >D> | @ | TEVA PARENTERAL | 3MG/ML | A076564 001 | Jun 16, 2004 | Apr | CAHN |
|-----|---|-----------------|--------|-------------|--------------|-----|------|

|     |   |  |        |             |              |     |      |
|-----|---|--|--------|-------------|--------------|-----|------|
| >D> | @ |  | 3MG/ML | A078676 001 | Jul 31, 2008 | Apr | CAHN |
|-----|---|--|--------|-------------|--------------|-----|------|

|     |   |                 |        |             |              |     |      |
|-----|---|-----------------|--------|-------------|--------------|-----|------|
| >A> | @ | TEVA PHARMS USA | 3MG/ML | A076564 001 | Jun 16, 2004 | Apr | CAHN |
|-----|---|-----------------|--------|-------------|--------------|-----|------|

|     |   |  |        |             |              |     |      |
|-----|---|--|--------|-------------|--------------|-----|------|
| >A> | @ |  | 3MG/ML | A078676 001 | Jul 31, 2008 | Apr | CAHN |
|-----|---|--|--------|-------------|--------------|-----|------|

ALBENDAZOLE

TABLET; ORAL

ALBENZA

|   |               |       |             |              |     |      |
|---|---------------|-------|-------------|--------------|-----|------|
| + | AMEDRA PHARMS | 200MG | N020666 001 | Jun 11, 1996 | Feb | CAHN |
|---|---------------|-------|-------------|--------------|-----|------|

ALBUTEROL SULFATE

AEROSOL, METERED; INHALATION

PROAIR HFA

|     |    |   |                    |                    |             |              |     |      |
|-----|----|---|--------------------|--------------------|-------------|--------------|-----|------|
| >A> | BX | + | TEVA BRANDED PHARM | EQ 0.09MG BASE/INH | N021457 001 | Oct 29, 2004 | Apr | CAHN |
|-----|----|---|--------------------|--------------------|-------------|--------------|-----|------|

|     |    |   |             |                    |             |              |     |      |
|-----|----|---|-------------|--------------------|-------------|--------------|-----|------|
| >D> | BX | + | TEVA GLOBAL | EQ 0.09MG BASE/INH | N021457 001 | Oct 29, 2004 | Apr | CAHN |
|-----|----|---|-------------|--------------------|-------------|--------------|-----|------|

SOLUTION; INHALATIONALBUTEROL SULFATE

|     |    |                        |                |             |              |     |      |
|-----|----|------------------------|----------------|-------------|--------------|-----|------|
| >D> | AN | APOTEX INC             | EQ 0.021% BASE | A078623 001 | Apr 05, 2010 | Apr | DISC |
| >A> |    | @                      | EQ 0.021% BASE | A078623 001 | Apr 05, 2010 | Apr | DISC |
| >D> | AN |                        | EQ 0.042% BASE | A078623 002 | Apr 05, 2010 | Apr | DISC |
| >A> |    | @                      | EQ 0.042% BASE | A078623 002 | Apr 05, 2010 | Apr | DISC |
| >D> | AN |                        | EQ 0.083% BASE | A075717 001 | Feb 02, 2007 | Apr | DISC |
| >A> |    | @                      | EQ 0.083% BASE | A075717 001 | Feb 02, 2007 | Apr | DISC |
| >A> |    | @                      | EQ 0.5% BASE   | A076391 001 | Apr 01, 2003 | Apr | DISC |
|     | AN | + MYLAN SPECLT         | EQ 0.083% BASE | A072652 001 | Feb 21, 1992 | Jan | CAHN |
| >D> | AN | NOVEX                  | EQ 0.5% BASE   | A076391 001 | Apr 01, 2003 | Apr | DISC |
|     |    | @ WOCKHARDT EU OPERATN | EQ 0.083% BASE | A075394 001 | Nov 22, 1999 | Mar | DISC |

ALBUTEROL SULFATE; IPRATROPIUM BROMIDESOLUTION; INHALATIONALBUTEROL SULFATE AND IPRATROPIUM BROMIDE

|     |    |              |                       |             |              |     |      |
|-----|----|--------------|-----------------------|-------------|--------------|-----|------|
| >D> | AN | APOTEX CORP  | EQ 0.083% BASE;0.017% | A077117 001 | Dec 31, 2007 | Apr | DISC |
| >A> |    | @ APOTEX INC | EQ 0.083% BASE;0.017% | A077117 001 | Dec 31, 2007 | Apr | DISC |

ALENDRONATE SODIUMSOLUTION; ORALALENDRONATE SODIUM

|    |   |         |                   |             |              |     |      |
|----|---|---------|-------------------|-------------|--------------|-----|------|
| AA |   | ROXANE  | EQ 70MG BASE/75ML | A090520 001 | Feb 25, 2013 | Feb | NEWA |
|    |   | FOSAMAX |                   |             |              |     |      |
| AA | + | MERCK   | EQ 70MG BASE/75ML | N021575 001 | Sep 17, 2003 | Feb | CFTG |

ALFUZOSIN HYDROCHLORIDETABLET, EXTENDED RELEASE; ORALUROXATRAL

|     |    |                     |      |             |              |     |      |
|-----|----|---------------------|------|-------------|--------------|-----|------|
| >A> | AB | + COVIS PHARMA SARL | 10MG | N021287 001 | Jun 12, 2003 | Apr | CAHN |
| >D> | AB | + SANOFI AVENTIS US | 10MG | N021287 001 | Jun 12, 2003 | Apr | CAHN |

ALLOPURINOLTABLET; ORALALLOPURINOL

|     |    |                 |       |             |              |     |      |
|-----|----|-----------------|-------|-------------|--------------|-----|------|
| >A> | AB | ACCORD HLTHCARE | 100MG | A203154 001 | May 06, 2013 | Apr | NEWA |
| >A> | AB |                 | 300MG | A203154 002 | May 06, 2013 | Apr | NEWA |

ALOGLIPTIN BENZOATETABLET; ORALNESINATAKEDA PHARMS USA

|  |   |  |                |             |              |     |      |
|--|---|--|----------------|-------------|--------------|-----|------|
|  |   |  | EQ 6.25MG BASE | N022271 001 | Jan 25, 2013 | Jan | NEWA |
|  |   |  | EQ 12.5MG BASE | N022271 002 | Jan 25, 2013 | Jan | NEWA |
|  | + |  | EQ 25MG BASE   | N022271 003 | Jan 25, 2013 | Jan | NEWA |

ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDETABLET; ORALKAZANOTAKEDA PHARMS USA

|  |   |  |                      |             |              |     |      |
|--|---|--|----------------------|-------------|--------------|-----|------|
|  |   |  | EQ 12.5MG BASE;500MG | N203414 001 | Jan 25, 2013 | Jan | NEWA |
|  | + |  | EQ 12.5MG BASE;1GM   | N203414 002 | Jan 25, 2013 | Jan | NEWA |

ALOGLIPTIN BENZOATE; PIOGLITAZONETABLET; ORALOSENITAKEDA PHARMS USA

|  |  |  |                             |             |              |     |      |
|--|--|--|-----------------------------|-------------|--------------|-----|------|
|  |  |  | EQ 12.5MG BASE;EQ 15MG BASE | N022426 004 | Jan 25, 2013 | Jan | NEWA |
|--|--|--|-----------------------------|-------------|--------------|-----|------|

## TABLET; ORAL

## OSEN

|   |                   |                             |             |              |     |      |
|---|-------------------|-----------------------------|-------------|--------------|-----|------|
|   | TAKEDA PHARMS USA | EQ 12.5MG BASE;EQ 30MG BASE | N022426 005 | Jan 25, 2013 | Jan | NEWA |
|   |                   | EQ 12.5MG BASE;EQ 45MG BASE | N022426 006 | Jan 25, 2013 | Jan | NEWA |
|   |                   | EQ 25MG BASE;EQ 15MG BASE   | N022426 001 | Jan 25, 2013 | Jan | NEWA |
|   |                   | EQ 25MG BASE;EQ 30MG BASE   | N022426 002 | Jan 25, 2013 | Jan | NEWA |
| + |                   | EQ 25MG BASE;EQ 45MG BASE   | N022426 003 | Jan 25, 2013 | Jan | NEWA |

ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE

## TABLET; ORAL

## OSEN

|   |                   |                             |             |              |     |      |
|---|-------------------|-----------------------------|-------------|--------------|-----|------|
|   | TAKEDA PHARMS USA | EQ 12.5MG BASE;EQ 15MG BASE | N022426 004 | Jan 25, 2013 | Feb | CAIN |
|   |                   | EQ 12.5MG BASE;EQ 30MG BASE | N022426 005 | Jan 25, 2013 | Feb | CAIN |
|   |                   | EQ 12.5MG BASE;EQ 45MG BASE | N022426 006 | Jan 25, 2013 | Feb | CAIN |
|   |                   | EQ 25MG BASE;EQ 15MG BASE   | N022426 001 | Jan 25, 2013 | Feb | CAIN |
|   |                   | EQ 25MG BASE;EQ 30MG BASE   | N022426 002 | Jan 25, 2013 | Feb | CAIN |
| + |                   | EQ 25MG BASE;EQ 45MG BASE   | N022426 003 | Jan 25, 2013 | Feb | CAIN |

ALPROSTADIL

## INJECTABLE; INJECTION

## ALPROSTADIL

|     |    |                 |          |             |              |     |      |
|-----|----|-----------------|----------|-------------|--------------|-----|------|
| >D> | AP | TEVA PARENTERAL | 0.5MG/ML | A075196 001 | Apr 30, 1999 | Apr | CAHN |
| >A> | AP | TEVA PHARMS USA | 0.5MG/ML | A075196 001 | Apr 30, 1999 | Apr | CAHN |

AMIKACIN SULFATE

## INJECTABLE; INJECTION

## AMIKACIN SULFATE

## @ HOSPIRA

EQ 250MG BASE/ML

A063264 001 Nov 30, 1994 Mar DISC

AMIODARONE HYDROCHLORIDE

## INJECTABLE; INJECTION

## AMIODARONE HYDROCHLORIDE

|     |    |                       |         |             |              |     |      |
|-----|----|-----------------------|---------|-------------|--------------|-----|------|
| >A> |    | @ APOTEX INC          | 50MG/ML | A076394 001 | Apr 25, 2003 | Apr | DISC |
| >D> | AP | + BIONICHE PHARMA     | 50MG/ML | A076217 001 | Oct 15, 2002 | Apr | CAHN |
| >D> | AP | + CLARIS LIFESCIENCES | 50MG/ML | A076394 001 | Apr 25, 2003 | Apr | DISC |
| >A> | AP | + MYLAN INSTITUTIONAL | 50MG/ML | A076217 001 | Oct 15, 2002 | Apr | CAHN |
| >D> |    | @ TEVA PARENTERAL     | 50MG/ML | A076163 001 | Sep 05, 2003 | Apr | CAHN |
| >A> |    | @ TEVA PHARMS USA     | 50MG/ML | A076163 001 | Sep 05, 2003 | Apr | CAHN |

AMLODIPINE BESYLATE

## TABLET; ORAL

## AMLODIPINE BESYLATE

|     |    |                 |               |             |              |     |      |
|-----|----|-----------------|---------------|-------------|--------------|-----|------|
| >A> | AB | ACCORD HLTHCARE | EQ 2.5MG BASE | A202553 001 | Apr 29, 2013 | Apr | NEWA |
| >A> | AB |                 | EQ 5MG BASE   | A202553 002 | Apr 29, 2013 | Apr | NEWA |
| >A> | AB |                 | EQ 10MG BASE  | A202553 003 | Apr 29, 2013 | Apr | NEWA |

AMLODIPINE BESYLATE; VALSARTAN

## TABLET; ORAL

## AMLODIPINE BESYLATE AND VALSARTAN

|    |               |                    |             |              |     |      |
|----|---------------|--------------------|-------------|--------------|-----|------|
| AB | PAR PHARM INC | EQ 5MG BASE;160MG  | A090011 001 | Mar 28, 2013 | Mar | NEWA |
| AB |               | EQ 5MG BASE;320MG  | A090144 001 | Mar 28, 2013 | Mar | NEWA |
| AB |               | EQ 10MG BASE;160MG | A090011 002 | Mar 28, 2013 | Mar | NEWA |
| AB |               | EQ 10MG BASE;320MG | A090011 004 | Mar 28, 2013 | Mar | NEWA |
|    | EXFORGE       |                    |             |              |     |      |
| AB | NOVARTIS      | EQ 5MG BASE;160MG  | N021990 002 | Jun 20, 2007 | Mar | CFTG |

## TABLET; ORAL

## EXFORGE

|    |          |                    |             |              |     |      |
|----|----------|--------------------|-------------|--------------|-----|------|
| AB | NOVARTIS | EQ 5MG BASE;320MG  | N021990 004 | Jun 20, 2007 | Mar | CFTG |
| AB | +        | EQ 10MG BASE;160MG | N021990 003 | Jun 20, 2007 | Mar | CFTG |
| AB | +        | EQ 10MG BASE;320MG | N021990 005 | Jun 20, 2007 | Mar | CFTG |

AMMONIA N-13

## INJECTABLE; INTRAVENOUS

## AMMONIA N 13

|    |                     |                                    |             |              |     |      |
|----|---------------------|------------------------------------|-------------|--------------|-----|------|
| AP | CARDINAL HEALTH 414 | 30MCI-300MCI/8ML (3.75-37.5MCI/ML) | A203700 001 | Feb 25, 2013 | Feb | NEWA |
| AP | +                   | FEINSTEIN                          | N022119 001 | Aug 23, 2007 | Feb | CFTG |
| AP | MCPRF               | 30MCI-300MCI/8ML (3.75-37.5MCI/ML) | A203321 001 | Feb 25, 2013 | Feb | NEWA |

AMOXICILLIN

## FOR SUSPENSION; ORAL

## AMOXICILLIN

|   |         |           |             |              |     |      |
|---|---------|-----------|-------------|--------------|-----|------|
| @ | RANBAXY | 200MG/5ML | A065113 001 | Nov 29, 2002 | Feb | DISC |
| @ |         | 400MG/5ML | A065113 002 | Nov 29, 2002 | Feb | DISC |

## TABLET, CHEWABLE; ORAL

## AMOXICILLIN

|   |                 |       |             |              |     |      |
|---|-----------------|-------|-------------|--------------|-----|------|
| @ | DAVA PHARMS INC | 125MG | A064139 001 | Jan 29, 1996 | Mar | DISC |
| @ |                 | 250MG | A064139 002 | Jan 29, 1996 | Mar | DISC |
| @ | RANBAXY         | 200MG | A065060 001 | Nov 29, 2000 | Feb | DISC |
| @ |                 | 400MG | A065060 002 | Nov 29, 2000 | Feb | DISC |

## AMOXIL

|   |                    |       |             |              |     |      |
|---|--------------------|-------|-------------|--------------|-----|------|
| @ | DR REDDYS LABS INC | 200MG | N050761 001 | Apr 15, 1999 | Feb | DISC |
| @ |                    | 400MG | N050761 002 | Apr 15, 1999 | Feb | DISC |

## TABLET, FOR SUSPENSION; ORAL

## AMOXICILLIN

|   |                      |       |             |              |     |      |
|---|----------------------|-------|-------------|--------------|-----|------|
| @ | AUROBINDO PHARMA LTD | 200MG | A065324 001 | Jan 17, 2007 | Jan | DISC |
| @ |                      | 400MG | A065324 002 | Jan 17, 2007 | Jan | DISC |

AMOXICILLIN; CLAVULANATE POTASSIUM

## TABLET; ORAL

## AMOXICILLIN AND CLAVULANATE POTASSIUM

|                 |    |                    |          |       |      |         |     |              |     |      |
|-----------------|----|--------------------|----------|-------|------|---------|-----|--------------|-----|------|
| >D>             | AB | APOTEX             | 250MG;EQ | 125MG | BASE | A065333 | 001 | Feb 24, 2009 | Apr | DISC |
| >D>             | AB |                    | 500MG;EQ | 125MG | BASE | A065333 | 002 | Feb 24, 2009 | Apr | DISC |
| >A>             |    | @ APOTEX INC       | 250MG;EQ | 125MG | BASE | A065333 | 001 | Feb 24, 2009 | Apr | DISC |
| >A>             |    | @                  | 500MG;EQ | 125MG | BASE | A065333 | 002 | Feb 24, 2009 | Apr | DISC |
| >D>             | AB |                    | 875MG;EQ | 125MG | BASE | A065317 | 003 | Oct 20, 2008 | Apr | DISC |
| >A>             |    | @                  | 875MG;EQ | 125MG | BASE | A065317 | 003 | Oct 20, 2008 | Apr | DISC |
| >D>             | AB | RANBAXY            | 500MG;EQ | 125MG | BASE | A065109 | 001 | Nov 04, 2002 | Apr | DISC |
| >A>             |    | @ RANBAXY LABS     | 500MG;EQ | 125MG | BASE | A065109 | 001 | Nov 04, 2002 | Apr | DISC |
| >D>             | AB | + TEVA             | 875MG;EQ | 125MG | BASE | A065096 | 001 | Oct 29, 2002 | Apr | CRLD |
| >A>             | AB | TEVA PHARMS USA    | 875MG;EQ | 125MG | BASE | A065096 | 001 | Oct 29, 2002 | Apr | CRLD |
| AUGMENTIN '250' |    |                    |          |       |      |         |     |              |     |      |
| >D>             | AB | DR REDDYS LABS INC | 250MG;EQ | 125MG | BASE | N050564 | 001 | Aug 06, 1984 | Apr | CRLD |
| >A>             | AB | +                  | 250MG;EQ | 125MG | BASE | N050564 | 001 | Aug 06, 1984 | Apr | CRLD |
| AUGMENTIN '500' |    |                    |          |       |      |         |     |              |     |      |
| >D>             | AB | DR REDDYS LABS INC | 500MG;EQ | 125MG | BASE | N050564 | 002 | Aug 06, 1984 | Apr | CRLD |
| >A>             | AB | +                  | 500MG;EQ | 125MG | BASE | N050564 | 002 | Aug 06, 1984 | Apr | CRLD |
| AUGMENTIN '875' |    |                    |          |       |      |         |     |              |     |      |
| >D>             | AB | DR REDDYS LABS INC | 875MG;EQ | 125MG | BASE | N050720 | 001 | Feb 13, 1996 | Apr | CRLD |
| >A>             | AB | +                  | 875MG;EQ | 125MG | BASE | N050720 | 001 | Feb 13, 1996 | Apr | CRLD |

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

## CAPSULE, EXTENDED RELEASE; ORAL

## AMPHETAMINE ASP AMPHETAMINE SULF DEXTROAMPHET SACCHARATE &amp; DEXTR SULF

|     |    |      |                             |             |              |     |      |
|-----|----|------|-----------------------------|-------------|--------------|-----|------|
| >A> | AB | TEVA | 1.25MG;1.25MG;1.25MG;1.25MG | A077488 001 | Apr 29, 2013 | Apr | NEWA |
| >A> | AB |      | 2.5MG;2.5MG;2.5MG;2.5MG     | A077488 002 | Apr 29, 2013 | Apr | NEWA |
| >A> | AB |      | 3.75MG;3.75MG;3.75MG;3.75MG | A077488 003 | Apr 29, 2013 | Apr | NEWA |
| >A> | AB |      | 5MG;5MG;5MG;5MG             | A077488 004 | Apr 29, 2013 | Apr | NEWA |
| >A> | AB |      | 6.25MG;6.25MG;6.25MG;6.25MG | A077488 005 | Apr 29, 2013 | Apr | NEWA |
| >A> | AB |      | 7.5MG;7.5MG;7.5MG;7.5MG     | A077488 006 | Apr 29, 2013 | Apr | NEWA |

## DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

|    |               |                             |             |              |     |      |
|----|---------------|-----------------------------|-------------|--------------|-----|------|
| AB | BARR LABS INC | 1.25MG;1.25MG;1.25MG;1.25MG | A076536 001 | Feb 12, 2013 | Jan | NEWA |
| AB |               | 2.5MG;2.5MG;2.5MG;2.5MG     | A076536 002 | Feb 12, 2013 | Jan | NEWA |
| AB |               | 3.75MG;3.75MG;3.75MG;3.75MG | A076536 003 | Feb 12, 2013 | Jan | NEWA |
| AB |               | 5MG;5MG;5MG;5MG             | A076536 004 | Feb 12, 2013 | Jan | NEWA |
| AB |               | 6.25MG;6.25MG;6.25MG;6.25MG | A076536 005 | Feb 12, 2013 | Jan | NEWA |
| AB |               | 7.5MG;7.5MG;7.5MG;7.5MG     | A076536 006 | Feb 12, 2013 | Jan | NEWA |

## TABLET; ORAL

## DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

|   |             |                             |             |              |     |      |
|---|-------------|-----------------------------|-------------|--------------|-----|------|
| @ | TEVA PHARMS | 1.25MG;1.25MG;1.25MG;1.25MG | A040472 001 | Sep 30, 2003 | Jan | DISC |
| @ |             | 2.5MG;2.5MG;2.5MG;2.5MG     | A040472 002 | Sep 30, 2003 | Jan | DISC |
| @ |             | 5MG;5MG;5MG;5MG             | A040472 003 | Sep 30, 2003 | Jan | DISC |
| @ |             | 7.5MG;7.5MG;7.5MG;7.5MG     | A040472 004 | Sep 30, 2003 | Jan | DISC |

AMPICILLIN SODIUM

## INJECTABLE; INJECTION

## AMPICILLIN SODIUM

|    |                |                    |             |              |     |      |
|----|----------------|--------------------|-------------|--------------|-----|------|
| AP | ACS DOBFAR SPA | EQ 500MG BASE/VIAL | A090884 001 | Apr 03, 2013 | Mar | NEWA |
| AP |                | EQ 1GM BASE/VIAL   | A090884 002 | Apr 03, 2013 | Mar | NEWA |
| AP |                | EQ 2GM BASE/VIAL   | A090884 003 | Apr 03, 2013 | Mar | NEWA |
| AP |                | EQ 10GM BASE/VIAL  | A090889 001 | Apr 03, 2013 | Mar | NEWA |

ANASTROZOLE

## TABLET; ORAL

## ANASTROZOLE

|     |    |                     |     |             |              |     |      |
|-----|----|---------------------|-----|-------------|--------------|-----|------|
| >A> | AB | ACCORD HLTHCARE     | 1MG | A090568 001 | Jun 28, 2010 | Apr | CAHN |
| >D> | AB | ACCORD HLTHCARE INC | 1MG | A090568 001 | Jun 28, 2010 | Apr | CAHN |
|     |    | @ KUDCO IRELAND     | 1MG | A091331 001 | Jan 05, 2011 | Feb | DISC |

ARIPIPRAZOLE

## FOR SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR

## ABILIFY MAINTENA KIT

|   |                     |            |             |              |     |      |
|---|---------------------|------------|-------------|--------------|-----|------|
|   | OTSUKA PHARM CO LTD | 300MG/VIAL | N202971 001 | Feb 28, 2013 | Feb | NEWA |
| + |                     | 400MG/VIAL | N202971 002 | Feb 28, 2013 | Feb | NEWA |

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

## TABLET; ORAL

## ORPHENGESIC

|     |   |                   |                 |             |              |     |      |
|-----|---|-------------------|-----------------|-------------|--------------|-----|------|
| >A> | @ | PRINSTON INC      | 385MG;30MG;25MG | A075141 001 | May 29, 1998 | Apr | CAHN |
| >D> | @ | SOLCO HLTHCARE    | 385MG;30MG;25MG | A075141 001 | May 29, 1998 | Apr | CAHN |
|     |   | ORPHENGESIC FORTE |                 |             |              |     |      |
| >A> | @ | PRINSTON INC      | 770MG;60MG;50MG | A075141 002 | May 29, 1998 | Apr | CAHN |
| >D> | @ | SOLCO HLTHCARE    | 770MG;60MG;50MG | A075141 002 | May 29, 1998 | Apr | CAHN |

ATENOLOL

TABLET; ORAL

ATENOLOL

@ WATSON LABS

50MG

A073352 001 Dec 27, 1991 Mar DISC

@

100MG

A073353 001 Dec 27, 1991 Mar DISC

ATORVASTATIN CALCIUM

TABLET; ORAL

ATORVASTATIN CALCIUM

AB KUDCO IRELAND

EQ 10MG BASE

A091624 001 Apr 05, 2013 Mar NEWA

AB

EQ 20MG BASE

A091624 002 Apr 05, 2013 Mar NEWA

AB

EQ 40MG BASE

A091624 003 Apr 05, 2013 Mar NEWA

AB

EQ 80MG BASE

A091624 004 Apr 05, 2013 Mar NEWA

AZITHROMYCIN

INJECTABLE; INJECTION

AZITHROMYCIN

AP SUN PHARM INDS LTD

EQ 500MG BASE/VIAL

A090923 001 Apr 02, 2013 Mar NEWA

BACITRACIN

POWDER; FOR RX COMPOUNDING

BACI-RX

@ X GEN PHARMS

5,000,000 UNITS/BOT

A061580 001 Mar DISC

BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE

GEL; TOPICAL

ACANYA

&gt;A&gt; + DOW PHARM

2.5%;1.2%

N050819 001 Oct 23, 2008 Apr CAHN

&gt;D&gt; + DOW PHARM SCI

2.5%;1.2%

N050819 001 Oct 23, 2008 Apr CAHN

BENZACLIN

&gt;A&gt; AB VALEANT BERMUDA

5%;EQ 1% BASE

N050756 001 Dec 21, 2000 Apr CAHN

&gt;A&gt; BT +

5%;EQ 1% BASE

N050756 002 Apr 20, 2007 Apr CAHN

&gt;D&gt; AB VALEANT INTL

5%;EQ 1% BASE

N050756 001 Dec 21, 2000 Apr CAHN

&gt;D&gt; BT +

5%;EQ 1% BASE

N050756 002 Apr 20, 2007 Apr CAHN

BENZPHETAMINE HYDROCHLORIDE

TABLET; ORAL

BENZPHETAMINE HYDROCHLORIDE

@ COREPHARMA

50MG

A040714 001 Oct 29, 2007 Feb DISC

BENZTROPINE MESYLATE

INJECTABLE; INJECTION

BENZTROPINE MESYLATE

AP NAVINTA LLC

1MG/ML

A091525 001 Feb 05, 2013 Jan NEWA

TABLET; ORAL

BENZTROPINE MESYLATE

@ PROSAM LABS

0.5MG

A040699 001 Feb 14, 2008 Mar DISC

@

1MG

A040705 001 Feb 14, 2008 Mar DISC

@

2MG

A040706 001 Feb 14, 2008 Mar DISC

BETAMETHASONE

SYRUP; ORAL

CELESTONE

&gt;A&gt; @ MERCK SHARP DOHME

0.6MG/5ML

N014215 002 Apr CAHN

|                                                              |                                           |            |                     |                       |             |              |     |      |  |
|--------------------------------------------------------------|-------------------------------------------|------------|---------------------|-----------------------|-------------|--------------|-----|------|--|
| SYRUP; ORAL                                                  |                                           |            |                     |                       |             |              |     |      |  |
| CELESTONE                                                    |                                           |            |                     |                       |             |              |     |      |  |
| >D>                                                          |                                           | @ SCHERING | 0.6MG/5ML           |                       | N014215 002 |              | Apr | CAHN |  |
| <u>BETAMETHASONE ACETATE; BETAMETHASONE SODIUM PHOSPHATE</u> |                                           |            |                     |                       |             |              |     |      |  |
| INJECTABLE; INJECTION                                        |                                           |            |                     |                       |             |              |     |      |  |
| CELESTONE SOLUSPAN                                           |                                           |            |                     |                       |             |              |     |      |  |
| >A>                                                          | AB                                        | +          | MERCK SHARP DOHME   | 3MG/ML;EQ 3MG BASE/ML | N014602 001 |              | Apr | CAHN |  |
| >D>                                                          | AB                                        | +          | SCHERING            | 3MG/ML;EQ 3MG BASE/ML | N014602 001 |              | Apr | CAHN |  |
| <u>BETAMETHASONE VALERATE</u>                                |                                           |            |                     |                       |             |              |     |      |  |
| AEROSOL, FOAM; TOPICAL                                       |                                           |            |                     |                       |             |              |     |      |  |
| BETAMETHASONE VALERATE                                       |                                           |            |                     |                       |             |              |     |      |  |
| >D>                                                          | AB                                        |            | PERRIGO             | EQ 0.12% BASE         | A078337 001 | Nov 26, 2012 | Apr | CPOT |  |
| >A>                                                          | AB                                        |            |                     | 0.12%                 | A078337 001 | Nov 26, 2012 | Apr | CPOT |  |
| LUXIQ                                                        |                                           |            |                     |                       |             |              |     |      |  |
| >D>                                                          | AB                                        | +          | STIEFEL             | EQ 0.12% BASE         | N020934 001 | Feb 28, 1999 | Apr | CPOT |  |
| >A>                                                          | AB                                        | +          |                     | 0.12%                 | N020934 001 | Feb 28, 1999 | Apr | CPOT |  |
| <u>BETAXOLOL HYDROCHLORIDE</u>                               |                                           |            |                     |                       |             |              |     |      |  |
| SOLUTION/DROPS; OPHTHALMIC                                   |                                           |            |                     |                       |             |              |     |      |  |
| BETAXOLOL HYDROCHLORIDE                                      |                                           |            |                     |                       |             |              |     |      |  |
| >A>                                                          |                                           | @          | APOTEX INC          | EQ 0.5% BASE          | A075446 001 | Sep 28, 2000 | Apr | DISC |  |
| >D>                                                          | AT                                        |            | NOVEX               | EQ 0.5% BASE          | A075446 001 | Sep 28, 2000 | Apr | DISC |  |
| <u>BEXAROTENE</u>                                            |                                           |            |                     |                       |             |              |     |      |  |
| GEL; TOPICAL                                                 |                                           |            |                     |                       |             |              |     |      |  |
| TARGRETIN                                                    |                                           |            |                     |                       |             |              |     |      |  |
|                                                              |                                           | +          | VALEANT PHARMS INC  | 1%                    | N021056 001 | Jun 28, 2000 | Feb | CAHN |  |
| <u>BICALUTAMIDE</u>                                          |                                           |            |                     |                       |             |              |     |      |  |
| TABLET; ORAL                                                 |                                           |            |                     |                       |             |              |     |      |  |
| BICALUTAMIDE                                                 |                                           |            |                     |                       |             |              |     |      |  |
| >A>                                                          | AB                                        |            | ACCORD HLTHCARE     | 50MG                  | A078917 001 | Jul 06, 2009 | Apr | CAHN |  |
| >D>                                                          | AB                                        |            | ACCORD HLTHCARE INC | 50MG                  | A078917 001 | Jul 06, 2009 | Apr | CAHN |  |
| <u>BLEOMYCIN SULFATE</u>                                     |                                           |            |                     |                       |             |              |     |      |  |
| INJECTABLE; INJECTION                                        |                                           |            |                     |                       |             |              |     |      |  |
| BLEOMYCIN SULFATE                                            |                                           |            |                     |                       |             |              |     |      |  |
|                                                              |                                           | @          | PHARMACHEMIE BV     | EQ 15 UNITS BASE/VIAL | A065201 001 | Dec 13, 2007 | Feb | DISC |  |
| >A>                                                          | <u>BRIMONIDINE TARTRATE; BRINZOLAMIDE</u> |            |                     |                       |             |              |     |      |  |
| >A>                                                          | SUSPENSION/DROPS; OPHTHALMIC              |            |                     |                       |             |              |     |      |  |
| >A>                                                          | SIMBRINZA                                 |            |                     |                       |             |              |     |      |  |
| >A>                                                          |                                           | +          | ALCON RES LTD       | 0.2%;1%               | N204251 001 | Apr 19, 2013 | Apr | NEWA |  |
| <u>BROMFENAC SODIUM</u>                                      |                                           |            |                     |                       |             |              |     |      |  |
| SOLUTION/DROPS; OPHTHALMIC                                   |                                           |            |                     |                       |             |              |     |      |  |
| BROMDAY                                                      |                                           |            |                     |                       |             |              |     |      |  |
| >D>                                                          |                                           | +          | ISTA PHARMS INC     | 0.09%                 | N021664 002 | Oct 16, 2010 | Apr | CPOT |  |
| >A>                                                          |                                           | +          |                     | EQ 0.09% ACID         | N021664 002 | Oct 16, 2010 | Apr | CPOT |  |
| BROMFENAC SODIUM                                             |                                           |            |                     |                       |             |              |     |      |  |
| >D>                                                          | AT                                        |            | COASTAL PHARMS      | 0.09%                 | A201211 001 | May 11, 2011 | Apr | CPOT |  |
| >A>                                                          | AT                                        |            |                     | EQ 0.09% ACID         | A201211 001 | May 11, 2011 | Apr | CPOT |  |
| >D>                                                          | AT                                        |            | LUITPOLD            | 0.09%                 | A202030 001 | Jan 09, 2013 | Apr | CPOT |  |

## SOLUTION/DROPS; OPHTHALMIC

## BROMFENAC SODIUM

|     |    |                   |               |         |     |              |     |      |
|-----|----|-------------------|---------------|---------|-----|--------------|-----|------|
| >A> | AT | LUITPOLD          | EQ 0.09% ACID | A202030 | 001 | Jan 09, 2013 | Apr | CPOT |
|     | AT |                   | 0.09%         | A202030 | 001 | Jan 09, 2013 | Feb | CAHN |
| >A> |    | PROLENSA          |               |         |     |              |     |      |
| >A> | +  | BAUSCH AND LOMB   | EQ 0.07% ACID | N203168 | 001 | Apr 05, 2013 | Apr | NEWA |
|     |    | XIBROM            |               |         |     |              |     |      |
| >D> |    | @ ISTA PHARMS INC | 0.09%         | N021664 | 001 | Mar 24, 2005 | Apr | CPOT |
| >A> |    | @                 | EQ 0.09% ACID | N021664 | 001 | Mar 24, 2005 | Apr | CPOT |

BUDESONIDE

## SUSPENSION; INHALATION

## BUDESONIDE

|     |    |              |            |         |     |              |     |      |
|-----|----|--------------|------------|---------|-----|--------------|-----|------|
| >D> | AN | APOTEX       | 0.25MG/2ML | A078202 | 001 | Mar 30, 2009 | Apr | DISC |
| >D> | AN |              | 0.5MG/2ML  | A078202 | 002 | Mar 30, 2009 | Apr | DISC |
| >A> |    | @ APOTEX INC | 0.25MG/2ML | A078202 | 001 | Mar 30, 2009 | Apr | DISC |
| >A> |    | @            | 0.5MG/2ML  | A078202 | 002 | Mar 30, 2009 | Apr | DISC |

## TABLET, EXTENDED RELEASE; ORAL

## UCERIS

|  |   |          |     |         |     |              |     |      |
|--|---|----------|-----|---------|-----|--------------|-----|------|
|  | + | SANTARUS | 9MG | N203634 | 001 | Jan 14, 2013 | Jan | NEWA |
|--|---|----------|-----|---------|-----|--------------|-----|------|

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE

## TABLET; SUBLINGUAL

## BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE DIHYDRATE

|     |    |                     |                           |         |     |              |     |      |
|-----|----|---------------------|---------------------------|---------|-----|--------------|-----|------|
| AB  |    | ACTAVIS ELIZABETH   | EQ 2MG BASE;EQ 0.5MG BASE | A091422 | 001 | Feb 22, 2013 | Feb | NEWA |
| >D> | AB |                     | EQ 8MG BASE;EQ 2MG BASE   | A091422 | 002 | Feb 22, 2013 | Apr | CRLD |
| >A> | AB | +                   | EQ 8MG BASE;EQ 2MG BASE   | A091422 | 002 | Feb 22, 2013 | Apr | CRLD |
|     | AB |                     | EQ 8MG BASE;EQ 2MG BASE   | A091422 | 002 | Feb 22, 2013 | Feb | NEWA |
|     | AB | AMNEAL PHARMS       | EQ 2MG BASE;EQ 0.5MG BASE | A203136 | 001 | Feb 22, 2013 | Feb | NEWA |
|     | AB |                     | EQ 8MG BASE;EQ 2MG BASE   | A203136 | 002 | Feb 22, 2013 | Feb | NEWA |
|     |    | SUBOXONE            |                           |         |     |              |     |      |
|     |    | @ RECKITT BENCKISER | EQ 2MG BASE;EQ 0.5MG BASE | N020733 | 001 | Oct 08, 2002 | Mar | DISC |
| AB  |    |                     | EQ 2MG BASE;EQ 0.5MG BASE | N020733 | 001 | Oct 08, 2002 | Feb | CFTG |
|     |    | @                   | EQ 8MG BASE;EQ 2MG BASE   | N020733 | 002 | Oct 08, 2002 | Mar | DISC |
| AB  | +  |                     | EQ 8MG BASE;EQ 2MG BASE   | N020733 | 002 | Oct 08, 2002 | Feb | CFTG |

BUPROPION HYDROBROMIDE

## TABLET, EXTENDED RELEASE; ORAL

## APLENZIN

|     |   |                 |       |         |     |              |     |      |
|-----|---|-----------------|-------|---------|-----|--------------|-----|------|
| >A> |   | VALEANT BERMUDA | 174MG | N022108 | 001 | Apr 23, 2008 | Apr | CAHN |
| >A> | + |                 | 348MG | N022108 | 002 | Apr 23, 2008 | Apr | CAHN |
| >A> |   |                 | 522MG | N022108 | 003 | Apr 23, 2008 | Apr | CAHN |
| >D> |   | VALEANT INTL    | 174MG | N022108 | 001 | Apr 23, 2008 | Apr | CAHN |
| >D> | + |                 | 348MG | N022108 | 002 | Apr 23, 2008 | Apr | CAHN |
| >D> |   |                 | 522MG | N022108 | 003 | Apr 23, 2008 | Apr | CAHN |

BUPROPION HYDROCHLORIDE

## TABLET; ORAL

## BUPROPION HYDROCHLORIDE

## @ TEVA

75MG

A075310 001 Nov 29, 1999 Feb CDFR

## @

100MG

A075310 002 Nov 29, 1999 Feb DISC

## TABLET, EXTENDED RELEASE; ORAL

## BUPROPION HYDROCHLORIDE

|     |     |         |       |         |     |              |     |      |
|-----|-----|---------|-------|---------|-----|--------------|-----|------|
| >D> | AB1 | ACTAVIS | 100MG | A077455 | 001 | Jul 19, 2010 | Apr | CAHN |
| >D> | AB3 |         | 150MG | A077285 | 001 | Nov 26, 2008 | Apr | CAHN |
| >D> | AB1 |         | 150MG | A077455 | 002 | Mar 12, 2008 | Apr | CAHN |

TABLET, EXTENDED RELEASE; ORALBUPROPION HYDROCHLORIDE

|     |     |                 |       |             |              |     |      |
|-----|-----|-----------------|-------|-------------|--------------|-----|------|
| >D> | AB1 | ACTAVIS         | 200MG | A077455 003 | Jul 19, 2010 | Apr | CAHN |
| >D> | AB3 |                 | 300MG | A077285 002 | Aug 15, 2008 | Apr | CAHN |
| >D> | BX  | IMPAX LABS      | 300MG | A077415 002 | Dec 15, 2006 | Apr | DISC |
| >A> | @   |                 | 300MG | A077415 002 | Dec 15, 2006 | Apr | DISC |
| >A> | AB1 | WATSON LABS INC | 100MG | A077455 001 | Jul 19, 2010 | Apr | CAHN |
| >A> | AB3 |                 | 150MG | A077285 001 | Nov 26, 2008 | Apr | CAHN |
| >A> | AB1 |                 | 150MG | A077455 002 | Mar 12, 2008 | Apr | CAHN |
| >A> | AB1 |                 | 200MG | A077455 003 | Jul 19, 2010 | Apr | CAHN |
| >A> | AB3 |                 | 300MG | A077285 002 | Aug 15, 2008 | Apr | CAHN |

BUTOCONAZOLE NITRATE

## CREAM; VAGINAL

BUTOCONAZOLE NITRATE

|   |                |    |             |              |     |      |
|---|----------------|----|-------------|--------------|-----|------|
| + | PERRIGO ISRAEL | 2% | A200923 001 | May 18, 2012 | Mar | CRLD |
|   | GYNAZOLE-1     |    |             |              |     |      |
| @ | KV PHARM       | 2% | N019881 001 | Feb 07, 1997 | Mar | DISC |

BUTORPHANOL TARTRATE

## INJECTABLE; INJECTION

BUTORPHANOL TARTRATE

|     |    |                                        |        |             |              |     |      |
|-----|----|----------------------------------------|--------|-------------|--------------|-----|------|
| >A> | @  | APOTEX INC                             | 2MG/ML | A075697 001 | Oct 23, 2001 | Apr | DISC |
| >D> | AP | CLARIS LIFESCIENCES                    | 2MG/ML | A075697 001 | Oct 23, 2001 | Apr | DISC |
|     |    | BUTORPHANOL TARTRATE PRESERVATIVE FREE |        |             |              |     |      |
| >A> | @  | APOTEX INC                             | 1MG/ML | A075695 001 | Oct 23, 2001 | Apr | DISC |
| >A> | @  |                                        | 2MG/ML | A075695 002 | Oct 23, 2001 | Apr | DISC |
| >D> | AP | CLARIS LIFESCIENCES                    | 1MG/ML | A075695 001 | Oct 23, 2001 | Apr | DISC |
| >D> | AP |                                        | 2MG/ML | A075695 002 | Oct 23, 2001 | Apr | DISC |

CABERGOLINE

## TABLET; ORAL

CABERGOLINE

|    |             |       |             |              |     |      |
|----|-------------|-------|-------------|--------------|-----|------|
| AB | APOTEX CORP | 0.5MG | A201503 001 | Mar 08, 2013 | Feb | NEWA |
|----|-------------|-------|-------------|--------------|-----|------|

CAFFEINE; ERGOTAMINE TARTRATE

## TABLET; ORAL

ERGOTAMINE TARTRATE AND CAFFEINE

|    |        |           |             |              |     |      |
|----|--------|-----------|-------------|--------------|-----|------|
| AA | MIKART | 100MG;1MG | A040590 001 | Sep 16, 2005 | Mar | CMFD |
|    | @      | 100MG;1MG | A040590 001 | Sep 16, 2005 | Jan | DISC |

CALCIUM ACETATE

## CAPSULE; ORAL

CALCIUM ACETATE

|    |                |                  |             |              |     |      |
|----|----------------|------------------|-------------|--------------|-----|------|
| AB | INVAGEN PHARMS | EQ 169MG CALCIUM | A203135 001 | Feb 07, 2013 | Jan | NEWA |
|----|----------------|------------------|-------------|--------------|-----|------|

## TABLET; ORAL

CALCIUM ACETATE

|    |                |                  |             |              |     |      |
|----|----------------|------------------|-------------|--------------|-----|------|
| AB | INVAGEN PHARMS | EQ 169MG CALCIUM | A202420 001 | Feb 05, 2013 | Jan | NEWA |
|----|----------------|------------------|-------------|--------------|-----|------|

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

## INJECTABLE; INJECTION

## ISOLYTE E IN DEXTROSE 5% IN PLASTIC CONTAINER

## @ B BRAUN

|                                            |             |              |     |      |
|--------------------------------------------|-------------|--------------|-----|------|
| 35MG/100ML;5GM/100ML;30MG/100ML;74MG/100ML | N019867 001 | Dec 20, 1993 | Mar | DISC |
|--------------------------------------------|-------------|--------------|-----|------|

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

## SOLUTION; INTRAPERITONEAL

INPERSOL-LC/LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

|             |                                                               |             |              |     |      |
|-------------|---------------------------------------------------------------|-------------|--------------|-----|------|
| @ FRESINIUS | 18.4MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N020374 001 | Jun 13, 1994 | Feb | DISC |
|-------------|---------------------------------------------------------------|-------------|--------------|-----|------|

INPERSOL-LC/LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

|             |                                                               |             |              |     |      |
|-------------|---------------------------------------------------------------|-------------|--------------|-----|------|
| @ FRESINIUS | 18.4MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N020374 002 | Jun 13, 1994 | Feb | DISC |
|-------------|---------------------------------------------------------------|-------------|--------------|-----|------|

INPERSOL-LC/LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

|             |                                                               |             |              |     |      |
|-------------|---------------------------------------------------------------|-------------|--------------|-----|------|
| @ FRESINIUS | 18.4MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N020374 003 | Jun 13, 1994 | Feb | DISC |
|-------------|---------------------------------------------------------------|-------------|--------------|-----|------|

INPERSOL-LC/LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

|             |                                                                |             |              |     |      |
|-------------|----------------------------------------------------------------|-------------|--------------|-----|------|
| @ FRESINIUS | 18.4MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N020374 004 | Jun 13, 1994 | Feb | DISC |
|-------------|----------------------------------------------------------------|-------------|--------------|-----|------|

CANAGLIFLOZIN

## TABLET; ORAL

INVOKANA

|     |                     |       |             |              |     |      |
|-----|---------------------|-------|-------------|--------------|-----|------|
| >A> | JANSSEN PHARMS      | 100MG | N204042 001 | Mar 29, 2013 | Apr | CAHN |
| >A> | +                   | 300MG | N204042 002 | Mar 29, 2013 | Apr | CAHN |
| >D> | JANSSEN RES AND DEV | 100MG | N204042 001 | Mar 29, 2013 | Apr | CAHN |
|     |                     | 100MG | N204042 001 | Mar 29, 2013 | Mar | NEWA |
| >D> | +                   | 300MG | N204042 002 | Mar 29, 2013 | Apr | CAHN |
|     | +                   | 300MG | N204042 002 | Mar 29, 2013 | Mar | NEWA |

CANDESARTAN CILEXETIL

## TABLET; ORAL

ATACAND

|     |                       |      |             |              |     |      |
|-----|-----------------------|------|-------------|--------------|-----|------|
| >D> | ASTRAZENECA           | 4MG  | N020838 001 | Jun 04, 1998 | Apr | CFTG |
| >A> | AB                    | 4MG  | N020838 001 | Jun 04, 1998 | Apr | CFTG |
| >D> |                       | 8MG  | N020838 002 | Jun 04, 1998 | Apr | CFTG |
| >A> | AB                    | 8MG  | N020838 002 | Jun 04, 1998 | Apr | CFTG |
| >D> |                       | 16MG | N020838 003 | Jun 04, 1998 | Apr | CFTG |
| >A> | AB                    | 16MG | N020838 003 | Jun 04, 1998 | Apr | CFTG |
| >D> | +                     | 32MG | N020838 004 | Jun 04, 1998 | Apr | CFTG |
| >A> | AB +                  | 32MG | N020838 004 | Jun 04, 1998 | Apr | CFTG |
| >A> | CANDESARTAN CILEXETIL |      |             |              |     |      |
| >A> | AB SANDOZ             | 4MG  | A078702 001 | May 03, 2013 | Apr | NEWA |
| >A> | AB                    | 8MG  | A078702 002 | May 03, 2013 | Apr | NEWA |
| >A> | AB                    | 16MG | A078702 003 | May 03, 2013 | Apr | NEWA |
| >A> | AB                    | 32MG | A078702 004 | May 03, 2013 | Apr | NEWA |

CARBIDOPA; LEVODOPA

## TABLET, EXTENDED RELEASE; ORAL

CARBIDOPA AND LEVODOPA

|    |                 |            |             |              |     |      |
|----|-----------------|------------|-------------|--------------|-----|------|
| AB | ACCORD HLTHCARE | 25MG;100MG | A202323 001 | Feb 08, 2013 | Jan | NEWA |
| AB |                 | 50MG;200MG | A202323 002 | Feb 08, 2013 | Jan | NEWA |

CARBINOXAMINE MALEATE

## SUSPENSION, EXTENDED RELEASE; ORAL

KARBINAL ER

|   |                 |         |             |              |     |      |
|---|-----------------|---------|-------------|--------------|-----|------|
| + | TRIS PHARMA INC | 4MG/5ML | N022556 001 | Mar 28, 2013 | Mar | NEWA |
|---|-----------------|---------|-------------|--------------|-----|------|

CARBOPLATIN

## INJECTABLE; INJECTION

## CARBOPLATIN

|         |            |             |              |     |      |
|---------|------------|-------------|--------------|-----|------|
| @ PLIVA | 50MG/VIAL  | A076602 001 | Nov 16, 2004 | Feb | DISC |
| @       | 150MG/VIAL | A076602 002 | Nov 16, 2004 | Feb | DISC |
| @       | 450MG/VIAL | A076602 003 | Nov 16, 2004 | Feb | DISC |

## INJECTABLE; IV (INFUSION)

## CARBOPLATIN

|     |                      |                      |                      |              |              |          |
|-----|----------------------|----------------------|----------------------|--------------|--------------|----------|
|     | @ FRESENIUS KABI USA | 50MG/5ML (10MG/ML)   | A077266 001          | Feb 15, 2006 | Mar          | DISC     |
|     | @                    | 150MG/15ML (10MG/ML) | A077266 002          | Feb 15, 2006 | Mar          | DISC     |
| >D> | AP                   | PHARMACHEMIE BV      | 50MG/5ML (10MG/ML)   | A077679 001  | Feb 25, 2009 | Apr DISC |
| >A> |                      | @                    | 50MG/5ML (10MG/ML)   | A077679 001  | Feb 25, 2009 | Apr DISC |
| >D> | AP                   |                      | 150MG/15ML (10MG/ML) | A077679 002  | Feb 25, 2009 | Apr DISC |
| >A> |                      | @                    | 150MG/15ML (10MG/ML) | A077679 002  | Feb 25, 2009 | Apr DISC |
| >D> | AP                   |                      | 450MG/45ML (10MG/ML) | A077679 003  | Feb 25, 2009 | Apr DISC |
| >A> |                      | @                    | 450MG/45ML (10MG/ML) | A077679 003  | Feb 25, 2009 | Apr DISC |

## PARAPLATIN

|                |                      |             |              |     |      |
|----------------|----------------------|-------------|--------------|-----|------|
| @ CORDENPHARMA | 50MG/5ML (10MG/ML)   | N020452 001 | Jul 14, 2003 | Mar | CAHN |
| @              | 150MG/15ML (10MG/ML) | N020452 002 | Jul 14, 2003 | Mar | CAHN |
| @              | 450MG/45ML (10MG/ML) | N020452 003 | Jul 14, 2003 | Mar | CAHN |
| @              | 600MG/60ML (10MG/ML) | N020452 004 | Jan 15, 2004 | Mar | CAHN |

CARISOPRODOL

## TABLET; ORAL

## CARISOPRODOL

|              |       |             |              |     |      |
|--------------|-------|-------------|--------------|-----|------|
| @ COREPHARMA | 350MG | A040397 001 | Sep 21, 2000 | Feb | DISC |
|--------------|-------|-------------|--------------|-----|------|

CARMUSTINE

## IMPLANT; INTRACRANIAL

## GLIADEL

|   |                  |       |             |              |     |      |
|---|------------------|-------|-------------|--------------|-----|------|
| + | ARBOR PHARMS LLC | 7.7MG | N020637 001 | Sep 23, 1996 | Mar | CAHN |
|---|------------------|-------|-------------|--------------|-----|------|

## INJECTABLE; INJECTION

## BICNU

|   |                   |            |             |  |     |      |
|---|-------------------|------------|-------------|--|-----|------|
| + | EMCURE PHARMS LTD | 100MG/VIAL | N017422 001 |  | Jan | CAHN |
|---|-------------------|------------|-------------|--|-----|------|

CARTEOLOL HYDROCHLORIDE

## SOLUTION/DROPS; OPHTHALMIC

## CARTEOLOL HYDROCHLORIDE

|     |    |              |    |             |              |          |
|-----|----|--------------|----|-------------|--------------|----------|
| >A> |    | @ APOTEX INC | 1% | A076097 001 | Feb 06, 2002 | Apr DISC |
| >D> | AT | NOVEX        | 1% | A076097 001 | Feb 06, 2002 | Apr DISC |

CARVEDILOL

## TABLET; ORAL

## CARVEDILOL

|                 |         |             |              |     |      |
|-----------------|---------|-------------|--------------|-----|------|
| @ WOCKHARDT LTD | 3.125MG | A078786 001 | Dec 22, 2009 | Feb | DISC |
| @               | 6.25MG  | A078786 002 | Dec 22, 2009 | Feb | DISC |
| @               | 12.5MG  | A078786 003 | Dec 22, 2009 | Feb | DISC |
| @               | 25MG    | A078786 004 | Dec 22, 2009 | Feb | DISC |

CEFADROXIL/CEFADROXIL HEMIHYDRATE

## FOR SUSPENSION; ORAL

## CEFADROXIL

|     |    |           |                   |             |              |          |
|-----|----|-----------|-------------------|-------------|--------------|----------|
| >A> | AB | AUROBINDO | EQ 250MG BASE/5ML | A065349 001 | Apr 25, 2013 | Apr NEWA |
| >A> | AB |           | EQ 500MG BASE/5ML | A065349 002 | Apr 25, 2013 | Apr NEWA |

## FOR SUSPENSION; ORAL

## CEFADROXIL

@ TEVA PHARMS USA

EQ 250MG BASE/5ML

A065278 001 Jan 20, 2006 Mar DISC

@

EQ 500MG BASE/5ML

A065278 002 Jan 20, 2006 Mar DISC

CEFAZOLIN SODIUM

## INJECTABLE; INJECTION

## CEFAZOLIN SODIUM

AP + HOSPIRA INC

EQ 500MG BASE/VIAL

A065226 001 Apr 21, 2005 Feb CRLD

AP +

EQ 1GM BASE/VIAL

A065244 001 Aug 12, 2005 Feb CRLD

AP +

EQ 1GM BASE/VIAL

A065226 002 Apr 21, 2005 Feb CRLD

AP +

EQ 10GM BASE/VIAL

A065247 001 Aug 12, 2005 Feb CRLD

CEFEPIME HYDROCHLORIDE

## INJECTABLE; INJECTION

## CEFEPIME HYDROCHLORIDE

@ SANDOZ

EQ 500MG BASE/VIAL

A090291 001 Dec 21, 2010 Mar DISC

@

EQ 1GM BASE/VIAL

A090291 002 Dec 21, 2010 Mar DISC

@

EQ 2GM BASE/VIAL

A090291 003 Dec 21, 2010 Mar DISC

CEFIXIME

## FOR SUSPENSION; ORAL

## SUPRAX

+ LUPIN LTD

500MG/5ML

N202091 001 Feb 20, 2013 Feb CDFR

LUPIN PHARMS

100MG/5ML

A065129 001 Feb 23, 2004 Feb CDFR

200MG/5ML

A065355 001 Apr 10, 2007 Feb CDFR

CEPHALEXIN

## CAPSULE; ORAL

## CEPHALEXIN

ALKEM LABS LTD

EQ 333MG BASE

A090836 003 Mar 29, 2013 Mar NEWA

AB

EQ 750MG BASE

A090836 004 Mar 29, 2013 Mar NEWA

## KEFLEX

AB + SHIONOGI INC

EQ 750MG BASE

N050405 005 May 12, 2006 Mar CTEC

CETIRIZINE HYDROCHLORIDE

## SYRUP; ORAL

## CETIRIZINE HYDROCHLORIDE

&gt;D&gt; AA

APOTEX INC

5MG/5ML

A078412 001 Jun 18, 2008 Apr DISC

&gt;A&gt;

@

5MG/5ML

A078412 001 Jun 18, 2008 Apr DISC

@ AUROBINDO PHARMA LTD

5MG/5ML

A090751 001 Dec 16, 2009 Feb DISC

CHLORHEXIDINE GLUCONATE

## SOLUTION; DENTAL

## CHLORHEXIDINE GLUCONATE

&gt;A&gt;

@ APOTEX INC

0.12%

A075561 001 Nov 14, 2000 Apr DISC

&gt;D&gt;

AT

JOHN O BUTLER CO

0.12%

A076434 001 Nov 29, 2005 Apr CTNA

&gt;D&gt;

AT

NOVEX

0.12%

A075561 001 Nov 14, 2000 Apr DISC

&gt;A&gt;

## PAROEX

&gt;A&gt;

AT

SUNSTAR AMERICAS

0.12%

A076434 001 Nov 29, 2005 Apr CTNA

CHLOROTHIAZIDE

## TABLET; ORAL

## DIURIL

@ OAK PHARMS AKORN

250MG

N011145 004

Jan CAHN

## TABLET; ORAL

## DIURIL

@ OAK PHARMS AKORN

500MG

N011145 002

Jan CAHN

CHLOROTHIAZIDE SODIUM

## INJECTABLE; INJECTION

## CHLOROTHIAZIDE SODIUM

&gt;A&gt;

AP

PHARMAFORCE

EQ 500MG BASE/VIAL

A202561 001 Apr 22, 2013 Apr NEWA

## DIURIL

AP

+

OAK PHARMS AKORN

EQ 500MG BASE/VIAL

N011145 005

Jan CAHN

CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE

## SOLUTION; ORAL

## VITUZ

+

CYPRESS PHARM

4MG/5ML;5MG/5ML

N204307 001 Feb 20, 2013 Feb NEWA

CHLORPROPAMIDE

## TABLET; ORAL

## CHLORPROPAMIDE

@ WATSON LABS INC

100MG

A088852 001 Sep 26, 1984 Jan DISC

@

250MG

A088826 001 Sep 26, 1984 Jan DISC

CHOLINE FENOFIBRATE

## CAPSULE, DELAYED RELEASE; ORAL

## FENOFIBRIC ACID

AB

MYLAN PHARMS INC

EQ 45MG FENOFIBRIC ACID

A200913 001 Mar 25, 2013 Mar NEWA

AB

EQ 135MG FENOFIBRIC ACID

A200913 002 Mar 25, 2013 Mar NEWA

## TRILIPIX

AB

ABBVIE

EQ 45MG FENOFIBRIC ACID

N022224 001 Dec 15, 2008 Mar CFTG

AB

+

EQ 135MG FENOFIBRIC ACID

N022224 002 Dec 15, 2008 Mar CFTG

CICLOPIROX

## SOLUTION; TOPICAL

## CICLOPIROX

&gt;D&gt;

AT

APOTEX CORP

8%

A078172 001 Sep 18, 2007 Apr DISC

&gt;A&gt;

@ APOTEX INC

8%

A078172 001 Sep 18, 2007 Apr DISC

@ TEVA PHARMS

8%

A078079 001 Sep 18, 2007 Jan DISC

## PENLAC

AT

+

VALEANT INTL

8%

N021022 001 Dec 17, 1999 Feb CAHN

CIMETIDINE HYDROCHLORIDE

## SOLUTION; ORAL

## CIMETIDINE HYDROCHLORIDE

&gt;A&gt;

@ APOTEX INC

EQ 300MG BASE/5ML

A075560 001 Mar 15, 2000 Apr DISC

&gt;D&gt;

AA

NOVEX

EQ 300MG BASE/5ML

A075560 001 Mar 15, 2000 Apr DISC

CIPROFLOXACIN

## INJECTABLE; INJECTION

## CIPROFLOXACIN

&gt;D&gt;

@ TEVA PARENTERAL

400MG/40ML (10MG/ML)

A077782 002 Aug 28, 2006 Apr CAHN

&gt;D&gt;

@

200MG/20ML (10MG/ML)

A077782 001 Aug 28, 2006 Apr CAHN

&gt;A&gt;

@ TEVA PHARMS USA

400MG/40ML (10MG/ML)

A077782 002 Aug 28, 2006 Apr CAHN

&gt;A&gt;

@

200MG/20ML (10MG/ML)

A077782 001 Aug 28, 2006 Apr CAHN

CIPROFLOXACIN HYDROCHLORIDE

## SOLUTION/DROPS; OPHTHALMIC

## CIPROFLOXACIN HYDROCHLORIDE

|     |    |              |              |             |              |     |      |
|-----|----|--------------|--------------|-------------|--------------|-----|------|
| >D> | AT | APOTEX       | EQ 0.3% BASE | A075928 001 | Jun 09, 2004 | Apr | DISC |
| >A> |    | @ APOTEX INC | EQ 0.3% BASE | A075928 001 | Jun 09, 2004 | Apr | DISC |

CISPLATIN

## INJECTABLE; INJECTION

## PLATINOL

|  |  |                   |           |             |  |     |      |
|--|--|-------------------|-----------|-------------|--|-----|------|
|  |  | @ HQ SPCLT PHARMA | 10MG/VIAL | N018057 001 |  | Jan | CAHN |
|  |  | @                 | 50MG/VIAL | N018057 002 |  | Jan | CAHN |

## PLATINOL-AQ

|  |  |                   |          |             |              |     |      |
|--|--|-------------------|----------|-------------|--------------|-----|------|
|  |  | @ HQ SPCLT PHARMA | 0.5MG/ML | N018057 003 | Jul 18, 1984 | Jan | CAHN |
|  |  | @                 | 1MG/ML   | N018057 004 | Nov 08, 1988 | Jan | CAHN |

CITALOPRAM HYDROBROMIDE

## SOLUTION; ORAL

## CITALOPRAM HYDROBROMIDE

|     |  |              |                  |             |              |     |      |
|-----|--|--------------|------------------|-------------|--------------|-----|------|
| >D> |  | @ APOTEX INC | EQ 10MG BASE/5ML | A077601 001 | Nov 15, 2005 | Apr | DISC |
| >A> |  | @            | EQ 10MG BASE/5ML | A077601 001 | Nov 15, 2005 | Apr | DISC |

## TABLET; ORAL

## CITALOPRAM HYDROBROMIDE

|  |  |              |              |             |              |     |      |
|--|--|--------------|--------------|-------------|--------------|-----|------|
|  |  | @ COREPHARMA | EQ 10MG BASE | A077036 001 | Oct 28, 2004 | Feb | DISC |
|  |  | @            | EQ 20MG BASE | A077036 002 | Oct 28, 2004 | Feb | DISC |
|  |  | @            | EQ 40MG BASE | A077036 003 | Oct 28, 2004 | Feb | DISC |

CLEMASTINE FUMARATE

## SYRUP; ORAL

## CLEMASTINE FUMARATE

|     |    |              |                   |             |              |     |      |
|-----|----|--------------|-------------------|-------------|--------------|-----|------|
| >A> |    | @ APOTEX INC | EQ 0.5MG BASE/5ML | A075703 001 | Nov 27, 2000 | Apr | DISC |
| >D> | AA | NOVEX        | EQ 0.5MG BASE/5ML | A075703 001 | Nov 27, 2000 | Apr | DISC |
|     |    | @ SILARX     | EQ 0.5MG BASE/5ML | A074884 001 | Dec 17, 1997 | Mar | DISC |

CLEVIDIPINE

## EMULSION; INTRAVENOUS

## CLEVIPREX

|   |  |              |                       |             |              |     |      |
|---|--|--------------|-----------------------|-------------|--------------|-----|------|
| + |  | MEDICINES CO | 25MG/50ML (0.5MG/ML)  | N022156 001 | Aug 01, 2008 | Feb | CAIN |
| + |  |              | 50MG/100ML (0.5MG/ML) | N022156 002 | Aug 01, 2008 | Feb | CAIN |

CLINDAMYCIN PALMITATE HYDROCHLORIDE

## FOR SOLUTION; ORAL

## CLINDAMYCIN PALMITATE HYDROCHLORIDE

|     |    |                      |                  |             |              |     |      |
|-----|----|----------------------|------------------|-------------|--------------|-----|------|
| >A> | AA | AUROBINDO PHARMA LTD | EQ 75MG BASE/5ML | A202409 001 | Apr 30, 2013 | Apr | NEWA |
|-----|----|----------------------|------------------|-------------|--------------|-----|------|

CLINDAMYCIN PHOSPHATE

## INJECTABLE; INJECTION

## CLINDAMYCIN PHOSPHATE IN 5% DEXTROSE IN PLASTIC CONTAINER

|    |  |           |                 |             |              |     |      |
|----|--|-----------|-----------------|-------------|--------------|-----|------|
| AP |  | AKORN INC | EQ 6MG BASE/ML  | A203048 001 | Apr 04, 2013 | Mar | NEWA |
| AP |  |           | EQ 12MG BASE/ML | A203048 002 | Apr 04, 2013 | Mar | NEWA |
| AP |  |           | EQ 18MG BASE/ML | A203048 003 | Apr 04, 2013 | Mar | NEWA |

## SOLUTION; TOPICAL

## CLINDAMYCIN PHOSPHATE

|  |  |                    |            |             |              |     |      |
|--|--|--------------------|------------|-------------|--------------|-----|------|
|  |  | @ PERRIGO NEW YORK | EQ 1% BASE | A064050 001 | Nov 30, 1995 | Feb | DISC |
|--|--|--------------------|------------|-------------|--------------|-----|------|

CLONAZEPAM

## TABLET; ORAL

## CLONAZEPAM

|     |    |                     |       |             |              |     |      |
|-----|----|---------------------|-------|-------------|--------------|-----|------|
| >A> | AB | ACCORD HLTHCARE     | 0.5MG | A077147 001 | May 02, 2005 | Apr | CAHN |
| >A> | AB |                     | 1MG   | A077147 002 | May 02, 2005 | Apr | CAHN |
| >A> | AB |                     | 2MG   | A077147 003 | May 02, 2005 | Apr | CAHN |
| >D> | AB | ACCORD HLTHCARE INC | 0.5MG | A077147 001 | May 02, 2005 | Apr | CAHN |
| >D> | AB |                     | 1MG   | A077147 002 | May 02, 2005 | Apr | CAHN |
| >D> | AB |                     | 2MG   | A077147 003 | May 02, 2005 | Apr | CAHN |
|     |    | @ APOTEX INC        | 0.5MG | A075468 001 | Oct 06, 2000 | Feb | DISC |
|     |    | @                   | 1MG   | A075468 002 | Oct 06, 2000 | Feb | DISC |
|     |    | @                   | 2MG   | A075468 003 | Oct 06, 2000 | Feb | DISC |

CLOPIDOGREL BISULFATE

## TABLET; ORAL

## CLOPIDOGREL BISULFATE

|    |                 |               |             |              |     |      |
|----|-----------------|---------------|-------------|--------------|-----|------|
| AB | ACCORD HLTHCARE | EQ 75MG BASE  | A202925 001 | Mar 27, 2013 | Mar | NEWA |
| AB |                 | EQ 300MG BASE | A202925 002 | Mar 27, 2013 | Mar | NEWA |

CLOZAPINE

## SUSPENSION; ORAL

## VERSACLOZ

|   |                 |         |             |              |     |      |
|---|-----------------|---------|-------------|--------------|-----|------|
| + | DOUGLAS PHARMS  | 50MG/ML | N203479 001 | Feb 06, 2013 | Feb | NEWA |
| + | JAZZ PHARMS III | 50MG/ML | N203479 001 | Feb 06, 2013 | Mar | CAHN |

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

## SYRUP; ORAL

## PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE

|     |    |               |                     |             |              |     |      |
|-----|----|---------------|---------------------|-------------|--------------|-----|------|
| >A> | AA | AMNEAL PHARMS | 10MG/5ML;6.25MG/5ML | A200894 001 | Apr 24, 2013 | Apr | NEWA |
|-----|----|---------------|---------------------|-------------|--------------|-----|------|

COSYNTROPIN

## INJECTABLE; INJECTION

## COSYNTROPIN

|    |           |             |             |              |     |      |
|----|-----------|-------------|-------------|--------------|-----|------|
| AP | MYLAN LLC | 0.25MG/VIAL | A090574 001 | Dec 17, 2009 | Feb | CAHN |
|----|-----------|-------------|-------------|--------------|-----|------|

CROMOLYN SODIUM

## CONCENTRATE; ORAL

## CROMOLYN SODIUM

|    |                      |           |             |              |     |      |
|----|----------------------|-----------|-------------|--------------|-----|------|
| AA | MICRO LABS LTD INDIA | 100MG/5ML | A202745 001 | Apr 04, 2013 | Mar | NEWA |
|----|----------------------|-----------|-------------|--------------|-----|------|

## SOLUTION; INHALATION

## CROMOLYN SODIUM

|     |              |         |             |              |              |      |      |
|-----|--------------|---------|-------------|--------------|--------------|------|------|
| >A> | @ APOTEX INC | 10MG/ML | A075333 001 | Apr 30, 2002 | Apr          | DISC |      |
| >D> | AN           | NOVEX   | 10MG/ML     | A075333 001  | Apr 30, 2002 | Apr  | DISC |

## SOLUTION/DROPS; OPHTHALMIC

## CROMOLYN SODIUM

|     |              |       |             |              |              |      |      |
|-----|--------------|-------|-------------|--------------|--------------|------|------|
| >A> | @ APOTEX INC | 4%    | A075615 001 | Jan 26, 2001 | Apr          | DISC |      |
| >D> | AT           | NOVEX | 4%          | A075615 001  | Jan 26, 2001 | Apr  | DISC |

CYCLOBENZAPRINE HYDROCHLORIDE

## CAPSULE, EXTENDED RELEASE; ORAL

## AMRIX

|    |           |      |             |              |     |      |
|----|-----------|------|-------------|--------------|-----|------|
| AB | IVAX INTL | 15MG | N021777 001 | Feb 01, 2007 | Jan | CAHN |
| AB | +         | 30MG | N021777 002 | Feb 01, 2007 | Jan | CAHN |

## CAPSULE, EXTENDED RELEASE; ORAL

## CYCLOBENZAPRINE HYDROCHLORIDE

|    |                |      |         |     |              |     |      |
|----|----------------|------|---------|-----|--------------|-----|------|
| AB | TWI PHARMS INC | 15MG | A091281 | 001 | Jan 31, 2013 | Jan | NEWA |
| AB |                | 30MG | A091281 | 002 | Jan 31, 2013 | Jan | NEWA |

## TABLET; ORAL

## CYCLOBENZAPRINE HYDROCHLORIDE

|     |                  |        |         |     |              |     |      |
|-----|------------------|--------|---------|-----|--------------|-----|------|
| AB  | MYLAN PHARMS INC | 7.5MG  | A073144 | 003 | Mar 25, 2013 | Mar | NEWA |
|     | @ PROSAM LABS    | 5MG    | A077291 | 001 | Feb 03, 2006 | Mar | DISC |
| >D> | AB               | SANDOZ | A072854 | 002 | Feb 03, 2006 | Apr | DISC |
| >A> | @                | 5MG    | A072854 | 002 | Feb 03, 2006 | Apr | DISC |
| >D> | AB               | 10MG   | A072854 | 001 | Nov 19, 1991 | Apr | DISC |
| >A> | @                | 10MG   | A072854 | 001 | Nov 19, 1991 | Apr | DISC |

CYCLOPENTOLATE HYDROCHLORIDE

## SOLUTION/DROPS; OPHTHALMIC

## AKPENTOLATE

|         |    |         |     |              |     |      |
|---------|----|---------|-----|--------------|-----|------|
| @ AKORN | 2% | A040165 | 001 | Jan 13, 1997 | Mar | DISC |
|---------|----|---------|-----|--------------|-----|------|

## CYCLOGYL

|                  |    |         |     |  |     |      |
|------------------|----|---------|-----|--|-----|------|
| + ALCON LABS INC | 2% | A084108 | 001 |  | Mar | CTEC |
|------------------|----|---------|-----|--|-----|------|

CYCLOPHOSPHAMIDE

## INJECTABLE; INJECTION

## CYTOXAN (LYOPHILIZED)

|    |   |                 |            |         |     |              |     |      |
|----|---|-----------------|------------|---------|-----|--------------|-----|------|
| AP | + | BAXTER HLTHCARE | 500MG/VIAL | N012142 | 003 |              | Mar | CTNA |
|    |   | @               | 500MG/VIAL | N012142 | 008 | Jan 04, 1984 | Jan | CTNA |
| AP | + |                 | 1GM/VIAL   | N012142 | 004 | Aug 30, 1982 | Mar | CTNA |
|    |   | @               | 1GM/VIAL   | N012142 | 010 | Sep 24, 1985 | Jan | CTNA |
| AP | + |                 | 2GM/VIAL   | N012142 | 005 | Aug 30, 1982 | Mar | CTNA |
|    |   | @               | 2GM/VIAL   | N012142 | 009 | Dec 10, 1985 | Jan | CTNA |

CYCLOSPORINE

## SOLUTION; ORAL

## CYCLOSPORINE

|     |              |          |         |     |              |     |      |
|-----|--------------|----------|---------|-----|--------------|-----|------|
| >A> | @ APOTEX INC | 100MG/ML | A065167 | 001 | Jan 05, 2005 | Apr | DISC |
| >D> | AB1          | NOVEX    | A065167 | 001 | Jan 05, 2005 | Apr | DISC |

CYPROHEPTADINE HYDROCHLORIDE

## SYRUP; ORAL

## CYPROHEPTADINE HYDROCHLORIDE

|    |             |         |         |     |              |     |      |
|----|-------------|---------|---------|-----|--------------|-----|------|
| AA | PHARM ASSOC | 2MG/5ML | A091295 | 001 | Mar 28, 2013 | Mar | NEWA |
|----|-------------|---------|---------|-----|--------------|-----|------|

CYSTEAMINE BITARTRATE

## CAPSULE, DELAYED RELEASE; ORAL

## PROCYSBI

|     |               |              |         |     |              |     |      |
|-----|---------------|--------------|---------|-----|--------------|-----|------|
| >A> | RAPTOR PHARMS | EQ 25MG BASE | N203389 | 001 | Apr 30, 2013 | Apr | NEWA |
| >A> | +             | EQ 75MG BASE | N203389 | 002 | Apr 30, 2013 | Apr | NEWA |

DACARBAZINE

## INJECTABLE; INJECTION

## DACARBAZINE

|     |    |                 |            |         |     |              |     |      |
|-----|----|-----------------|------------|---------|-----|--------------|-----|------|
| >D> | AP | TEVA PARENTERAL | 200MG/VIAL | A075259 | 002 | Aug 27, 1998 | Apr | CAHN |
| >D> | AP | +               | 500MG/VIAL | A075259 | 001 | Sep 22, 2000 | Apr | CAHN |
| >A> | AP | TEVA PHARMS USA | 200MG/VIAL | A075259 | 002 | Aug 27, 1998 | Apr | CAHN |
| >A> | AP | +               | 500MG/VIAL | A075259 | 001 | Sep 22, 2000 | Apr | CAHN |

DAUNORUBICIN HYDROCHLORIDE

## INJECTABLE; INJECTION

## DAUNORUBICIN HYDROCHLORIDE

|     |    |                 |                |             |              |     |      |
|-----|----|-----------------|----------------|-------------|--------------|-----|------|
| >D> | AP | TEVA PARENTERAL | EQ 5MG BASE/ML | A065035 001 | Jan 24, 2000 | Apr | CAHN |
| >A> | AP | TEVA PHARMS USA | EQ 5MG BASE/ML | A065035 001 | Jan 24, 2000 | Apr | CAHN |

DESMOPRESSIN ACETATE

## INJECTABLE; INJECTION

## DESMOPRESSIN ACETATE

|     |    |                    |            |             |              |     |      |
|-----|----|--------------------|------------|-------------|--------------|-----|------|
|     | AP | SUN PHARM INDS LTD | 0.004MG/ML | A091280 001 | Jan 25, 2013 | Jan | NEWA |
| >D> | AP | TEVA PARENTERAL    | 0.004MG/ML | A074888 001 | Oct 15, 1997 | Apr | CAHN |
| >A> | AP | TEVA PHARMS USA    | 0.004MG/ML | A074888 001 | Oct 15, 1997 | Apr | CAHN |

DESOGESTREL; ETHINYL ESTRADIOL

## TABLET; ORAL-28

## ENSKYCE

|  |    |           |               |             |              |     |      |
|--|----|-----------|---------------|-------------|--------------|-----|------|
|  | AB | LUPIN LTD | 0.15MG;0.03MG | A201887 001 | Mar 07, 2013 | Feb | NEWA |
|--|----|-----------|---------------|-------------|--------------|-----|------|

DESOXIMETASONE

|     |   |                |       |             |              |     |      |
|-----|---|----------------|-------|-------------|--------------|-----|------|
| >A> |   | SPRAY; TOPICAL |       |             |              |     |      |
| >A> |   | TOPICORT       |       |             |              |     |      |
| >A> | + | TARO           | 0.25% | N204141 001 | Apr 11, 2013 | Apr | NEWA |

DESVENLAFAXINE

## TABLET, EXTENDED RELEASE; ORAL

## DESVENLAFAXINE

|     |   |                    |       |             |              |     |      |
|-----|---|--------------------|-------|-------------|--------------|-----|------|
| >D> |   | ALEMBIC PHARMS LTD | 50MG  | N204150 001 | Mar 04, 2013 | Apr | CRLD |
| >A> | + |                    | 50MG  | N204150 001 | Mar 04, 2013 | Apr | CRLD |
|     |   |                    | 50MG  | N204150 001 | Mar 04, 2013 | Mar | NEWA |
|     | + |                    | 100MG | N204150 002 | Mar 04, 2013 | Mar | NEWA |

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

## SUSPENSION/DROPS; OPHTHALMIC

## NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

|  |   |                  |                                       |             |              |     |      |
|--|---|------------------|---------------------------------------|-------------|--------------|-----|------|
|  | @ | ALCON PHARMS LTD | 0.1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML | A062721 001 | Nov 17, 1986 | Jan | DISC |
|--|---|------------------|---------------------------------------|-------------|--------------|-----|------|

DEXMEDETOMIDINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## PRECEDEX

|   |         |                                        |             |              |     |      |
|---|---------|----------------------------------------|-------------|--------------|-----|------|
| + | HOSPIRA | EQ 200MCG BASE/50ML (EQ 4MCG BASE/ML)  | N021038 002 | Mar 13, 2013 | Mar | NEWA |
| + |         | EQ 400MCG BASE/100ML (EQ 4MCG BASE/ML) | N021038 003 | Mar 13, 2013 | Mar | NEWA |

DEXTROSE; POTASSIUM CHLORIDE

## INJECTABLE; INJECTION

## POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% IN PLASTIC CONTAINER

|  |   |         |                       |             |              |     |      |
|--|---|---------|-----------------------|-------------|--------------|-----|------|
|  | @ | B BRAUN | 5GM/100ML;220MG/100ML | N018744 003 | Nov 09, 1982 | Jan | DISC |
|--|---|---------|-----------------------|-------------|--------------|-----|------|

DIAZOXIDE

## SUSPENSION; ORAL

## PROGLYCEM

|     |   |                    |         |             |  |     |      |
|-----|---|--------------------|---------|-------------|--|-----|------|
| >A> | + | TEVA BRANDED PHARM | 50MG/ML | N017453 001 |  | Apr | CAHN |
| >D> | + | TEVA GLOBAL        | 50MG/ML | N017453 001 |  | Apr | CAHN |

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC  
DICLOFENAC SODIUM

|     |    |            |      |             |              |     |      |
|-----|----|------------|------|-------------|--------------|-----|------|
| >D> | AT | APOTEX INC | 0.1% | A077600 001 | Nov 13, 2008 | Apr | DISC |
| >A> |    | @          | 0.1% | A077600 001 | Nov 13, 2008 | Apr | DISC |

DICLOFENAC SODIUM; MISOPROSTOL

TABLET, DELAYED RELEASE; ORAL  
DICLOFENAC SODIUM AND MISOPROSTOL

|     |    |        |            |             |              |     |      |
|-----|----|--------|------------|-------------|--------------|-----|------|
| >A> | AB | SANDOZ | 50MG;0.2MG | A200158 001 | May 09, 2013 | Apr | NEWA |
| >A> | AB |        | 75MG;0.2MG | A200158 002 | May 09, 2013 | Apr | NEWA |

DIDANOSINE

>D> TABLET, CHEWABLE; ORAL  
>D> DIDANOSINE

|     |  |           |       |             |              |     |      |
|-----|--|-----------|-------|-------------|--------------|-----|------|
| >D> |  | AUROBINDO | 100MG | A077275 001 | Aug 14, 2012 | Apr | CDFR |
| >D> |  |           | 150MG | A077275 002 | Aug 14, 2012 | Apr | CDFR |
| >D> |  | +         | 200MG | A077275 003 | Aug 14, 2012 | Apr | CDFR |

>A> TABLET, FOR SUSPENSION; ORAL

|     |  |            |       |             |              |     |      |
|-----|--|------------|-------|-------------|--------------|-----|------|
| >A> |  | DIDANOSINE |       |             |              |     |      |
| >A> |  | AUROBINDO  | 100MG | A077275 001 | Aug 14, 2012 | Apr | CDFR |
| >A> |  |            | 150MG | A077275 002 | Aug 14, 2012 | Apr | CDFR |
| >A> |  | +          | 200MG | A077275 003 | Aug 14, 2012 | Apr | CDFR |

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL  
DILTIAZEM HYDROCHLORIDE

|     |  |           |       |             |              |     |      |
|-----|--|-----------|-------|-------------|--------------|-----|------|
| AB3 |  | PAR PHARM | 120MG | A074984 001 | Dec 20, 1999 | Jan | CAHN |
| AB3 |  |           | 180MG | A074984 002 | Dec 20, 1999 | Jan | CAHN |
| AB3 |  |           | 240MG | A074984 003 | Dec 20, 1999 | Jan | CAHN |
| AB3 |  |           | 300MG | A074984 004 | Dec 20, 1999 | Jan | CAHN |
| AB4 |  | SANDOZ    | 120MG | A091022 001 | Sep 28, 2012 | Feb | CAHN |
| AB4 |  |           | 180MG | A091022 002 | Sep 28, 2012 | Feb | CAHN |
| AB4 |  |           | 240MG | A091022 003 | Sep 28, 2012 | Feb | CAHN |
| AB4 |  |           | 300MG | A091022 004 | Sep 28, 2012 | Feb | CAHN |
| AB4 |  |           | 360MG | A091022 005 | Sep 28, 2012 | Feb | CAHN |
| AB4 |  |           | 420MG | A091022 006 | Sep 28, 2012 | Feb | CAHN |

INJECTABLE; INJECTION

DILTIAZEM HYDROCHLORIDE

|     |    |                   |         |             |              |     |      |
|-----|----|-------------------|---------|-------------|--------------|-----|------|
| >D> | AP | AGILA SPECLTS     | 5MG/ML  | A075375 001 | Sep 30, 1999 | Apr | DISC |
| >A> | AP | APOTEX INC        | 5MG/ML  | A075375 001 | Sep 30, 1999 | Apr | DISC |
| >D> |    | @ TEVA PARENTERAL | 5MG/ML  | A074894 001 | Aug 26, 1997 | Apr | CAHN |
| >D> |    | +                 | 10MG/ML | A074894 002 | Apr 19, 2002 | Apr | CAHN |
| >A> |    | @ TEVA PHARMS USA | 5MG/ML  | A074894 001 | Aug 26, 1997 | Apr | CAHN |
| >A> |    | +                 | 10MG/ML | A074894 002 | Apr 19, 2002 | Apr | CAHN |

TABLET; ORAL

DILTIAZEM HYDROCHLORIDE

|  |   |                 |       |             |              |     |      |
|--|---|-----------------|-------|-------------|--------------|-----|------|
|  | @ | DAVA PHARMS INC | 30MG  | A074093 001 | Nov 05, 1992 | Jan | DISC |
|  | @ |                 | 60MG  | A074093 002 | Nov 05, 1992 | Jan | DISC |
|  | @ |                 | 90MG  | A074093 003 | Nov 05, 1992 | Jan | DISC |
|  | @ |                 | 120MG | A074093 004 | Nov 05, 1992 | Jan | DISC |

DIMENHYDRINATE

## INJECTABLE; INJECTION

## DIMENHYDRINATE

|     |    |                    |         |         |     |              |     |      |
|-----|----|--------------------|---------|---------|-----|--------------|-----|------|
| >D> | AP | FRESENIUS KABI USA | 50MG/ML | A040519 | 001 | Jun 23, 2004 | Apr | CRLD |
| >A> |    | +                  | 50MG/ML | A040519 | 001 | Jun 23, 2004 | Apr | CRLD |
| >D> | AP | + WATSON LABS      | 50MG/ML | A080615 | 001 |              | Apr | DISC |
| >A> |    | @                  | 50MG/ML | A080615 | 001 |              | Apr | DISC |

DIMETHYL FUMARATE

## CAPSULE, DELAYED RELEASE; ORAL

## TECFIDERA

|  |  |                 |       |         |     |              |     |      |
|--|--|-----------------|-------|---------|-----|--------------|-----|------|
|  |  | BIOGEN IDEC INC | 120MG | N204063 | 001 | Mar 27, 2013 | Mar | NEWA |
|  |  | +               | 240MG | N204063 | 002 | Mar 27, 2013 | Mar | NEWA |

DIPHENHYDRAMINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## DIPHENHYDRAMINE HYDROCHLORIDE

|  |  |                   |         |         |     |  |     |      |
|--|--|-------------------|---------|---------|-----|--|-----|------|
|  |  | @ WATSON LABS INC | 10MG/ML | A080873 | 001 |  | Mar | DISC |
|  |  | @                 | 50MG/ML | A080873 | 002 |  | Mar | DISC |

## DIPHENHYDRAMINE HYDROCHLORIDE PRESERVATIVE FREE

|    |  |                   |         |         |     |              |     |      |
|----|--|-------------------|---------|---------|-----|--------------|-----|------|
| AP |  | BD RX             | 50MG/ML | A091526 | 001 | Mar 26, 2013 | Mar | NEWA |
|    |  | @ WATSON LABS INC | 50MG/ML | A080873 | 003 |              | Mar | DISC |

DIPYRIDAMOLE

## INJECTABLE; INJECTION

## DIPYRIDAMOLE

|     |    |                     |        |         |     |              |     |      |
|-----|----|---------------------|--------|---------|-----|--------------|-----|------|
| >A> |    | @ APOTEX INC        | 5MG/ML | A075769 | 001 | Nov 27, 2002 | Apr | DISC |
| >D> | AP | CLARIS LIFESCIENCES | 5MG/ML | A075769 | 001 | Nov 27, 2002 | Apr | DISC |

DIVALPROEX SODIUM

## TABLET, EXTENDED RELEASE; ORAL

## DIVALPROEX SODIUM

|  |  |                   |                        |         |     |              |     |      |
|--|--|-------------------|------------------------|---------|-----|--------------|-----|------|
|  |  | @ TEVA PHARMS USA | EQ 500MG VALPROIC ACID | A078700 | 001 | Aug 03, 2009 | Mar | DISC |
|--|--|-------------------|------------------------|---------|-----|--------------|-----|------|

DOCETAXEL

## INJECTABLE; INJECTION

## DOCETAXEL

|     |    |             |                     |         |     |              |     |      |
|-----|----|-------------|---------------------|---------|-----|--------------|-----|------|
| >A> | AP | ACTAVIS INC | 20MG/ML (20MG/ML)   | N203551 | 001 | Apr 12, 2013 | Apr | NEWA |
| >A> | AP |             | 80MG/4ML (20MG/ML)  | N203551 | 002 | Apr 12, 2013 | Apr | NEWA |
| >A> |    |             | 140MG/7ML (20MG/ML) | N203551 | 003 | Apr 12, 2013 | Apr | NEWA |

DONEPEZIL HYDROCHLORIDE

## TABLET; ORAL

## DONEPEZIL HYDROCHLORIDE

|     |    |                    |      |         |     |              |     |      |
|-----|----|--------------------|------|---------|-----|--------------|-----|------|
|     |    | @ ACCORD HLTHCARE  | 5MG  | A201335 | 001 | Aug 29, 2011 | Jan | DISC |
|     |    | @                  | 10MG | A201335 | 002 | Aug 29, 2011 | Jan | DISC |
| >A> | AB | ACTAVIS GRP PTC    | 5MG  | A090551 | 001 | May 31, 2011 | Apr | CAHN |
| >A> | AB |                    | 10MG | A090551 | 002 | May 31, 2011 | Apr | CAHN |
| >D> | AB | ACTAVIS PHARMA     | 5MG  | A090551 | 001 | May 31, 2011 | Apr | CAHN |
| >D> | AB |                    | 10MG | A090551 | 002 | May 31, 2011 | Apr | CAHN |
|     | AB | ALEMBIC PHARMS LTD | 5MG  | A201724 | 001 | Feb 25, 2013 | Feb | NEWA |
|     | AB |                    | 10MG | A201724 | 002 | Feb 25, 2013 | Feb | NEWA |

DORZOLAMIDE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC  
DORZOLAMIDE HYDROCHLORIDE

|     |    |            |            |         |     |              |     |      |
|-----|----|------------|------------|---------|-----|--------------|-----|------|
| >D> | AT | APOTEX INC | EQ 2% BASE | A078395 | 001 | Oct 28, 2008 | Apr | DISC |
| >A> |    | @          | EQ 2% BASE | A078395 | 001 | Oct 28, 2008 | Apr | DISC |

DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC  
DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE

|     |    |            |                         |         |     |              |     |      |
|-----|----|------------|-------------------------|---------|-----|--------------|-----|------|
| >D> | AT | APOTEX INC | EQ 2% BASE;EQ 0.5% BASE | A078201 | 001 | Oct 28, 2008 | Apr | DISC |
| >A> |    | @          | EQ 2% BASE;EQ 0.5% BASE | A078201 | 001 | Oct 28, 2008 | Apr | DISC |

DOXAZOSIN MESYLATE

TABLET; ORAL  
DOXAZOSIN MESYLATE

|  |   |                 |             |         |     |              |     |      |
|--|---|-----------------|-------------|---------|-----|--------------|-----|------|
|  | @ | WATSON LABS INC | EQ 1MG BASE | A075426 | 001 | Oct 18, 2000 | Jan | DISC |
|  | @ |                 | EQ 2MG BASE | A075426 | 002 | Oct 18, 2000 | Jan | DISC |
|  | @ |                 | EQ 4MG BASE | A075426 | 003 | Oct 18, 2000 | Jan | DISC |
|  | @ |                 | EQ 8MG BASE | A075426 | 004 | Oct 18, 2000 | Jan | DISC |

DOXEPIH HYDROCHLORIDE

CONCENTRATE; ORAL  
DOXEPIH HYDROCHLORIDE

|  |   |             |                 |         |     |              |     |      |
|--|---|-------------|-----------------|---------|-----|--------------|-----|------|
|  | @ | PHARM ASSOC | EQ 10MG BASE/ML | A075924 | 001 | Jan 15, 2004 | Mar | DISC |
|--|---|-------------|-----------------|---------|-----|--------------|-----|------|

TABLET; ORAL  
SILENOR

|     |   |                    |             |         |     |              |     |      |
|-----|---|--------------------|-------------|---------|-----|--------------|-----|------|
| >A> |   | PERNIX THERAPS LLC | EQ 3MG BASE | N022036 | 001 | Mar 17, 2010 | Apr | CAHN |
| >A> | + |                    | EQ 6MG BASE | N022036 | 002 | Mar 17, 2010 | Apr | CAHN |
| >D> |   | SOMAXON            | EQ 3MG BASE | N022036 | 001 | Mar 17, 2010 | Apr | CAHN |
| >D> | + |                    | EQ 6MG BASE | N022036 | 002 | Mar 17, 2010 | Apr | CAHN |

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION  
DOXORUBICIN HYDROCHLORIDE

|    |  |               |        |         |     |              |     |      |
|----|--|---------------|--------|---------|-----|--------------|-----|------|
| AP |  | SAGENT PHARMS | 2MG/ML | A091495 | 001 | Mar 18, 2013 | Mar | NEWA |
|----|--|---------------|--------|---------|-----|--------------|-----|------|

INJECTABLE, LIPOSOMAL; INJECTION

|     |    |                                       |                     |                    |         |     |              |          |
|-----|----|---------------------------------------|---------------------|--------------------|---------|-----|--------------|----------|
| >D> |    | DOXIL                                 |                     |                    |         |     |              |          |
| >D> | AB | +                                     | JANSSEN RES AND DEV | 20MG/10ML (2MG/ML) | N050718 | 001 | Nov 17, 1995 | Apr CTNA |
|     | AB | +                                     |                     | 20MG/10ML (2MG/ML) | N050718 | 001 | Nov 17, 1995 | Jan CFTG |
| >D> | AB | +                                     |                     | 50MG/25ML (2MG/ML) | N050718 | 002 | Jun 13, 2000 | Apr CTNA |
|     | AB | +                                     |                     | 50MG/25ML (2MG/ML) | N050718 | 002 | Jun 13, 2000 | Jan CFTG |
| >A> |    | DOXIL (LIPOSOMAL)                     |                     |                    |         |     |              |          |
| >A> | AB | +                                     | JANSSEN RES AND DEV | 20MG/10ML (2MG/ML) | N050718 | 001 | Nov 17, 1995 | Apr CTNA |
| >A> | AB | +                                     |                     | 50MG/25ML (2MG/ML) | N050718 | 002 | Jun 13, 2000 | Apr CTNA |
| >D> |    | DOXORUBICIN HYDROCHLORIDE             |                     |                    |         |     |              |          |
| >D> | AB |                                       | SUN PHARMA GLOBAL   | 20MG/10ML (2MG/ML) | A203263 | 001 | Feb 04, 2013 | Apr CTNA |
|     | AB |                                       |                     | 20MG/10ML (2MG/ML) | A203263 | 001 | Feb 04, 2013 | Jan NEWA |
| >D> | AB |                                       |                     | 50MG/25ML (2MG/ML) | A203263 | 002 | Feb 04, 2013 | Apr CTNA |
|     | AB |                                       |                     | 50MG/25ML (2MG/ML) | A203263 | 002 | Feb 04, 2013 | Jan NEWA |
| >A> |    | DOXORUBICIN HYDROCHLORIDE (LIPOSOMAL) |                     |                    |         |     |              |          |
| >A> | AB |                                       | SUN PHARMA GLOBAL   | 20MG/10ML (2MG/ML) | A203263 | 001 | Feb 04, 2013 | Apr CTNA |
| >A> | AB |                                       |                     | 50MG/25ML (2MG/ML) | A203263 | 002 | Feb 04, 2013 | Apr CTNA |

DOXYCYCLINEFOR SUSPENSION; ORAL  
DOXYCYCLINE

|    |           |                  |             |              |     |      |
|----|-----------|------------------|-------------|--------------|-----|------|
| AB | LUPIN LTD | EQ 25MG BASE/5ML | A201678 001 | Mar 18, 2013 | Mar | NEWA |
|----|-----------|------------------|-------------|--------------|-----|------|

DOXYCYCLINE HYCLATE

TABLET; ORAL

DOXYCYCLINE HYCLATE

@ BLU CARIBE INC

EQ 50MG BASE

A062269 003

Mar CAHN

@

EQ 100MG BASE

A062269 002 Nov 08, 1982 Mar CAHN

TABLET, DELAYED RELEASE; ORAL

DORYX

|     |              |              |             |              |     |      |
|-----|--------------|--------------|-------------|--------------|-----|------|
| >A> | MAYNE PHARMA | EQ 80MG BASE | N050795 004 | Apr 11, 2013 | Apr | NEWA |
|-----|--------------|--------------|-------------|--------------|-----|------|

|     |  |               |             |              |     |      |
|-----|--|---------------|-------------|--------------|-----|------|
| >A> |  | EQ 200MG BASE | N050795 005 | Apr 11, 2013 | Apr | NEWA |
|-----|--|---------------|-------------|--------------|-----|------|

DOXYCYCLINE HYCLATE

|     |    |                     |              |             |              |     |      |
|-----|----|---------------------|--------------|-------------|--------------|-----|------|
| >A> | AB | HERITAGE PHARMS INC | EQ 75MG BASE | A200856 001 | Apr 30, 2013 | Apr | NEWA |
|-----|----|---------------------|--------------|-------------|--------------|-----|------|

|     |    |  |               |             |              |     |      |
|-----|----|--|---------------|-------------|--------------|-----|------|
| >A> | AB |  | EQ 100MG BASE | A200856 002 | Apr 30, 2013 | Apr | NEWA |
|-----|----|--|---------------|-------------|--------------|-----|------|

|     |    |  |               |             |              |     |      |
|-----|----|--|---------------|-------------|--------------|-----|------|
| >A> | AB |  | EQ 150MG BASE | A200856 003 | Apr 30, 2013 | Apr | NEWA |
|-----|----|--|---------------|-------------|--------------|-----|------|

>A> DOXYLAMINE SUCCINATE; PYRIDOXINE HYDROCHLORIDE

&gt;A&gt; TABLET, DELAYED RELEASE; ORAL

&gt;A&gt; DICLEGIS

|     |   |           |           |             |              |     |      |
|-----|---|-----------|-----------|-------------|--------------|-----|------|
| >A> | + | DUCHESNAY | 10MG;10MG | N021876 001 | Apr 08, 2013 | Apr | NEWA |
|-----|---|-----------|-----------|-------------|--------------|-----|------|

ECONAZOLE NITRATE

CREAM; TOPICAL

ECONAZOLE NITRATE

|    |              |    |             |              |     |      |
|----|--------------|----|-------------|--------------|-----|------|
| AB | IGI LABS INC | 1% | A076574 001 | Dec 17, 2004 | Mar | CAHN |
|----|--------------|----|-------------|--------------|-----|------|

ENTACAPONE

TABLET; ORAL

ENTACAPONE

|     |    |                  |       |             |              |     |      |
|-----|----|------------------|-------|-------------|--------------|-----|------|
| >A> | AB | MYLAN PHARMS INC | 200MG | A202394 001 | May 13, 2013 | Apr | NEWA |
|-----|----|------------------|-------|-------------|--------------|-----|------|

EPIRUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

EPIRUBICIN HYDROCHLORIDE

@ MYLAN LLC

50MG/25ML (2MG/ML)

A065371 001 Nov 28, 2007 Feb DISC

@

200MG/100ML (2MG/ML)

A065371 002 Nov 28, 2007 Feb DISC

|     |    |                 |                    |             |              |     |      |
|-----|----|-----------------|--------------------|-------------|--------------|-----|------|
| >D> | AP | TEVA PARENTERAL | 50MG/25ML (2MG/ML) | A065331 001 | Aug 09, 2007 | Apr | CAHN |
|-----|----|-----------------|--------------------|-------------|--------------|-----|------|

|     |    |  |                      |             |              |     |      |
|-----|----|--|----------------------|-------------|--------------|-----|------|
| >D> | AP |  | 200MG/100ML (2MG/ML) | A065331 002 | Aug 09, 2007 | Apr | CAHN |
|-----|----|--|----------------------|-------------|--------------|-----|------|

|     |    |                 |                      |             |              |     |      |
|-----|----|-----------------|----------------------|-------------|--------------|-----|------|
| >A> | AP | TEVA PHARMS USA | 200MG/100ML (2MG/ML) | A065331 002 | Aug 09, 2007 | Apr | CAHN |
|-----|----|-----------------|----------------------|-------------|--------------|-----|------|

|     |    |  |                    |             |              |     |      |
|-----|----|--|--------------------|-------------|--------------|-----|------|
| >A> | AP |  | 50MG/25ML (2MG/ML) | A065331 001 | Aug 09, 2007 | Apr | CAHN |
|-----|----|--|--------------------|-------------|--------------|-----|------|

EPOPROSTENOL SODIUM

INJECTABLE; INJECTION

EPOPROSTENOL SODIUM

|     |    |                 |                    |             |              |     |      |
|-----|----|-----------------|--------------------|-------------|--------------|-----|------|
| >D> | AP | TEVA PARENTERAL | EQ 0.5MG BASE/VIAL | A078396 001 | Apr 23, 2008 | Apr | CAHN |
|-----|----|-----------------|--------------------|-------------|--------------|-----|------|

|     |    |  |                    |             |              |     |      |
|-----|----|--|--------------------|-------------|--------------|-----|------|
| >D> | AP |  | EQ 1.5MG BASE/VIAL | A078396 002 | Apr 23, 2008 | Apr | CAHN |
|-----|----|--|--------------------|-------------|--------------|-----|------|

|     |    |                 |                    |             |              |     |      |
|-----|----|-----------------|--------------------|-------------|--------------|-----|------|
| >A> | AP | TEVA PHARMS USA | EQ 0.5MG BASE/VIAL | A078396 001 | Apr 23, 2008 | Apr | CAHN |
|-----|----|-----------------|--------------------|-------------|--------------|-----|------|

|     |    |  |                    |             |              |     |      |
|-----|----|--|--------------------|-------------|--------------|-----|------|
| >A> | AP |  | EQ 1.5MG BASE/VIAL | A078396 002 | Apr 23, 2008 | Apr | CAHN |
|-----|----|--|--------------------|-------------|--------------|-----|------|

ERYTHROMYCINCAPSULE, DELAYED REL PELLETS; ORAL  
ERYC

|     |    |                     |       |             |  |     |      |
|-----|----|---------------------|-------|-------------|--|-----|------|
| AB  | +  | MAYNE PHARMA        | 250MG | N050536 001 |  | Mar | CAHN |
| >D> | AB | WARNER CHILCOTT LLC | 250MG | A062338 001 |  | Apr | DISC |
| >A> |    | @                   | 250MG | A062338 001 |  | Apr | DISC |

## SOLUTION; TOPICAL

## SANSAC

|     |  |                      |    |             |              |     |      |
|-----|--|----------------------|----|-------------|--------------|-----|------|
| >A> |  | @ DOW PHARM          | 2% | A062522 001 | Jan 24, 1985 | Apr | CAHN |
| >D> |  | @ DOW PHARM SCIENCES | 2% | A062522 001 | Jan 24, 1985 | Apr | CAHN |

ESOMEPRAZOLE SODIUM

## INJECTABLE; INTRAVENOUS

## ESOMEPRAZOLE SODIUM

|    |   |                   |                   |             |              |     |      |
|----|---|-------------------|-------------------|-------------|--------------|-----|------|
| AP |   | SUN PHARMA GLOBAL | EQ 20MG BASE/VIAL | A200882 001 | Mar 18, 2013 | Mar | NEWA |
| AP |   |                   | EQ 40MG BASE/VIAL | A200882 002 | Mar 18, 2013 | Mar | NEWA |
|    |   | NEXIUM IV         |                   |             |              |     |      |
| AP | + | ASTRAZENECA       | EQ 20MG BASE/VIAL | N021689 001 | Mar 31, 2005 | Mar | CFTG |
| AP | + |                   | EQ 40MG BASE/VIAL | N021689 002 | Mar 31, 2005 | Mar | CFTG |

ESTROPIPATE

## TABLET; ORAL

## ORTHO-EST

|     |    |                     |        |             |              |     |      |
|-----|----|---------------------|--------|-------------|--------------|-----|------|
| >A> |    | @ CARACO            | 0.75MG | A089567 001 | Feb 27, 1991 | Apr | DISC |
| >A> |    | @                   | 1.5MG  | A089582 001 | Jul 17, 1991 | Apr | DISC |
| >D> | AB | SUN PHARM INDS (IN) | 0.75MG | A089567 001 | Feb 27, 1991 | Apr | DISC |
| >D> | AB |                     | 1.5MG  | A089582 001 | Jul 17, 1991 | Apr | DISC |

ESZOPICLONE

## TABLET; ORAL

## ESZOPICLONE

|    |   |                     |     |             |              |     |      |
|----|---|---------------------|-----|-------------|--------------|-----|------|
| AB |   | MYLAN PHARMS INC    | 1MG | A091151 001 | Mar 26, 2013 | Mar | NEWA |
| AB |   |                     | 2MG | A091151 002 | Mar 26, 2013 | Mar | NEWA |
| AB |   |                     | 3MG | A091151 003 | Mar 26, 2013 | Mar | NEWA |
| AB |   | SUN PHARMA GLOBAL   | 1MG | A091103 001 | Apr 03, 2013 | Mar | NEWA |
| AB |   |                     | 2MG | A091103 002 | Apr 03, 2013 | Mar | NEWA |
| AB |   |                     | 3MG | A091103 003 | Apr 03, 2013 | Mar | NEWA |
|    |   | LUNESTA             |     |             |              |     |      |
| AB |   | SUNOVION PHARMS INC | 1MG | N021476 001 | Dec 15, 2004 | Mar | CTEC |
| AB |   |                     | 2MG | N021476 002 | Dec 15, 2004 | Mar | CTEC |
| AB | + |                     | 3MG | N021476 003 | Dec 15, 2004 | Mar | CTEC |

ETHINYL ESTRADIOL; LEVONORGESTREL

## TABLET; ORAL

## DAYSEE

|    |   |                    |                                                              |             |              |     |      |
|----|---|--------------------|--------------------------------------------------------------|-------------|--------------|-----|------|
| AB |   | LUPIN LTD          | 0.03MG, 0.01MG; 0.15MG, N/A                                  | A091467 001 | Apr 10, 2013 | Mar | NEWA |
|    |   | QUARTETTE          |                                                              |             |              |     |      |
|    | + | TEVA BRANDED PHARM | 0.02MG, 0.15MG; 0.025MG, 0.15MG; 0.03MG, 0.15MG; 0.01MG, N/A | N204061 001 | Mar 28, 2013 | Mar | NEWA |

## TABLET; ORAL-28

## LEVONORGESTREL AND ETHINYL ESTRADIOL

|     |  |           |               |             |              |     |      |
|-----|--|-----------|---------------|-------------|--------------|-----|------|
| AB1 |  | LUPIN LTD | 0.02MG; 0.1MG | A091425 001 | Jan 18, 2013 | Jan | NEWA |
|-----|--|-----------|---------------|-------------|--------------|-----|------|

ETHINYL ESTRADIOL; NORETHINDRONE

|     |                 |                |                                          |         |     |              |          |
|-----|-----------------|----------------|------------------------------------------|---------|-----|--------------|----------|
|     | TABLET; ORAL-28 |                |                                          |         |     |              |          |
| >A> |                 | PIRMELLA 1/35  |                                          |         |     |              |          |
| >A> | AB              | LUPIN LTD      | 0.035MG;1MG                              | A201512 | 001 | Apr 24, 2013 | Apr NEWA |
| >A> |                 | PIRMELLA 7/7/7 |                                          |         |     |              |          |
| >A> | AB              | LUPIN LTD      | 0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG | A201510 | 001 | Apr 24, 2013 | Apr NEWA |

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

|     |                                             |                     |             |         |     |              |          |
|-----|---------------------------------------------|---------------------|-------------|---------|-----|--------------|----------|
| >A> | CAPSULE; ORAL                               |                     |             |         |     |              |          |
| >A> | MINASTRIN 24 FE                             |                     |             |         |     |              |          |
| >A> | +                                           | WARNER CHILCOTT     | 0.02MG;1MG  | N204426 | 001 | Apr 19, 2013 | Apr NEWA |
|     | TABLET; ORAL                                |                     |             |         |     |              |          |
|     | FEMHRT                                      |                     |             |         |     |              |          |
|     | @                                           | WARNER CHILCOTT LLC | 0.005MG;1MG | N021065 | 002 | Oct 15, 1999 | Jan DISC |
|     | NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL |                     |             |         |     |              |          |
|     | +                                           | BARR LABS INC       | 0.005MG;1MG | A076221 | 001 | Nov 06, 2009 | Jan CRLD |

ETHINYL ESTRADIOL; NORGESTIMATE

|     |                 |               |                                               |         |     |              |          |
|-----|-----------------|---------------|-----------------------------------------------|---------|-----|--------------|----------|
|     | TABLET; ORAL-28 |               |                                               |         |     |              |          |
|     | ESTARYLLA       |               |                                               |         |     |              |          |
|     | AB              | SANDOZ        | 0.035MG;0.25MG                                | A090794 | 001 | Jan 30, 2013 | Jan NEWA |
| >D> | TRI LO SPRINTC  |               |                                               |         |     |              |          |
| >D> | AB              | BARR          | 0.025MG,0.025MG,0.025MG;0.18MG,0.215MG,0.25MG | A076784 | 001 | Jun 29, 2009 | Apr DISC |
| >A> | @               | BARR LABS INC | 0.025MG,0.025MG,0.025MG;0.18MG,0.215MG,0.25MG | A076784 | 001 | Jun 29, 2009 | Apr DISC |
|     | TRI-ESTARYLLA   |               |                                               |         |     |              |          |
|     | AB              | SANDOZ        | 0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG | A090793 | 001 | Jan 30, 2013 | Jan NEWA |

ETODOLAC

|  |              |             |       |         |     |              |          |
|--|--------------|-------------|-------|---------|-----|--------------|----------|
|  | TABLET; ORAL |             |       |         |     |              |          |
|  | ETODOLAC     |             |       |         |     |              |          |
|  | @            | PROSAM LABS | 400MG | A074819 | 001 | Feb 28, 1997 | Mar DISC |
|  | @            |             | 500MG | A074819 | 002 | Apr 28, 1998 | Mar DISC |

ETOPOSIDE

|     |                       |                     |         |         |     |              |          |
|-----|-----------------------|---------------------|---------|---------|-----|--------------|----------|
|     | INJECTABLE; INJECTION |                     |         |         |     |              |          |
|     | ETOPOSIDE             |                     |         |         |     |              |          |
| >A> | AP                    | ACCORD HLTHCARE     | 20MG/ML | A074513 | 001 | Mar 14, 1996 | Apr CAHN |
| >D> | AP                    | ACCORD HLTHCARE INC | 20MG/ML | A074513 | 001 | Mar 14, 1996 | Apr CAHN |
| >D> | AP                    | PHARMACHEMIE        | 20MG/ML | A074227 | 001 | Feb 22, 1996 | Apr DISC |
| >A> | @                     |                     | 20MG/ML | A074227 | 001 | Feb 22, 1996 | Apr DISC |
| >D> | AP                    | TEVA PARENTERAL     | 20MG/ML | A074529 | 001 | Jul 24, 1996 | Apr CAHN |
| >A> | AP                    | TEVA PHARMS USA     | 20MG/ML | A074529 | 001 | Jul 24, 1996 | Apr CAHN |

FAMOTIDINE

|     |                              |            |         |         |     |              |          |
|-----|------------------------------|------------|---------|---------|-----|--------------|----------|
|     | INJECTABLE; INJECTION        |            |         |         |     |              |          |
|     | FAMOTIDINE                   |            |         |         |     |              |          |
| >D> | @                            | APOTEX INC | 10MG/ML | A075942 | 001 | Aug 02, 2002 | Apr DISC |
| >A> | @                            |            | 10MG/ML | A075942 | 001 | Aug 02, 2002 | Apr DISC |
|     | FAMOTIDINE PRESERVATIVE FREE |            |         |         |     |              |          |
| >D> | AP                           | AKORN INC  | 10MG/ML | A076324 | 001 | Nov 27, 2002 | Apr DISC |
|     | AP                           |            | 10MG/ML | A076324 | 001 | Nov 27, 2002 | Mar CAHN |
| >A> | @                            | APOTEX INC | 10MG/ML | A076324 | 001 | Nov 27, 2002 | Apr DISC |

INJECTABLE; INJECTION

|     |    |                                               |          |         |     |         |      |     |      |
|-----|----|-----------------------------------------------|----------|---------|-----|---------|------|-----|------|
| >D> |    | FAMOTIDINE PRESERVATIVE FREE (PHARMACY BULK)  |          |         |     |         |      |     |      |
| >D> | AP | AKORN INC                                     | 10MG/ML  | A076322 | 001 | Nov 27, | 2002 | Apr | DISC |
|     | AP |                                               | 10MG/ML  | A076322 | 001 | Nov 27, | 2002 | Mar | CAHN |
| >A> |    | @ APOTEX INC                                  | 10MG/ML  | A076322 | 001 | Nov 27, | 2002 | Apr | DISC |
|     |    | PEPCID PRESERVATIVE FREE IN PLASTIC CONTAINER |          |         |     |         |      |     |      |
| >D> |    | @ MERCK                                       | 0.4MG/ML | N020249 | 001 | Feb 18, | 1994 | Apr | CAHN |
| >A> |    | @ MERCK SHARP DOHME                           | 0.4MG/ML | N020249 | 001 | Feb 18, | 1994 | Apr | CAHN |

FENOFIBRIC ACID

## TABLET; ORAL

## FIBRICOR

|  |   |                     |       |         |     |         |      |     |      |
|--|---|---------------------|-------|---------|-----|---------|------|-----|------|
|  |   | MUTUAL PHARM CO INC | 35MG  | N022418 | 001 | Aug 14, | 2009 | Feb | CAHN |
|  | + |                     | 105MG | N022418 | 002 | Aug 14, | 2009 | Feb | CAHN |

FENOPROFEN CALCIUM

## TABLET; ORAL

## FENOPROFEN CALCIUM

|  |   |                        |               |         |     |         |      |     |      |
|--|---|------------------------|---------------|---------|-----|---------|------|-----|------|
|  |   | @ IVAX SUB TEVA PHARMS | EQ 600MG BASE | A072557 | 001 | Aug 29, | 1988 | Mar | DISC |
|  | + | MYLAN PHARMS INC       | EQ 600MG BASE | A072267 | 001 | Aug 17, | 1988 | Mar | CTEC |

FENTANYL CITRATE

## TABLET; BUCCAL, SUBLINGUAL

## FENTORA

|    |   |          |               |         |     |         |      |     |      |
|----|---|----------|---------------|---------|-----|---------|------|-----|------|
| AB |   | CEPHALON | EQ 0.1MG BASE | N021947 | 001 | Sep 25, | 2006 | Feb | CDFR |
| AB |   |          | EQ 0.2MG BASE | N021947 | 002 | Sep 25, | 2006 | Feb | CDFR |
|    |   | @        | EQ 0.3MG BASE | N021947 | 006 | Mar 02, | 2007 | Feb | CDFR |
| AB | + |          | EQ 0.4MG BASE | N021947 | 003 | Sep 25, | 2006 | Feb | CDFR |
| AB |   |          | EQ 0.6MG BASE | N021947 | 004 | Sep 25, | 2006 | Feb | CDFR |
| AB |   |          | EQ 0.8MG BASE | N021947 | 005 | Sep 25, | 2006 | Feb | CDFR |

FERUMOXSYL

## SUSPENSION; ORAL

## GASTROMARK

|  |  |                   |                    |         |     |         |      |     |      |
|--|--|-------------------|--------------------|---------|-----|---------|------|-----|------|
|  |  | @ AMAG PHARMS INC | EQ 0.175MG IRON/ML | N020410 | 001 | Dec 06, | 1996 | Feb | DISC |
|--|--|-------------------|--------------------|---------|-----|---------|------|-----|------|

FINASTERIDE

## TABLET; ORAL

## FINASTERIDE

|     |    |                     |     |         |     |         |      |     |      |
|-----|----|---------------------|-----|---------|-----|---------|------|-----|------|
| >A> | AB | ACCORD HLTHCARE     | 5MG | A090121 | 001 | Feb 23, | 2010 | Apr | CAHN |
| >D> | AB | ACCORD HLTHCARE INC | 5MG | A090121 | 001 | Feb 23, | 2010 | Apr | CAHN |
| >D> | AB | HETERO DRUGS LTD    | 5MG | A090061 | 001 | Jun 07, | 2010 | Apr | CAHN |
| >A> | AB | HETERO LABS LTD III | 5MG | A090061 | 001 | Jun 07, | 2010 | Apr | CAHN |

FLECAINIDE ACETATE

## TABLET; ORAL

## FLECAINIDE ACETATE

|     |    |            |       |         |     |         |      |     |      |
|-----|----|------------|-------|---------|-----|---------|------|-----|------|
| >D> | AB | APOTEX INC | 50MG  | A079164 | 001 | Jul 09, | 2009 | Apr | DISC |
| >A> |    | @          | 50MG  | A079164 | 001 | Jul 09, | 2009 | Apr | DISC |
| >D> | AB |            | 100MG | A079164 | 002 | Jul 09, | 2009 | Apr | DISC |
| >A> |    | @          | 100MG | A079164 | 002 | Jul 09, | 2009 | Apr | DISC |
| >D> | AB |            | 150MG | A079164 | 003 | Jul 09, | 2009 | Apr | DISC |
| >A> |    | @          | 150MG | A079164 | 003 | Jul 09, | 2009 | Apr | DISC |

FLUCONAZOLE

## FOR SUSPENSION; ORAL

## FLUCONAZOLE

@ TARO PHARM INDS

50MG/5ML

A076918 001 Dec 18, 2006 Mar DISC

@

200MG/5ML

A076918 002 Dec 18, 2006 Mar DISC

## INJECTABLE; INJECTION

## FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER

&gt;D&gt; AP AGILA SPECLTS 200MG/100ML (2MG/ML) A076888 001 Mar 25, 2005 Apr DISC

&gt;D&gt; AP 400MG/200ML (2MG/ML) A076888 002 Mar 25, 2005 Apr DISC

&gt;A&gt; @ APOTEX INC 200MG/100ML (2MG/ML) A076888 001 Mar 25, 2005 Apr DISC

&gt;A&gt; @ 400MG/200ML (2MG/ML) A076888 002 Mar 25, 2005 Apr DISC

## FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

&gt;D&gt; @ AGILA SPECLTS 200MG/100ML (2MG/ML) A076889 001 Mar 25, 2005 Apr DISC

&gt;D&gt; @ 400MG/200ML (2MG/ML) A076889 002 Mar 25, 2005 Apr DISC

&gt;A&gt; @ APOTEX INC 200MG/100ML (2MG/ML) A076889 001 Mar 25, 2005 Apr DISC

&gt;A&gt; @ 400MG/200ML (2MG/ML) A076889 002 Mar 25, 2005 Apr DISC

FLUDARABINE PHOSPHATE

## INJECTABLE; INJECTION

## FLUDARABINE PHOSPHATE

AP + FRESENIUS KABI USA 50MG/2ML (25MG/ML) A078393 001 Oct 15, 2007 Jan CRLD

&gt;D&gt; AP TEVA PARENTERAL 50MG/VIAL A076349 001 Aug 28, 2003 Apr CAHN

&gt;D&gt; AP 50MG/2ML (25MG/ML) A076661 001 Apr 28, 2004 Apr CAHN

AP 50MG/2ML (25MG/ML) A076661 001 Apr 28, 2004 Jan CRLD

&gt;A&gt; AP TEVA PHARMS USA 50MG/2ML (25MG/ML) A076661 001 Apr 28, 2004 Apr CAHN

&gt;A&gt; AP 50MG/VIAL A076349 001 Aug 28, 2003 Apr CAHN

FLUDEOXYGLUCOSE F-18

## INJECTABLE; INTRAVENOUS

## FLUDEOXYGLUCOSE F18

+ FEINSTEIN

20-300mCi/ML

N021870 002 Nov 21, 2008 Jan CFTG

HOUSTON CYCLOTRON

20-500mCi/ML

A203665 001 Feb 14, 2013 Jan NEWA

FLUMAZENIL

## INJECTABLE; INJECTION

## FLUMAZENIL

&gt;A&gt; @ APOTEX INC 0.5MG/5ML (0.1MG/ML) A076755 002 Oct 12, 2004 Apr DISC

&gt;A&gt; @ 1MG/10ML (0.1MG/ML) A076755 001 Oct 12, 2004 Apr DISC

&gt;D&gt; AP CLARIS LIFESCIENCES 0.5MG/5ML (0.1MG/ML) A076755 002 Oct 12, 2004 Apr DISC

&gt;D&gt; AP 1MG/10ML (0.1MG/ML) A076755 001 Oct 12, 2004 Apr DISC

&gt;D&gt; @ TEVA PARENTERAL 0.5MG/5ML (0.1MG/ML) A076589 002 Oct 12, 2004 Apr CAHN

&gt;D&gt; @ 1MG/10ML (0.1MG/ML) A076589 001 Oct 12, 2004 Apr CAHN

&gt;A&gt; @ TEVA PHARMS USA 0.5MG/5ML (0.1MG/ML) A076589 002 Oct 12, 2004 Apr CAHN

&gt;A&gt; @ 1MG/10ML (0.1MG/ML) A076589 001 Oct 12, 2004 Apr CAHN

FLUOCINONIDE

## CREAM; TOPICAL

## LIDEX

@ CNTY LINE PHARMS

0.05%

N016908 002 Jan CAHN

## LIDEX-E

@ CNTY LINE PHARMS

0.05%

N016908 003 Jan CAHN

## GEL; TOPICAL

## FLUOCINONIDE

AB + TARO 0.05% A074935 001 Jul 29, 1997 Jan CRLD

## GEL; TOPICAL

## LIDEX

@ CNTY LINE PHARMS

0.05%

N017373 001

Jan CAHN

## OINTMENT; TOPICAL

## FLUOCINONIDE

AB + TARO

0.05%

A075008 001 Jun 30, 1999 Jan CRLD

## LIDEX

@ CNTY LINE PHARMS

0.05%

N016909 002

Jan CAHN

## SOLUTION; TOPICAL

## FLUOCINONIDE

AT + TARO

0.05%

A074799 001 Dec 31, 1996 Jan CRLD

## LIDEX

@ MEDICIS

0.05%

N018849 001 Apr 06, 1984 Jan DISC

FLUOROURACIL

## INJECTABLE; INJECTION

## FLUOROURACIL

AP + MYLAN LLC

500MG/10ML (50MG/ML)

A040743 002 Apr 26, 2007 Feb CAHN

AP +

1GM/20ML (50MG/ML)

A040743 001 Apr 26, 2007 Feb CAHN

FLUOXETINE HYDROCHLORIDE

## CAPSULE; ORAL

## FLUOXETINE HYDROCHLORIDE

@ CARLSBAD

EQ 10MG BASE

A076022 001 Jan 30, 2002 Mar DISC

@

EQ 20MG BASE

A076022 002 Jan 30, 2002 Mar DISC

&gt;D&gt; AB1 CR DOUBLE CRANE

EQ 10MG BASE

A076165 001 Feb 01, 2002 Apr DISC

&gt;A&gt; @

EQ 10MG BASE

A076165 001 Feb 01, 2002 Apr DISC

AB1

EQ 10MG BASE

A076165 001 Feb 01, 2002 Mar CAHN

&gt;D&gt; AB1

EQ 20MG BASE

A076165 002 Feb 01, 2002 Apr DISC

&gt;A&gt; @

EQ 20MG BASE

A076165 002 Feb 01, 2002 Apr DISC

AB1

EQ 20MG BASE

A076165 002 Feb 01, 2002 Mar CAHN

@ WOCKHARDT LTD

EQ 10MG BASE

A078143 001 Jan 16, 2008 Feb DISC

@

EQ 20MG BASE

A078143 002 Jan 16, 2008 Feb DISC

@

EQ 40MG BASE

A078143 003 Jan 16, 2008 Feb DISC

## SOLUTION; ORAL

## FLUOXETINE HYDROCHLORIDE

&gt;A&gt; @ APOTEX INC

EQ 20MG BASE/5ML

A075292 001 Feb 07, 2002 Apr DISC

&gt;D&gt; AA

NOVEX

EQ 20MG BASE/5ML

A075292 001 Feb 07, 2002 Apr DISC

FLUOXETINE HYDROCHLORIDE; OLANZAPINE

## CAPSULE; ORAL

## OLANZAPINE AND FLUOXETINE HYDROCHLORIDE

AB TEVA PHARMS

EQ 25MG BASE;EQ 3MG BASE

A202074 001 Mar 25, 2013 Mar NEWA

FLUPHENAZINE DECANOATE

## INJECTABLE; INJECTION

## FLUPHENAZINE DECANOATE

&gt;A&gt; @ APOTEX INC

25MG/ML

A075918 001 Aug 17, 2001 Apr DISC

&gt;D&gt; AO

CLARIS LIFESCIENCES

25MG/ML

A075918 001 Aug 17, 2001 Apr DISC

FLUVOXAMINE MALEATE

## CAPSULE, EXTENDED RELEASE; ORAL

## FLUVOXAMINE MALEATE

&gt;A&gt; AB ACTAVIS ELIZABETH

100MG

A091482 001 Apr 23, 2013 Apr NEWA

AB

ANCHEN PHARMS

100MG

A091476 001 Mar 13, 2013 Mar NEWA

AB

150MG

A091476 002 Mar 13, 2013 Mar NEWA

CAPSULE, EXTENDED RELEASE; ORAL  
LUVOX CR

|    |             |       |             |              |     |      |
|----|-------------|-------|-------------|--------------|-----|------|
| AB | JAZZ PHARMS | 100MG | N022033 001 | Feb 28, 2008 | Mar | CFTG |
| AB | +           | 150MG | N022033 002 | Feb 28, 2008 | Mar | CFTG |

FOSINOPRIL SODIUM

## TABLET; ORAL

## FOSINOPRIL SODIUM

|               |      |             |              |     |      |
|---------------|------|-------------|--------------|-----|------|
| @ WATSON LABS | 10MG | A076987 001 | Dec 23, 2004 | Mar | DISC |
| @             | 20MG | A076987 002 | Dec 23, 2004 | Mar | DISC |
| @             | 40MG | A076987 003 | Dec 23, 2004 | Mar | DISC |

FOSPHENYTOIN SODIUM

## INJECTABLE; INJECTION

## FOSPHENYTOIN SODIUM

|     |    |            |                         |             |              |     |      |
|-----|----|------------|-------------------------|-------------|--------------|-----|------|
| >D> | AP | APOTEX INC | EQ 50MG PHENYTOIN NA/ML | A078126 001 | Aug 06, 2007 | Apr | DISC |
| >A> |    | @          | EQ 50MG PHENYTOIN NA/ML | A078126 001 | Aug 06, 2007 | Apr | DISC |

FUROSEMIDE

## INJECTABLE; INJECTION

## FUROSEMIDE

|                   |         |             |  |     |      |
|-------------------|---------|-------------|--|-----|------|
| @ INTL MEDICATION | 10MG/ML | N018025 001 |  | Jan | DISC |
|-------------------|---------|-------------|--|-----|------|

## TABLET; ORAL

## FUROSEMIDE

|                   |      |             |              |     |      |
|-------------------|------|-------------|--------------|-----|------|
| @ DAVA PHARMS INC | 20MG | N018415 001 | Jul 27, 1982 | Feb | DISC |
| @                 | 40MG | N018415 002 | Jul 27, 1982 | Feb | DISC |
| @                 | 80MG | N018415 003 | Nov 26, 1984 | Feb | DISC |

GADOTERATE MEGLUMINE

## SOLUTION; INTRAVENOUS

## DOTAREM

|   |         |                            |             |              |     |      |
|---|---------|----------------------------|-------------|--------------|-----|------|
| + | GUERBET | 37.69GM/100ML (376.9MG/ML) | N204781 001 | Mar 20, 2013 | Mar | NEWA |
| + |         | 3.769GM/10ML (376.9MG/ML)  | N204781 002 | Mar 20, 2013 | Mar | NEWA |
| + |         | 5.6535GM/15ML (376.9MG/ML) | N204781 003 | Mar 20, 2013 | Mar | NEWA |
| + |         | 7.538GM/20ML (376.9MG/ML)  | N204781 004 | Mar 20, 2013 | Mar | NEWA |

GADOXETATE DISODIUM

## SOLUTION; INTRAVENOUS

## EOVIST

|                |                              |             |              |     |      |
|----------------|------------------------------|-------------|--------------|-----|------|
| BAYER HLTHCARE | 2.72145GM/15ML (181.43MG/ML) | N022090 002 | Feb 04, 2013 | Feb | NEWA |
|----------------|------------------------------|-------------|--------------|-----|------|

GATIFLOXACIN

## SOLUTION/DROPS; OPHTHALMIC

## GATIFLOXACIN

|     |    |              |      |             |              |     |
|-----|----|--------------|------|-------------|--------------|-----|
| >D> |    |              |      |             |              |     |
| >D> | AT | APOTEX CORP  | 0.3% | A079084 001 | Aug 19, 2011 | Apr |
| >A> |    | @ APOTEX INC | 0.3% | A079084 001 | Aug 19, 2011 | Apr |

GEMCITABINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## GEMCITABINE HYDROCHLORIDE

|     |    |                      |                    |             |              |     |      |
|-----|----|----------------------|--------------------|-------------|--------------|-----|------|
| >A> | AP | DR REDDYS LABS LTD   | EQ 2GM BASE/VIAL   | A202997 001 | May 07, 2013 | Apr | NEWA |
| >A> | AP | JIANGSU HANSON PHARM | EQ 200MG BASE/VIAL | A202485 001 | May 07, 2013 | Apr | NEWA |
| >A> | AP |                      | EQ 1GM BASE/VIAL   | A202485 002 | May 07, 2013 | Apr | NEWA |
| >A> | AP | PHARMAFORCE          | EQ 200MG BASE/VIAL | A202031 001 | May 07, 2013 | Apr | NEWA |
| >A> | AP |                      | EQ 1GM BASE/VIAL   | A202031 002 | May 07, 2013 | Apr | NEWA |

## INJECTABLE; INJECTION

## GEMCITABINE HYDROCHLORIDE

|     |    |               |                    |             |              |     |      |
|-----|----|---------------|--------------------|-------------|--------------|-----|------|
| >A> | AP | SAGENT PHARMS | EQ 200MG BASE/VIAL | A091597 001 | May 07, 2013 | Apr | NEWA |
| >A> | AP |               | EQ 1GM BASE/VIAL   | A091597 002 | May 07, 2013 | Apr | NEWA |

## GLATIRAMER ACETATE

## FOR SOLUTION; SUBCUTANEOUS

## COPAXONE

|     |  |                   |           |             |              |     |      |
|-----|--|-------------------|-----------|-------------|--------------|-----|------|
| >D> |  | @ TEVA            | 20MG/VIAL | N020622 001 | Dec 20, 1996 | Apr | CAHN |
| >A> |  | @ TEVA PHARMS USA | 20MG/VIAL | N020622 001 | Dec 20, 1996 | Apr | CAHN |

## INJECTABLE; SUBCUTANEOUS

## COPAXONE

|     |   |                 |         |             |              |     |      |
|-----|---|-----------------|---------|-------------|--------------|-----|------|
| >D> | + | TEVA            | 20MG/ML | N020622 002 | Feb 12, 2002 | Apr | CAHN |
| >A> | + | TEVA PHARMS USA | 20MG/ML | N020622 002 | Feb 12, 2002 | Apr | CAHN |

## GLIMEPIRIDE

## TABLET; ORAL

## GLIMEPIRIDE

|     |    |                 |     |             |              |     |      |
|-----|----|-----------------|-----|-------------|--------------|-----|------|
|     |    | @ COREPHARMA    | 1MG | A077274 001 | Oct 06, 2005 | Feb | DISC |
|     |    | @               | 2MG | A077274 002 | Oct 06, 2005 | Feb | DISC |
|     |    | @               | 4MG | A077274 003 | Oct 06, 2005 | Feb | DISC |
| >A> | AB | INDOCO REMEDIES | 1MG | A202112 001 | Apr 17, 2013 | Apr | NEWA |
| >A> | AB |                 | 2MG | A202112 002 | Apr 17, 2013 | Apr | NEWA |
| >A> | AB |                 | 4MG | A202112 003 | Apr 17, 2013 | Apr | NEWA |

## GLIPIZIDE

## TABLET; ORAL

## GLIPIZIDE

|     |    |                     |      |             |              |     |      |
|-----|----|---------------------|------|-------------|--------------|-----|------|
| >A> | AB | ACCORD HLTHCARE     | 5MG  | A074550 001 | Sep 11, 1997 | Apr | CAHN |
| >A> | AB |                     | 10MG | A074550 002 | Sep 11, 1997 | Apr | CAHN |
| >D> | AB | ACCORD HLTHCARE INC | 5MG  | A074550 001 | Sep 11, 1997 | Apr | CAHN |
| >D> | AB |                     | 10MG | A074550 002 | Sep 11, 1997 | Apr | CAHN |

## GLYCEROL PHENYLBUTYRATE

## LIQUID; ORAL

## RAVICTI

|  |   |                     |          |             |              |     |      |
|--|---|---------------------|----------|-------------|--------------|-----|------|
|  | + | HYPERION THERAP INC | 1.1GM/ML | N203284 001 | Feb 01, 2013 | Feb | NEWA |
|--|---|---------------------|----------|-------------|--------------|-----|------|

## GLYCOPYRROLATE

## INJECTABLE; INJECTION

## ROBINUL

|     |    |   |                 |          |             |  |     |      |
|-----|----|---|-----------------|----------|-------------|--|-----|------|
| >D> | AP | + | BAXTER HLTHCARE | 0.2MG/ML | N017558 001 |  | Apr | CAHN |
| >A> | AP | + | HIKMA MAPLE     | 0.2MG/ML | N017558 001 |  | Apr | CAHN |

## TABLET; ORAL

## GLYCOPYRROLATE

|     |    |                     |     |             |              |     |      |
|-----|----|---------------------|-----|-------------|--------------|-----|------|
| >A> | AA | AUROLIFE PHARMA LLC | 1MG | A202675 001 | Apr 15, 2013 | Apr | NEWA |
|     |    | @ COREPHARMA        | 1MG | A040568 001 | Dec 22, 2004 | Mar | DISC |
|     |    | @                   | 2MG | A040568 002 | Dec 22, 2004 | Mar | DISC |

## GRANISETRON HYDROCHLORIDE

## INJECTABLE; INJECTION

## GRANISETRON HYDROCHLORIDE

|     |  |              |                                     |             |              |     |      |
|-----|--|--------------|-------------------------------------|-------------|--------------|-----|------|
| >A> |  | @ APOTEX INC | EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) | A078197 001 | Dec 31, 2007 | Apr | DISC |
| >A> |  | @            | EQ 1MG BASE/ML (EQ 1MG BASE/ML)     | A078198 001 | Jun 30, 2008 | Apr | DISC |
| >A> |  | @            | EQ 4MG BASE/4ML (EQ 1MG BASE/ML)    | A078198 002 | Jun 30, 2008 | Apr | DISC |

## INJECTABLE; INJECTION

## GRANISETRON HYDROCHLORIDE

|     |    |                     |                                     |             |              |     |      |
|-----|----|---------------------|-------------------------------------|-------------|--------------|-----|------|
| >D> | AP | CLARIS LIFESCIENCES | EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) | A078197 001 | Dec 31, 2007 | Apr | DISC |
| >D> | AP |                     | EQ 1MG BASE/ML (EQ 1MG BASE/ML)     | A078198 001 | Jun 30, 2008 | Apr | DISC |
| >D> | AP |                     | EQ 4MG BASE/4ML (EQ 1MG BASE/ML)    | A078198 002 | Jun 30, 2008 | Apr | DISC |
|     |    | @ EBEWE PHARMA      | EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) | A078808 001 | Apr 29, 2008 | Feb | DISC |

## GRISEOFULVIN, MICROSIZE

## SUSPENSION; ORAL

## GRIFULVIN V

|     |    |   |                     |           |             |              |     |      |
|-----|----|---|---------------------|-----------|-------------|--------------|-----|------|
| >A> | AB | + | VALEANT LUXEMBOURG  | 125MG/5ML | A062483 001 | Jan 26, 1984 | Apr | CAHN |
| >D> | AB | + | VALEANT PHARM NORTH | 125MG/5ML | A062483 001 | Jan 26, 1984 | Apr | CAHN |

## HALOBETASOL PROPIONATE

## OINTMENT; TOPICAL

|     |    |   |                        |       |             |              |     |      |
|-----|----|---|------------------------|-------|-------------|--------------|-----|------|
| >D> |    |   | HALOBETASOL PROPIONATE |       |             |              |     |      |
| >D> | AB |   | FOUGERA PHARMS         | 0.05% | A076903 001 | Dec 16, 2004 | Apr | DISC |
| >A> |    | @ |                        | 0.05% | A076903 001 | Dec 16, 2004 | Apr | DISC |
|     |    | @ | TARO                   | 0.05% | A076994 001 | Dec 16, 2004 | Mar | DISC |

## HALOPERIDOL DECANOATE

## INJECTABLE; INJECTION

## HALOPERIDOL DECANOATE

|     |    |   |                     |                  |             |              |     |      |
|-----|----|---|---------------------|------------------|-------------|--------------|-----|------|
| >A> |    | @ | APOTEX INC          | EQ 50MG BASE/ML  | A075440 001 | Feb 28, 2000 | Apr | DISC |
| >A> |    | @ |                     | EQ 100MG BASE/ML | A075440 002 | Feb 28, 2000 | Apr | DISC |
| >D> | A0 |   | CLARIS LIFESCIENCES | EQ 50MG BASE/ML  | A075440 001 | Feb 28, 2000 | Apr | DISC |
| >D> | A0 |   |                     | EQ 100MG BASE/ML | A075440 002 | Feb 28, 2000 | Apr | DISC |

## HALOPERIDOL LACTATE

## INJECTABLE; INJECTION

## HALOPERIDOL

|     |    |   |                     |                |             |              |     |      |
|-----|----|---|---------------------|----------------|-------------|--------------|-----|------|
| >A> |    | @ | APOTEX INC          | EQ 5MG BASE/ML | A076828 001 | Aug 25, 2004 | Apr | DISC |
| >A> |    | @ |                     | EQ 5MG BASE/ML | A076791 001 | Aug 25, 2004 | Apr | DISC |
| >D> | AP |   | CLARIS LIFESCIENCES | EQ 5MG BASE/ML | A076828 001 | Aug 25, 2004 | Apr | DISC |
| >D> | AP |   |                     | EQ 5MG BASE/ML | A076791 001 | Aug 25, 2004 | Apr | DISC |

## HYDRALAZINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## HYDRALAZINE HYDROCHLORIDE

|  |    |  |             |         |             |              |     |      |
|--|----|--|-------------|---------|-------------|--------------|-----|------|
|  | AP |  | NAVINTA LLC | 20MG/ML | A202938 001 | Mar 28, 2013 | Mar | NEWA |
|--|----|--|-------------|---------|-------------|--------------|-----|------|

## TABLET; ORAL

## HYDRALAZINE HYDROCHLORIDE

|     |    |  |                 |       |             |              |     |      |
|-----|----|--|-----------------|-------|-------------|--------------|-----|------|
| >A> | AA |  | ACTAVIS GRP PTC | 10MG  | A091679 001 | Mar 04, 2013 | Apr | CAHN |
| >A> | AA |  |                 | 25MG  | A091679 002 | Mar 04, 2013 | Apr | CAHN |
| >A> | AA |  |                 | 50MG  | A091679 003 | Mar 04, 2013 | Apr | CAHN |
| >A> | AA |  |                 | 100MG | A091679 004 | Mar 04, 2013 | Apr | CAHN |
| >D> | AA |  | ACTAVIS PHARMA  | 10MG  | A091679 001 | Mar 04, 2013 | Apr | CAHN |
|     | AA |  |                 | 10MG  | A091679 001 | Mar 04, 2013 | Feb | NEWA |
| >D> | AA |  |                 | 25MG  | A091679 002 | Mar 04, 2013 | Apr | CAHN |
|     | AA |  |                 | 25MG  | A091679 002 | Mar 04, 2013 | Feb | NEWA |
| >D> | AA |  |                 | 50MG  | A091679 003 | Mar 04, 2013 | Apr | CAHN |
|     | AA |  |                 | 50MG  | A091679 003 | Mar 04, 2013 | Feb | NEWA |
| >D> | AA |  |                 | 100MG | A091679 004 | Mar 04, 2013 | Apr | CAHN |
|     | AA |  |                 | 100MG | A091679 004 | Mar 04, 2013 | Feb | NEWA |

## TABLET; ORAL

## HYDRALAZINE HYDROCHLORIDE

|     |    |                      |       |         |     |              |     |      |
|-----|----|----------------------|-------|---------|-----|--------------|-----|------|
| >D> | AB | ALKEM LABS LTD       | 10MG  | A200737 | 001 | Dec 07, 2012 | Apr | CTEC |
| >A> | AA |                      | 10MG  | A200737 | 001 | Dec 07, 2012 | Apr | CTEC |
| >D> | AB |                      | 25MG  | A200737 | 002 | Dec 07, 2012 | Apr | CTEC |
| >A> | AA |                      | 25MG  | A200737 | 002 | Dec 07, 2012 | Apr | CTEC |
| >D> | AB |                      | 50MG  | A200737 | 003 | Dec 07, 2012 | Apr | CTEC |
| >A> | AA |                      | 50MG  | A200737 | 003 | Dec 07, 2012 | Apr | CTEC |
| >D> | AB |                      | 100MG | A200737 | 004 | Dec 07, 2012 | Apr | CTEC |
| >A> | AA |                      | 100MG | A200737 | 004 | Dec 07, 2012 | Apr | CTEC |
| >A> | AA | HETERO LABS LTD III  | 10MG  | A040901 | 001 | Sep 12, 2008 | Apr | CAHN |
| >A> | AA |                      | 25MG  | A040901 | 002 | Sep 12, 2008 | Apr | CAHN |
| >A> | AA |                      | 50MG  | A040901 | 003 | Sep 12, 2008 | Apr | CAHN |
| >A> | AA |                      | 100MG | A040901 | 004 | Sep 12, 2008 | Apr | CAHN |
| >D> | AA | HETERO LABS UNIT III | 10MG  | A040901 | 001 | Sep 12, 2008 | Apr | CAHN |
| >D> | AA |                      | 25MG  | A040901 | 002 | Sep 12, 2008 | Apr | CAHN |
| >D> | AA |                      | 50MG  | A040901 | 003 | Sep 12, 2008 | Apr | CAHN |
| >D> | AA |                      | 100MG | A040901 | 004 | Sep 12, 2008 | Apr | CAHN |
| >A> | AA | STRIDES ARCOLAB LTD  | 25MG  | A200770 | 001 | May 03, 2013 | Apr | NEWA |
| >A> | AA |                      | 50MG  | A200770 | 002 | May 03, 2013 | Apr | NEWA |
| >A> | AA |                      | 100MG | A200770 | 003 | May 03, 2013 | Apr | NEWA |

HYDROCHLOROTHIAZIDE

## TABLET; ORAL

## HYDROCHLOROTHIAZIDE

|               |      |         |     |              |     |      |
|---------------|------|---------|-----|--------------|-----|------|
| @ WATSON LABS | 25MG | A081189 | 001 | Jan 24, 1992 | Mar | DISC |
|---------------|------|---------|-----|--------------|-----|------|

HYDROCHLOROTHIAZIDE; IRBESARTAN

## TABLET; ORAL

## IRBESARTAN AND HYDROCHLOROTHIAZIDE

|    |                      |              |         |     |              |     |      |
|----|----------------------|--------------|---------|-----|--------------|-----|------|
| AB | AUROBINDO PHARMA LTD | 12.5MG;150MG | A203630 | 001 | Feb 22, 2013 | Feb | NEWA |
| AB |                      | 12.5MG;300MG | A203630 | 002 | Feb 22, 2013 | Feb | NEWA |
| AB | LUPIN LTD            | 12.5MG;150MG | A201524 | 001 | Feb 27, 2013 | Feb | NEWA |
| AB |                      | 12.5MG;300MG | A201524 | 002 | Feb 27, 2013 | Feb | NEWA |

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

## TABLET; ORAL

## LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

|    |               |              |         |     |              |     |      |
|----|---------------|--------------|---------|-----|--------------|-----|------|
| AB | IPCA LABS LTD | 12.5MG;50MG  | A201682 | 001 | Mar 01, 2013 | Feb | NEWA |
| AB |               | 12.5MG;100MG | A201682 | 002 | Mar 01, 2013 | Feb | NEWA |
| AB |               | 25MG;100MG   | A201682 | 003 | Mar 01, 2013 | Feb | NEWA |

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

## TABLET; ORAL

## QUINAPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

|    |             |                     |         |     |              |     |      |
|----|-------------|---------------------|---------|-----|--------------|-----|------|
| AB | APOTEX CORP | 12.5MG;EQ 10MG BASE | A091524 | 001 | Mar 12, 2013 | Mar | NEWA |
| AB |             | 12.5MG;EQ 20MG BASE | A091524 | 002 | Mar 12, 2013 | Mar | NEWA |
| AB |             | 25MG;EQ 20MG BASE   | A091524 | 003 | Mar 12, 2013 | Mar | NEWA |

HYDROCHLOROTHIAZIDE; TRIAMTERENE

## TABLET; ORAL

## TRIAMTERENE AND HYDROCHLOROTHIAZIDE

|               |           |         |     |              |     |      |
|---------------|-----------|---------|-----|--------------|-----|------|
| @ WATSON LABS | 50MG;75MG | A071969 | 001 | Apr 17, 1988 | Jan | DISC |
|---------------|-----------|---------|-----|--------------|-----|------|

HYDROCHLOROTHIAZIDE; VALSARTAN

## TABLET; ORAL

## VALSARTAN AND HYDROCHLOROTHIAZIDE

|     |                      |                     |         |     |              |     |      |
|-----|----------------------|---------------------|---------|-----|--------------|-----|------|
| AB  | ALEMBIC LTD          | 12.5MG;80MG         | A201662 | 001 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 12.5MG;160MG        | A201662 | 002 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 12.5MG;320MG        | A201662 | 003 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 25MG;160MG          | A201662 | 004 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 25MG;320MG          | A201662 | 005 | Mar 21, 2013 | Mar | NEWA |
| AB  | APOTEX INC           | 12.5MG;80MG         | A203026 | 001 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 12.5MG;160MG        | A203026 | 002 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 12.5MG;320MG        | A203026 | 003 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 25MG;160MG          | A203026 | 004 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 25MG;320MG          | A203026 | 005 | Mar 21, 2013 | Mar | NEWA |
| AB  | AUROBINDO PHARMA LTD | 12.5MG;80MG         | A202519 | 001 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 12.5MG;160MG        | A202519 | 002 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 12.5MG;320MG        | A202519 | 003 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 25MG;160MG          | A202519 | 004 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 25MG;320MG          | A202519 | 005 | Mar 21, 2013 | Mar | NEWA |
| AB  | LUPIN LTD            | 12.5MG;80MG         | A078946 | 003 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 12.5MG;160MG        | A078946 | 004 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 12.5MG;320MG        | A078946 | 001 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 25MG;160MG          | A078946 | 005 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 25MG;320MG          | A078946 | 002 | Mar 21, 2013 | Mar | NEWA |
| >A> | AB                   | MACLEODS PHARMS LTD | A203145 | 001 | Apr 19, 2013 | Apr | NEWA |
| >A> | AB                   |                     | A203145 | 002 | Apr 19, 2013 | Apr | NEWA |
| >A> | AB                   |                     | A203145 | 003 | Apr 19, 2013 | Apr | NEWA |
| >A> | AB                   |                     | A203145 | 004 | Apr 19, 2013 | Apr | NEWA |
| >A> | AB                   |                     | A203145 | 005 | Apr 19, 2013 | Apr | NEWA |
| AB  | WATSON LABS INC      | 12.5MG;80MG         | A091519 | 001 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 12.5MG;160MG        | A091519 | 002 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 12.5MG;320MG        | A091519 | 003 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 25MG;160MG          | A091519 | 004 | Mar 21, 2013 | Mar | NEWA |
| AB  |                      | 25MG;320MG          | A091519 | 005 | Mar 21, 2013 | Mar | NEWA |

HYDROCORTISONE

## LOTION; TOPICAL

## STIE-CORT

## @ PERRIGO CO

1%

A089066 001 Nov 25, 1985 Feb DISC

## OINTMENT; TOPICAL

## HYDROCORTISONE

## @ TARO

2.5%

A040310 001 Dec 29, 2000 Mar DISC

HYDROCORTISONE ACETATE

## PASTE; TOPICAL

## ORABASE HCA

## @ COLGATE

0.5%

A083205 001 Mar DISC

HYDROCORTISONE VALERATE

## OINTMENT; TOPICAL

## HYDROCORTISONE VALERATE

## @ FOUGERA PHARMS

0.2%

A075085 001 Jul 31, 2001 Feb DISC

## + TARO

0.2%

A075043 001 Aug 25, 1998 Feb CRLD

## WESTCORT

## @ RANBAXY

0.2%

N018726 001 Aug 08, 1983 Feb DISC

HYDROMORPHONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL  
EXALGO

MALLINCKRODT INC 16MG  
+ 32MG

N021217 003 Mar 01, 2010 Jan CRLD

N021217 004 Aug 24, 2012 Jan CRLD

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HYDROCHLORIDE

>A> AB HETERO LABS LTD III 10MG  
>A> AB 25MG  
>A> AB 50MG  
>D> AB HETERO LABS UNIT III 10MG  
>D> AB 25MG  
>D> AB 50MG

A040805 001 May 29, 2008 Apr CAHN

A040805 002 May 29, 2008 Apr CAHN

A040805 003 May 29, 2008 Apr CAHN

A040805 001 May 29, 2008 Apr CAHN

A040805 002 May 29, 2008 Apr CAHN

A040805 003 May 29, 2008 Apr CAHN

IDARUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

IDARUBICIN HYDROCHLORIDE PFS

>D> AP TEVA PARENTERAL 1MG/ML  
>A> AP TEVA PHARMS USA 1MG/ML

A065036 001 May 01, 2002 Apr CAHN

A065036 001 May 01, 2002 Apr CAHN

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HYDROCHLORIDE

@ PROSAM LABS 10MG  
@ 25MG  
@ 50MG

A040753 001 Feb 28, 2008 Mar DISC

A040752 001 Feb 28, 2008 Mar DISC

A040751 001 Feb 28, 2008 Mar DISC

INDOMETHACIN

CAPSULE; ORAL

INDOCIN

@ ICEUTICA OPERATIONS 25MG  
@ 50MG

N016059 001 Mar CAHN

N016059 002 Mar CAHN

INDOMETHACIN

>A> AB HETERO LABS LTD III 25MG  
>A> AB 50MG  
>D> AB HETERO LABS UNIT III 25MG  
>D> AB 50MG  
AB SUN PHARM INDS INC 25MG  
AB 50MG

A091240 001 Apr 12, 2011 Apr CAHN

A091240 002 Apr 12, 2011 Apr CAHN

A091240 001 Apr 12, 2011 Apr CAHN

A091240 002 Apr 12, 2011 Apr CAHN

A091401 001 Mar 28, 2013 Mar NEWA

A091401 002 Mar 28, 2013 Mar NEWA

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPRATROPIUM BROMIDE

>A> @ APOTEX INC 0.02%  
>D> AN NOVEX 0.02%  
@ TEVA PHARMS USA 0.02%

A075441 001 Mar 28, 2001 Apr DISC

A075441 001 Mar 28, 2001 Apr DISC

A075313 001 Feb 07, 2000 Mar DISC

SPRAY, METERED; NASAL

IPRATROPIUM BROMIDE

>A> @ APOTEX INC 0.021MG/SPRAY  
>A> @ 0.042MG/SPRAY  
>D> AB NOVEX 0.021MG/SPRAY  
>D> AB 0.042MG/SPRAY

A076156 001 Apr 18, 2003 Apr DISC

A076155 001 Apr 18, 2003 Apr DISC

A076156 001 Apr 18, 2003 Apr DISC

A076155 001 Apr 18, 2003 Apr DISC

IRON SUCROSE

INJECTABLE; INTRAVENOUS  
VENOFER

LUITPOLD

EQ 65MG BASE/3.25ML (EQ 20MG  
BASE/ML)

N021135 005 Mar 29, 2013 Mar NEWA

ISONIAZID; RIFAMPIN

CAPSULE; ORAL  
RIFAMATE

>D> AB + SANOFI AVENTIS US 150MG;300MG  
>A> + 150MG;300MG

A061884 001 Apr CTEC  
A061884 001 Apr CTEC

RIFAMPIN AND ISONIAZID

>A> @ WEST WARD PHARM CORP 150MG;300MG  
>D> AB WESTWARD 150MG;300MG

A065221 001 Jul 29, 2005 Apr DISC  
A065221 001 Jul 29, 2005 Apr DISC

ISOPROTERENOL HYDROCHLORIDE

INJECTABLE; INJECTION  
ISOPROTERENOL HYDROCHLORIDE

@ INTL MEDICATION 0.2MG/ML

A083724 001 Mar DISC

ISUPREL

+ HOSPIRA 0.2MG/ML

N010515 001 Mar CTEC

ISOSORBIDE DINITRATE

TABLET; ORAL  
ISORDIL

>A> AB VALEANT BERMUDA 5MG  
>A> AB 10MG  
>A> AB 20MG  
>A> AB + 30MG  
>A> + 40MG  
>D> AB VALEANT PHARM NORTH 5MG  
AB 5MG  
>D> AB 10MG  
AB 10MG  
>D> AB 20MG  
AB 20MG  
>D> AB + 30MG  
AB + 30MG  
>D> + 40MG  
+ 40MG

N012093 007 Jul 29, 1988 Apr CAHN  
N012093 002 Jul 29, 1988 Apr CAHN  
N012093 006 Jul 29, 1988 Apr CAHN  
N012093 005 Jul 29, 1988 Apr CAHN  
N012093 001 Jul 29, 1988 Apr CAHN  
N012093 007 Jul 29, 1988 Apr CAHN  
N012093 007 Jul 29, 1988 Mar CAHN  
N012093 002 Jul 29, 1988 Apr CAHN  
N012093 002 Jul 29, 1988 Mar CAHN  
N012093 006 Jul 29, 1988 Apr CAHN  
N012093 006 Jul 29, 1988 Mar CAHN  
N012093 005 Jul 29, 1988 Apr CAHN  
N012093 005 Jul 29, 1988 Mar CAHN  
N012093 001 Jul 29, 1988 Apr CAHN  
N012093 001 Jul 29, 1988 Mar CAHN

ISOSORBIDE DINITRATE

>D> @ PAR PHARM 5MG  
>A> AB 5MG  
@ 5MG  
>D> AB WATSON LABS 5MG  
>A> @ 5MG  
>D> AB 10MG  
>A> @ 10MG

A086923 001 Mar 12, 1987 Apr CMFD  
A086923 001 Mar 12, 1987 Apr CMFD  
A086923 001 Mar 12, 1987 Feb DISC  
A086034 001 Jan 06, 1988 Apr DISC  
A086034 001 Jan 06, 1988 Apr DISC  
A086032 001 Jan 07, 1988 Apr DISC  
A086032 001 Jan 07, 1988 Apr DISC

ISOTRETINOIN

CAPSULE; ORAL  
ABSORICA

BX RANBAXY 10MG  
BX 20MG  
BX 30MG

N021951 001 May 25, 2012 Feb CAHN  
N021951 002 May 25, 2012 Feb CAHN  
N021951 003 May 25, 2012 Feb CAHN

CAPSULE; ORALABSORICA

|    |  |         |      |             |              |     |      |
|----|--|---------|------|-------------|--------------|-----|------|
| BX |  | RANBAXY | 40MG | N021951 004 | May 25, 2012 | Feb | CAHN |
|----|--|---------|------|-------------|--------------|-----|------|

AMNESTEEM

|     |    |   |       |      |             |              |     |      |
|-----|----|---|-------|------|-------------|--------------|-----|------|
| >D> | AB | + | MYLAN | 20MG | A075945 002 | Nov 08, 2002 | Apr | CRLD |
|-----|----|---|-------|------|-------------|--------------|-----|------|

|     |    |  |                  |      |             |              |     |      |
|-----|----|--|------------------|------|-------------|--------------|-----|------|
| >A> | AB |  | MYLAN PHARMS INC | 20MG | A075945 002 | Nov 08, 2002 | Apr | CRLD |
|-----|----|--|------------------|------|-------------|--------------|-----|------|

CLARAVIS

|     |    |  |      |      |             |              |     |      |
|-----|----|--|------|------|-------------|--------------|-----|------|
| >D> | AB |  | BARR | 30MG | A076135 003 | May 11, 2006 | Apr | CRLD |
|-----|----|--|------|------|-------------|--------------|-----|------|

|     |    |  |  |      |             |              |     |      |
|-----|----|--|--|------|-------------|--------------|-----|------|
| >D> | AB |  |  | 40MG | A076135 001 | Apr 11, 2003 | Apr | CRLD |
|-----|----|--|--|------|-------------|--------------|-----|------|

|     |    |  |                 |      |             |              |     |      |
|-----|----|--|-----------------|------|-------------|--------------|-----|------|
| >A> | AB |  | TEVA PHARMS USA | 30MG | A076135 003 | May 11, 2006 | Apr | CRLD |
|-----|----|--|-----------------|------|-------------|--------------|-----|------|

|     |    |   |  |      |             |              |     |      |
|-----|----|---|--|------|-------------|--------------|-----|------|
| >A> | AB | + |  | 40MG | A076135 001 | Apr 11, 2003 | Apr | CRLD |
|-----|----|---|--|------|-------------|--------------|-----|------|

ZENATANE

|    |  |  |                    |      |             |              |     |      |
|----|--|--|--------------------|------|-------------|--------------|-----|------|
| AB |  |  | DR REDDYS LABS LTD | 10MG | A202099 001 | Mar 25, 2013 | Mar | NEWA |
|----|--|--|--------------------|------|-------------|--------------|-----|------|

|    |  |  |  |      |             |              |     |      |
|----|--|--|--|------|-------------|--------------|-----|------|
| AB |  |  |  | 20MG | A202099 002 | Mar 25, 2013 | Mar | NEWA |
|----|--|--|--|------|-------------|--------------|-----|------|

|    |  |  |  |      |             |              |     |      |
|----|--|--|--|------|-------------|--------------|-----|------|
| AB |  |  |  | 40MG | A202099 003 | Mar 25, 2013 | Mar | NEWA |
|----|--|--|--|------|-------------|--------------|-----|------|

KETOROLAC TROMETHAMINEINJECTABLE; INJECTIONKETOROLAC TROMETHAMINE

|     |  |  |              |         |             |              |     |      |
|-----|--|--|--------------|---------|-------------|--------------|-----|------|
| >A> |  |  | @ APOTEX INC | 15MG/ML | A075631 002 | Jun 29, 2001 | Apr | DISC |
|-----|--|--|--------------|---------|-------------|--------------|-----|------|

|     |  |  |   |         |             |              |     |      |
|-----|--|--|---|---------|-------------|--------------|-----|------|
| >D> |  |  | @ | 30MG/ML | A075626 001 | Jul 24, 2001 | Apr | DISC |
|-----|--|--|---|---------|-------------|--------------|-----|------|

|     |  |  |   |         |             |              |     |      |
|-----|--|--|---|---------|-------------|--------------|-----|------|
| >D> |  |  | @ | 30MG/ML | A077201 001 | Oct 14, 2005 | Apr | DISC |
|-----|--|--|---|---------|-------------|--------------|-----|------|

|     |  |  |   |         |             |              |     |      |
|-----|--|--|---|---------|-------------|--------------|-----|------|
| >A> |  |  | @ | 30MG/ML | A075626 001 | Jul 24, 2001 | Apr | DISC |
|-----|--|--|---|---------|-------------|--------------|-----|------|

|     |  |  |   |         |             |              |     |      |
|-----|--|--|---|---------|-------------|--------------|-----|------|
| >A> |  |  | @ | 30MG/ML | A077201 001 | Oct 14, 2005 | Apr | DISC |
|-----|--|--|---|---------|-------------|--------------|-----|------|

|     |  |  |   |         |             |              |     |      |
|-----|--|--|---|---------|-------------|--------------|-----|------|
| >A> |  |  | @ | 30MG/ML | A075631 001 | Jun 29, 2001 | Apr | DISC |
|-----|--|--|---|---------|-------------|--------------|-----|------|

|     |    |  |                     |         |             |              |     |      |
|-----|----|--|---------------------|---------|-------------|--------------|-----|------|
| >D> | AP |  | CLARIS LIFESCIENCES | 15MG/ML | A075631 002 | Jun 29, 2001 | Apr | DISC |
|-----|----|--|---------------------|---------|-------------|--------------|-----|------|

|     |    |  |  |         |             |              |     |      |
|-----|----|--|--|---------|-------------|--------------|-----|------|
| >D> | AP |  |  | 30MG/ML | A075631 001 | Jun 29, 2001 | Apr | DISC |
|-----|----|--|--|---------|-------------|--------------|-----|------|

LABETALOL HYDROCHLORIDEINJECTABLE; INJECTIONLABETALOL HYDROCHLORIDE

|     |  |  |              |        |             |              |     |      |
|-----|--|--|--------------|--------|-------------|--------------|-----|------|
| >A> |  |  | @ APOTEX INC | 5MG/ML | A076051 001 | Jul 05, 2002 | Apr | DISC |
|-----|--|--|--------------|--------|-------------|--------------|-----|------|

|     |    |  |                     |        |             |              |     |      |
|-----|----|--|---------------------|--------|-------------|--------------|-----|------|
| >D> | AP |  | CLARIS LIFESCIENCES | 5MG/ML | A076051 001 | Jul 05, 2002 | Apr | DISC |
|-----|----|--|---------------------|--------|-------------|--------------|-----|------|

TABLET; ORALLABETALOL HYDROCHLORIDE

|    |   |  |        |       |             |              |     |      |
|----|---|--|--------|-------|-------------|--------------|-----|------|
| AB | + |  | SANDOZ | 200MG | A075113 002 | Aug 04, 1998 | Jan | CRLD |
|----|---|--|--------|-------|-------------|--------------|-----|------|

TRANDATE

|  |  |  |                   |       |             |              |     |      |
|--|--|--|-------------------|-------|-------------|--------------|-----|------|
|  |  |  | @ PROMETHEUS LABS | 100MG | N018716 001 | May 24, 1985 | Jan | DISC |
|--|--|--|-------------------|-------|-------------|--------------|-----|------|

|  |  |  |   |       |             |              |     |      |
|--|--|--|---|-------|-------------|--------------|-----|------|
|  |  |  | @ | 200MG | N018716 002 | Aug 01, 1984 | Jan | DISC |
|--|--|--|---|-------|-------------|--------------|-----|------|

LACTULOSESOLUTION; ORALLACTULOSE

|     |  |  |              |           |             |              |     |      |
|-----|--|--|--------------|-----------|-------------|--------------|-----|------|
| >A> |  |  | @ APOTEX INC | 10GM/15ML | A075911 001 | Feb 21, 2002 | Apr | DISC |
|-----|--|--|--------------|-----------|-------------|--------------|-----|------|

|     |    |  |       |           |             |              |     |      |
|-----|----|--|-------|-----------|-------------|--------------|-----|------|
| >D> | AA |  | NOVEX | 10GM/15ML | A075911 001 | Feb 21, 2002 | Apr | DISC |
|-----|----|--|-------|-----------|-------------|--------------|-----|------|

SOLUTION; ORAL, RECTALLACTULOSE

|     |  |  |              |           |             |              |     |      |
|-----|--|--|--------------|-----------|-------------|--------------|-----|------|
| >A> |  |  | @ APOTEX INC | 10GM/15ML | A076645 001 | Jul 28, 2003 | Apr | DISC |
|-----|--|--|--------------|-----------|-------------|--------------|-----|------|

|     |    |  |       |           |             |              |     |      |
|-----|----|--|-------|-----------|-------------|--------------|-----|------|
| >D> | AA |  | NOVEX | 10GM/15ML | A076645 001 | Jul 28, 2003 | Apr | DISC |
|-----|----|--|-------|-----------|-------------|--------------|-----|------|

LAMOTRIGINETABLET; ORALLAMICTAL

|    |   |  |                     |      |             |              |     |      |
|----|---|--|---------------------|------|-------------|--------------|-----|------|
| AB | + |  | GLAXOSMITHKLINE LLC | 25MG | N020241 005 | Dec 27, 1994 | Mar | CAHN |
|----|---|--|---------------------|------|-------------|--------------|-----|------|

|  |  |  |   |      |             |              |     |      |
|--|--|--|---|------|-------------|--------------|-----|------|
|  |  |  | @ | 50MG | N020241 006 | Dec 27, 1994 | Mar | CAHN |
|--|--|--|---|------|-------------|--------------|-----|------|

|    |  |  |  |       |             |              |     |      |
|----|--|--|--|-------|-------------|--------------|-----|------|
| AB |  |  |  | 100MG | N020241 001 | Dec 27, 1994 | Mar | CAHN |
|----|--|--|--|-------|-------------|--------------|-----|------|

## TABLET; ORAL

## LAMICTAL

|    |                     |       |             |              |     |      |
|----|---------------------|-------|-------------|--------------|-----|------|
| AB | GLAXOSMITHKLINE LLC | 150MG | N020241 002 | Dec 27, 1994 | Mar | CAHN |
| AB |                     | 200MG | N020241 003 | Dec 27, 1994 | Mar | CAHN |
|    | @                   | 250MG | N020241 004 | Dec 27, 1994 | Mar | CAHN |

## TABLET, CHEWABLE; ORAL

## LAMICTAL CD

|    |                     |       |             |              |     |      |
|----|---------------------|-------|-------------|--------------|-----|------|
| AB | GLAXOSMITHKLINE LLC | 2MG   | N020764 004 | Sep 08, 2000 | Mar | CAHN |
| AB |                     | 5MG   | N020764 001 | Aug 24, 1998 | Mar | CAHN |
| AB | +                   | 25MG  | N020764 002 | Aug 24, 1998 | Mar | CAHN |
|    | @                   | 100MG | N020764 003 | Aug 24, 1998 | Mar | CAHN |

## TABLET, EXTENDED RELEASE; ORAL

## LAMICTAL XR

|    |                     |       |             |              |     |      |
|----|---------------------|-------|-------------|--------------|-----|------|
| AB | GLAXOSMITHKLINE LLC | 25MG  | N022115 001 | May 29, 2009 | Mar | CAHN |
| AB | +                   | 50MG  | N022115 002 | May 29, 2009 | Mar | CAHN |
| AB |                     | 100MG | N022115 003 | May 29, 2009 | Mar | CAHN |
| AB |                     | 200MG | N022115 004 | May 29, 2009 | Mar | CAHN |
| AB |                     | 250MG | N022115 006 | Jun 21, 2011 | Mar | CAHN |
| AB |                     | 300MG | N022115 005 | Apr 14, 2010 | Mar | CAHN |

## LAMOTRIGINE

|    |           |       |             |              |     |      |
|----|-----------|-------|-------------|--------------|-----|------|
| AB | PAR PHARM | 25MG  | A201791 001 | Jan 18, 2013 | Jan | NEWA |
| AB |           | 50MG  | A201791 002 | Jan 18, 2013 | Jan | NEWA |
| AB |           | 100MG | A201791 003 | Jan 18, 2013 | Jan | NEWA |
| AB |           | 200MG | A201791 004 | Jan 18, 2013 | Jan | NEWA |
| AB |           | 250MG | A201791 005 | Jan 18, 2013 | Jan | NEWA |
| AB |           | 300MG | A201791 006 | Jan 18, 2013 | Jan | NEWA |

## TABLET, ORALLY DISINTEGRATING; ORAL

## LAMICTAL ODT

|   |                     |       |             |              |     |      |
|---|---------------------|-------|-------------|--------------|-----|------|
|   | GLAXOSMITHKLINE LLC | 25MG  | N022251 001 | May 08, 2009 | Mar | CAHN |
| + |                     | 50MG  | N022251 002 | May 08, 2009 | Mar | CAHN |
|   |                     | 100MG | N022251 003 | May 08, 2009 | Mar | CAHN |
|   |                     | 200MG | N022251 004 | May 08, 2009 | Mar | CAHN |

LATANOPROST

## SOLUTION/DROPS; OPHTHALMIC

## LATANOPROST

|     |    |                    |        |             |              |     |      |
|-----|----|--------------------|--------|-------------|--------------|-----|------|
| >D> | AT | APOTEX             | 0.005% | A077697 001 | Mar 22, 2011 | Apr | DISC |
| >A> |    | @ APOTEX INC       | 0.005% | A077697 001 | Mar 22, 2011 | Apr | DISC |
|     | AT | DR REDDYS LABS LTD | 0.005% | A202077 001 | Feb 11, 2013 | Jan | NEWA |

LETROZOLE

## TABLET; ORAL

## LETROZOLE

|     |    |                     |       |             |              |     |      |
|-----|----|---------------------|-------|-------------|--------------|-----|------|
| >A> | AB | JIANGSU HENGRUI MED | 2.5MG | A202716 001 | May 16, 2013 | Apr | NEWA |
|-----|----|---------------------|-------|-------------|--------------|-----|------|

LEUCOVORIN CALCIUM

## INJECTABLE; INJECTION

## LEUCOVORIN CALCIUM

|    |                 |                    |             |              |     |      |
|----|-----------------|--------------------|-------------|--------------|-----|------|
| AP | TEVA PHARMS USA | EQ 100MG BASE/VIAL | A081277 001 | Sep 28, 1993 | Mar | CAHN |
| AP |                 | EQ 350MG BASE/VIAL | A040174 001 | Jun 12, 1997 | Mar | CAHN |

LEUPROLIDE ACETATE

## INJECTABLE; INJECTION

## LEUPROLIDE ACETATE

|    |                 |           |             |              |     |      |
|----|-----------------|-----------|-------------|--------------|-----|------|
| AP | TEVA PHARMS USA | 1MG/0.2ML | A075471 001 | Oct 25, 2000 | Mar | CAHN |
|----|-----------------|-----------|-------------|--------------|-----|------|

## INJECTABLE; INJECTION

## LUPRON DEPOT

|     |   |                      |             |         |     |              |     |      |
|-----|---|----------------------|-------------|---------|-----|--------------|-----|------|
| >D> | + | ABBOTT ENDOCRINE     | 3.75MG/VIAL | N020011 | 001 | Oct 22, 1990 | Apr | CAHN |
| >A> | + | ABBVIE ENDOCRINE INC | 3.75MG/VIAL | N020011 | 001 | Oct 22, 1990 | Apr | CAHN |

LEVALBUTEROL HYDROCHLORIDE

## SOLUTION; INHALATION

## LEVALBUTEROL HYDROCHLORIDE

|     |     |                 |                 |         |              |              |      |      |
|-----|-----|-----------------|-----------------|---------|--------------|--------------|------|------|
| AN  | DEY | EQ 0.0103% BASE | A077800         | 001     | Mar 15, 2013 | Mar          | NEWA |      |
| AN  |     | EQ 0.021% BASE  | A077800         | 002     | Mar 15, 2013 | Mar          | NEWA |      |
| AN  |     | EQ 0.042% BASE  | A077800         | 003     | Mar 15, 2013 | Mar          | NEWA |      |
| >A> | AN  | TEVA PHARMS USA | EQ 0.0103% BASE | A090297 | 001          | Apr 26, 2013 | Apr  | NEWA |
| >A> | AN  |                 | EQ 0.021% BASE  | A090297 | 002          | Apr 26, 2013 | Apr  | NEWA |
| >A> | AN  |                 | EQ 0.042% BASE  | A090297 | 003          | Apr 26, 2013 | Apr  | NEWA |

LEVETIRACETAM

## SOLUTION; ORAL

## LEVETIRACETAM

|     |    |                     |          |         |     |              |     |      |
|-----|----|---------------------|----------|---------|-----|--------------|-----|------|
| >D> | AA | APOTEX              | 100MG/ML | A090187 | 001 | Aug 05, 2011 | Apr | DISC |
| >A> |    | @ APOTEX INC        | 100MG/ML | A090187 | 001 | Aug 05, 2011 | Apr | DISC |
| >D> | AA | HETERO DRUGS LTD    | 100MG/ML | A203052 | 001 | Feb 28, 2013 | Apr | CAHN |
|     | AA |                     | 100MG/ML | A203052 | 001 | Feb 28, 2013 | Feb | NEWA |
| >A> | AA | HETERO LABS LTD III | 100MG/ML | A203052 | 001 | Feb 28, 2013 | Apr | CAHN |
| >A> | AA | ORIT LABS LLC       | 100MG/ML | A203067 | 001 | May 09, 2013 | Apr | NEWA |

## TABLET; ORAL

## LEVETIRACETAM

|     |    |                     |       |         |     |              |     |      |
|-----|----|---------------------|-------|---------|-----|--------------|-----|------|
| >D> | AB | HETERO DRUGS LTD    | 250MG | A090515 | 001 | Oct 08, 2010 | Apr | CAHN |
| >D> | AB |                     | 500MG | A090515 | 002 | Oct 08, 2010 | Apr | CAHN |
| >D> | AB |                     | 750MG | A090515 | 003 | Oct 08, 2010 | Apr | CAHN |
| >D> | AB |                     | 1GM   | A090515 | 004 | Oct 08, 2010 | Apr | CAHN |
| >A> | AB | HETERO LABS LTD III | 250MG | A090515 | 001 | Oct 08, 2010 | Apr | CAHN |
| >A> | AB |                     | 500MG | A090515 | 002 | Oct 08, 2010 | Apr | CAHN |
| >A> | AB |                     | 750MG | A090515 | 003 | Oct 08, 2010 | Apr | CAHN |
| >A> | AB |                     | 1GM   | A090515 | 004 | Oct 08, 2010 | Apr | CAHN |
| >A> | AB | PRINSTON INC        | 250MG | A078106 | 001 | Feb 10, 2009 | Apr | CAHN |
| >A> | AB |                     | 500MG | A078106 | 002 | Feb 10, 2009 | Apr | CAHN |
| >A> | AB |                     | 750MG | A078106 | 003 | Feb 10, 2009 | Apr | CAHN |
| >A> | AB |                     | 1GM   | A078106 | 004 | Feb 10, 2009 | Apr | CAHN |
| >D> | AB | SOLCO HLTHCARE      | 250MG | A078106 | 001 | Feb 10, 2009 | Apr | CAHN |
| >D> | AB |                     | 500MG | A078106 | 002 | Feb 10, 2009 | Apr | CAHN |
| >D> | AB |                     | 750MG | A078106 | 003 | Feb 10, 2009 | Apr | CAHN |
| >D> | AB |                     | 1GM   | A078106 | 004 | Feb 10, 2009 | Apr | CAHN |

## TABLET, EXTENDED RELEASE; ORAL

## LEVETIRACETAM

|    |  |                    |       |         |     |              |     |      |
|----|--|--------------------|-------|---------|-----|--------------|-----|------|
|    |  | @ SANDOZ           | 500MG | A091668 | 001 | Nov 01, 2012 | Mar | DISC |
|    |  | @                  | 750MG | A091668 | 002 | Nov 01, 2012 | Mar | DISC |
| AB |  | VINTAGE PHARMS LLC | 500MG | A202533 | 001 | Jul 20, 2012 | Jan | NEWA |
| AB |  |                    | 750MG | A202533 | 002 | Jul 20, 2012 | Jan | NEWA |

LEVOBUNOLOL HYDROCHLORIDE

## SOLUTION/DROPS; OPHTHALMIC

## LEVOBUNOLOL HYDROCHLORIDE

|     |    |              |       |         |     |              |     |      |
|-----|----|--------------|-------|---------|-----|--------------|-----|------|
| >A> |    | @ APOTEX INC | 0.25% | A075473 | 001 | Aug 03, 2000 | Apr | DISC |
| >A> |    | @            | 0.5%  | A075475 | 001 | Aug 03, 2000 | Apr | DISC |
| >D> | AT | NOVEX        | 0.25% | A075473 | 001 | Aug 03, 2000 | Apr | DISC |
| >D> | AT |              | 0.5%  | A075475 | 001 | Aug 03, 2000 | Apr | DISC |

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET; ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

|    |                   |     |         |     |              |     |      |
|----|-------------------|-----|---------|-----|--------------|-----|------|
| AB | SANDOZ            | 5MG | A090486 | 001 | Mar 26, 2013 | Mar | NEWA |
| AB | SUN PHARMA GLOBAL | 5MG | A090362 | 001 | Jan 31, 2013 | Jan | NEWA |

LEVOFLOXACIN

INJECTABLE; INJECTION

LEVOFLOXACIN

|    |                      |                            |         |     |              |     |      |
|----|----------------------|----------------------------|---------|-----|--------------|-----|------|
| AP | AUROBINDO PHARMA LTD | EQ 500MG/20ML (EQ 25MG/ML) | A202328 | 001 | Jan 24, 2013 | Jan | NEWA |
| AP |                      | EQ 750MG/30ML (EQ 25MG/ML) | A202328 | 002 | Jan 24, 2013 | Jan | NEWA |
| AP | EMCURE PHARMS LTD    | EQ 500MG/20ML (EQ 25MG/ML) | A202590 | 001 | Jan 24, 2013 | Jan | NEWA |
| AP |                      | EQ 750MG/30ML (EQ 25MG/ML) | A202590 | 002 | Jan 24, 2013 | Jan | NEWA |

SOLUTION/DROPS; OPHTHALMIC

LEVOFLOXACIN

|     |    |              |      |         |     |              |     |      |
|-----|----|--------------|------|---------|-----|--------------|-----|------|
| >D> | AT | APOTEX       | 0.5% | A078282 | 001 | Dec 20, 2010 | Apr | DISC |
| >A> |    | @ APOTEX INC | 0.5% | A078282 | 001 | Dec 20, 2010 | Apr | DISC |

LEVONORGESTREL

INTRAUTERINE DEVICE; INTRAUTERINE

SKYLA

|   |                |        |         |     |              |     |      |
|---|----------------|--------|---------|-----|--------------|-----|------|
| + | BAYER HLTHCARE | 13.5MG | N203159 | 001 | Jan 09, 2013 | Jan | NEWA |
|---|----------------|--------|---------|-----|--------------|-----|------|

TABLET; ORAL

LEVONORGESTREL

|    |                |        |         |     |              |     |      |
|----|----------------|--------|---------|-----|--------------|-----|------|
| AB | LUPIN LTD      | 0.75MG | A091328 | 001 | Jan 23, 2013 | Jan | NEWA |
| AB | NOVEL LABS INC | 1.5MG  | A202508 | 001 | Feb 22, 2013 | Feb | NEWA |

PLAN B ONE-STEP

|     |    |   |                    |       |         |     |              |     |      |
|-----|----|---|--------------------|-------|---------|-----|--------------|-----|------|
| >D> | AB | + | DURAMED            | 1.5MG | N021998 | 001 | Jul 10, 2009 | Apr | CAHN |
| >A> | AB | + | TEVA BRANDED PHARM | 1.5MG | N021998 | 001 | Jul 10, 2009 | Apr | CAHN |

LEVOTHYROXINE SODIUM\*\*

\*\*Refer to Annual Edition Preface Section 1.8 Levothyroxine Sodium for amplifying information

TABLET; ORAL

LEVOXYL

|               |                     |         |         |     |              |     |      |
|---------------|---------------------|---------|---------|-----|--------------|-----|------|
| AB1,<br>AB3   | KING PHARMS R AND D | 0.025MG | N021301 | 001 | May 25, 2001 | Mar | CAHN |
| AB1,<br>AB3   |                     | 0.05MG  | N021301 | 002 | May 25, 2001 | Mar | CAHN |
| AB1,<br>AB3   |                     | 0.075MG | N021301 | 003 | May 25, 2001 | Mar | CAHN |
| AB1,<br>AB3   |                     | 0.088MG | N021301 | 004 | May 25, 2001 | Mar | CAHN |
| AB1,<br>AB3   |                     | 0.1MG   | N021301 | 005 | May 25, 2001 | Mar | CAHN |
| AB1,<br>AB3   |                     | 0.112MG | N021301 | 006 | May 25, 2001 | Mar | CAHN |
| AB1,<br>AB3   |                     | 0.125MG | N021301 | 007 | May 25, 2001 | Mar | CAHN |
| AB1,<br>AB3   |                     | 0.137MG | N021301 | 008 | May 25, 2001 | Mar | CAHN |
| AB1,<br>AB3   |                     | 0.15MG  | N021301 | 009 | May 25, 2001 | Mar | CAHN |
| AB1,<br>AB3   |                     | 0.175MG | N021301 | 010 | May 25, 2001 | Mar | CAHN |
| AB1, +<br>AB3 |                     | 0.2MG   | N021301 | 011 | May 25, 2001 | Mar | CAHN |
|               | @                   | 0.3MG   | N021301 | 012 | May 25, 2001 | Mar | CAHN |

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HYDROCHLORIDE

@ LUITPOLD

2%

A083198 001

Mar DISC

LIDOCAINE HYDROCHLORIDE PRESERVATIVE FREE

AP AUROBINDO PHARMA LTD

1%

A203040 001 Mar 14, 2013 Mar NEWA

AP 1%

A203082 001 Mar 14, 2013 Mar NEWA

AP 2%

A203082 002 Mar 14, 2013 Mar NEWA

AP 2%

A203040 002 Mar 14, 2013 Mar NEWA

LIOTHYRONINE SODIUM

TABLET; ORAL

CYTOMEL

AB KING PHARMS R AND D

EQ 0.005MG BASE

N010379 001

Mar CAHN

AB EQ 0.025MG BASE

N010379 002

Mar CAHN

AB + EQ 0.05MG BASE

N010379 003

Mar CAHN

LISINOPRIL

TABLET; ORAL

LISINOPRIL

@ SANDOZ

2.5MG

A075999 001 Jul 01, 2002 Jan CAHN

@ 5MG

A075999 002 Jul 01, 2002 Jan CAHN

@ 10MG

A075999 003 Jul 01, 2002 Jan CAHN

@ 20MG

A075999 004 Jul 01, 2002 Jan CAHN

@ 30MG

A075999 005 Jul 01, 2002 Jan CAHN

@ 40MG

A075999 006 Jul 01, 2002 Jan CAHN

LITHIUM CARBONATE

CAPSULE; ORAL

LITHIUM CARBONATE

@ APOTEX INC

300MG

A076795 001 Nov 22, 2004 Feb DISC

&gt;D&gt; AB HETERO DRUGS LTD

150MG

A090702 001 Sep 25, 2009 Apr CAHN

&gt;D&gt; AB 300MG

A090702 002 Sep 25, 2009 Apr CAHN

&gt;D&gt; AB 600MG

A090702 003 Sep 25, 2009 Apr CAHN

&gt;A&gt; AB HETERO LABS LTD III

150MG

A090702 001 Sep 25, 2009 Apr CAHN

&gt;A&gt; AB 300MG

A090702 002 Sep 25, 2009 Apr CAHN

&gt;A&gt; AB 600MG

A090702 003 Sep 25, 2009 Apr CAHN

LOMUSTINE

CAPSULE; ORAL

CEENU

&gt;D&gt; BRISTOL MYERS SQUIBB

10MG

N017588 001

Apr CAHN

&gt;D&gt; 40MG

N017588 002

Apr CAHN

&gt;D&gt; + 100MG

N017588 003

Apr CAHN

&gt;A&gt; CORDEN PHARMA

10MG

N017588 001

Apr CAHN

&gt;A&gt; 40MG

N017588 002

Apr CAHN

&gt;A&gt; + 100MG

N017588 003

Apr CAHN

LORAZEPAM

CONCENTRATE; ORAL

LORAZEPAM

AA LUPIN LTD

2MG/ML

A091407 001 Feb 19, 2013 Feb NEWA

## TABLET; ORAL

## LORAZEPAM

|     |    |        |       |             |              |     |      |
|-----|----|--------|-------|-------------|--------------|-----|------|
| >D> | AB | SANDOZ | 0.5MG | A071193 001 | Apr 15, 1988 | Apr | DISC |
| >A> |    | @      | 0.5MG | A071193 001 | Apr 15, 1988 | Apr | DISC |
| >D> | AB |        | 1MG   | A071194 001 | Apr 15, 1988 | Apr | DISC |
| >A> |    | @      | 1MG   | A071194 001 | Apr 15, 1988 | Apr | DISC |
| >D> | AB |        | 2MG   | A071195 001 | Apr 15, 1988 | Apr | DISC |
| >A> |    | @      | 2MG   | A071195 001 | Apr 15, 1988 | Apr | DISC |

LOSARTAN POTASSIUM

## TABLET; ORAL

## LOSARTAN POTASSIUM

|    |  |                 |       |             |              |     |      |
|----|--|-----------------|-------|-------------|--------------|-----|------|
| AB |  | ACTAVIS GRP PTC | 25MG  | A090382 001 | Oct 06, 2010 | Mar | CAHN |
| AB |  |                 | 50MG  | A090382 002 | Oct 06, 2010 | Mar | CAHN |
| AB |  |                 | 100MG | A090382 003 | Oct 06, 2010 | Mar | CAHN |

LOVASTATIN

## TABLET; ORAL

## LOVASTATIN

|    |   |          |      |             |              |     |      |
|----|---|----------|------|-------------|--------------|-----|------|
| AB | + | CARLSBAD | 40MG | A075991 003 | Jun 05, 2002 | Feb | CRLD |
|    |   | MEVACOR  |      |             |              |     |      |
|    |   | @ MERCK  | 20MG | N019643 003 | Aug 31, 1987 | Feb | DISC |
|    |   | @        | 40MG | N019643 004 | Dec 14, 1988 | Feb | DISC |

MAFENIDE ACETATE

## FOR SOLUTION; TOPICAL

## MAFENIDE ACETATE

|    |   |             |    |             |              |     |      |
|----|---|-------------|----|-------------|--------------|-----|------|
| AB |   | PAR FORM    | 5% | A201511 001 | Feb 12, 2013 | Jan | NEWA |
|    |   | SULFAMYLLON |    |             |              |     |      |
| AB | + | MYLAN LLC   | 5% | N019832 003 | Jun 05, 1998 | Jan | CFTG |

MAGNESIUM SULFATE, POTASSIUM SULFATE, SODIUM SULFATE; POLYETHYLENE GLYCOL 3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE

## SOLUTION, FOR SOLUTION; ORAL, ORAL

## SUCLEAR

|   |                |                                                                                                    |             |              |     |      |
|---|----------------|----------------------------------------------------------------------------------------------------|-------------|--------------|-----|------|
| + | BRAINTREE LABS | 1.6GM/BOT, 3.13GM/BOT, 17.5GM/BOT, N/A, N/A, N/A, N/A, N/A, N/A, N/A, 210GM, 0.74GM, 2.86GM, 5.6GM | N203595 001 | Jan 18, 2013 | Jan | NEWA |
|---|----------------|----------------------------------------------------------------------------------------------------|-------------|--------------|-----|------|

MANNITOL

## INJECTABLE; INJECTION

## MANNITOL 20%

## @ B BRAUN

20GM/100ML

N014738 001

Jan DISC

MECANYLAMINE HYDROCHLORIDE

## TABLET; ORAL

## MECANYLAMINE HYDROCHLORIDE

## NEXGEN PHARMA

2.5MG

A204054 001 Mar 19, 2013 Mar NEWA

MEFENAMIC ACID

## CAPSULE; ORAL

## MEFENAMIC ACID

AB CYPRESS PHARM

250MG

A090359 001 Feb 05, 2013 Jan NEWA

MEGESTROL ACETATE

## SUSPENSION; ORAL

## MEGESTROL ACETATE

|     |    |            |         |             |              |     |      |
|-----|----|------------|---------|-------------|--------------|-----|------|
| >D> | AB | APOTEX INC | 40MG/ML | A077404 001 | Feb 16, 2006 | Apr | DISC |
| >A> |    | @          | 40MG/ML | A077404 001 | Feb 16, 2006 | Apr | DISC |

MELOXICAM

## TABLET; ORAL

## MELOXICAM

|     |    |                 |       |             |              |     |      |
|-----|----|-----------------|-------|-------------|--------------|-----|------|
|     |    | @ COREPHARMA    | 7.5MG | A077930 001 | Jul 19, 2006 | Feb | DISC |
|     |    | @               | 15MG  | A077930 002 | Jul 19, 2006 | Feb | DISC |
| >D> | AB | CR DOUBLE CRANE | 7.5MG | A078039 001 | Dec 14, 2006 | Apr | DISC |
| >A> |    | @               | 7.5MG | A078039 001 | Dec 14, 2006 | Apr | DISC |
|     | AB |                 | 7.5MG | A078039 001 | Dec 14, 2006 | Mar | CAHN |
| >D> | AB |                 | 15MG  | A078039 002 | Dec 14, 2006 | Apr | DISC |
| >A> |    | @               | 15MG  | A078039 002 | Dec 14, 2006 | Apr | DISC |
|     | AB |                 | 15MG  | A078039 002 | Dec 14, 2006 | Mar | CAHN |

MEPROBAMATE

## TABLET; ORAL

## MEPROBAMATE

|  |  |        |       |             |              |     |      |
|--|--|--------|-------|-------------|--------------|-----|------|
|  |  | @ TARO | 200MG | A200998 001 | May 23, 2011 | Jan | DISC |
|  |  | @      | 400MG | A200998 002 | May 23, 2011 | Jan | DISC |

MESALAMINE

## CAPSULE, DELAYED RELEASE; ORAL

## DELZICOL

|   |  |                     |       |             |              |     |      |
|---|--|---------------------|-------|-------------|--------------|-----|------|
| + |  | WARNER CHILCOTT LLC | 400MG | N204412 001 | Feb 01, 2013 | Feb | NEWA |
|---|--|---------------------|-------|-------------|--------------|-----|------|

## SUPPOSITORY; RECTAL

## CANASA

|   |  |                   |     |             |              |     |      |
|---|--|-------------------|-----|-------------|--------------|-----|------|
| + |  | APTALIS PHARMA US | 1GM | N021252 002 | Nov 05, 2004 | Feb | CRLD |
|---|--|-------------------|-----|-------------|--------------|-----|------|

METAPROTERENOL SULFATE

## SOLUTION; INHALATION

## METAPROTERENOL SULFATE

|     |    |              |      |             |              |     |      |
|-----|----|--------------|------|-------------|--------------|-----|------|
| >A> |    | @ APOTEX INC | 0.4% | A075402 001 | Feb 28, 2001 | Apr | DISC |
| >A> |    | @            | 0.6% | A075403 001 | Feb 28, 2001 | Apr | DISC |
| >D> | AN | NOVEX        | 0.4% | A075402 001 | Feb 28, 2001 | Apr | DISC |
| >D> | AN |              | 0.6% | A075403 001 | Feb 28, 2001 | Apr | DISC |

## SYRUP; ORAL

## METAPROTERENOL SULFATE

|     |  |              |          |             |              |     |      |
|-----|--|--------------|----------|-------------|--------------|-----|------|
| >A> |  | @ APOTEX INC | 10MG/5ML | A075235 001 | Jan 27, 2000 | Apr | DISC |
| >D> |  | @ NOVEX      | 10MG/5ML | A075235 001 | Jan 27, 2000 | Apr | DISC |
|     |  | @            | 10MG/5ML | A075235 001 | Jan 27, 2000 | Feb | DISC |
| +   |  | SILARX       | 10MG/5ML | A073632 001 | Jul 22, 1992 | Feb | CTEC |

## TABLET; ORAL

## METAPROTERENOL SULFATE

|   |  |               |      |             |              |     |      |
|---|--|---------------|------|-------------|--------------|-----|------|
|   |  | PAR PHARM     | 10MG | A072024 001 | Jun 28, 1988 | Mar | CTEC |
| + |  |               | 20MG | A072025 001 | Jun 28, 1988 | Mar | CTEC |
|   |  | @ WATSON LABS | 10MG | A073013 001 | Jan 31, 1991 | Mar | DISC |
|   |  | @             | 20MG | A072795 001 | Jan 31, 1991 | Mar | DISC |

METFORMIN HYDROCHLORIDE

## TABLET; ORAL

## METFORMIN HYDROCHLORIDE

@ SANDOZ 500MG

A075965 001 Jan 25, 2002 Mar DISC

@ 850MG

A075965 002 Jan 25, 2002 Mar DISC

@ 1GM

A075965 003 Jan 25, 2002 Mar DISC

## TABLET, EXTENDED RELEASE; ORAL

## METFORMIN HYDROCHLORIDE

@ WATSON LABS INC 500MG

A076818 001 Dec 14, 2004 Mar DISC

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

## TABLET; ORAL

## PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE

AB AUROBINDO PHARMA LTD 500MG;EQ 15MG BASE

A200823 001 Feb 13, 2013 Jan NEWA

AB 850MG;EQ 15MG BASE

A200823 002 Feb 13, 2013 Jan NEWA

&gt;A&gt; AB SANDOZ 500MG;EQ 15MG BASE

A091273 001 Apr 16, 2013 Apr NEWA

&gt;A&gt; AB 850MG;EQ 15MG BASE

A091273 002 Apr 16, 2013 Apr NEWA

AB TORRENT PHARMS LTD 500MG;EQ 15MG BASE

A202001 001 Feb 13, 2013 Jan NEWA

AB 850MG;EQ 15MG BASE

A202001 002 Feb 13, 2013 Jan NEWA

METHADONE HYDROCHLORIDE

## TABLET, FOR SUSPENSION; ORAL

## METHADONE HYDROCHLORIDE

AA MALLINCKRODT INC 40MG

A077142 001 Jul 12, 2005 Mar CDFR

AA + ROXANE 40MG

N017058 001 Mar CDFR

AA SANDOZ 40MG

A075082 001 Mar 25, 1998 Mar CDFR

## METHADOSE

AA MALLINCKRODT 40MG

A074184 001 Apr 29, 1993 Mar CDFR

METHOCARBAMOL

## TABLET; ORAL

## METHOCARBAMOL

@ AUSTARPHARMA LLC 500MG

A200958 001 Oct 21, 2011 Jan DISC

@ 750MG

A200958 002 Oct 21, 2011 Jan DISC

&gt;D&gt; AA HETERO DRUGS 500MG

A090200 001 Nov 06, 2009 Apr CAHN

&gt;D&gt; AA 750MG

A090200 002 Nov 06, 2009 Apr CAHN

&gt;A&gt; AA HETERO LABS LTD III 500MG

A090200 001 Nov 06, 2009 Apr CAHN

&gt;A&gt; AA 750MG

A090200 002 Nov 06, 2009 Apr CAHN

AA PRINSTON INC 500MG

A086989 001 Feb CMFD

AA 750MG

A086988 001 Feb CAHN

@ SOLCO HLTHCARE 500MG

A086989 001 Jan DISC

METHOXSALLEN

## CAPSULE; ORAL

## OXSORALEN-ULTRA

&gt;A&gt; + DOW PHARM 10MG

N019600 001 Oct 30, 1986 Apr CAHN

&gt;D&gt; + VALEANT PHARM INTL 10MG

N019600 001 Oct 30, 1986 Apr CAHN

METHYCLOTHIAZIDE

## TABLET; ORAL

## METHYCLOTHIAZIDE

+ MYLAN PHARMS INC 5MG

A087672 001 Aug 17, 1982 Jan CTEC

@ WATSON LABS 5MG

A088724 001 Sep 06, 1984 Jan DISC

METHYLDOPA

TABLET; ORAL

METHYLDOPA

|     |    |                   |       |             |              |     |      |
|-----|----|-------------------|-------|-------------|--------------|-----|------|
| >D> |    | @ ACCORD HLTH     | 125MG | A070070 003 | Oct 15, 1985 | Apr | CAHN |
| >D> | AB |                   | 250MG | A070084 001 | Oct 15, 1985 | Apr | CAHN |
| >D> | AB |                   | 500MG | A070085 001 | Oct 15, 1985 | Apr | CAHN |
| >A> |    | @ ACCORD HLTHCARE | 125MG | A070070 003 | Oct 15, 1985 | Apr | CAHN |
| >A> | AB |                   | 250MG | A070084 001 | Oct 15, 1985 | Apr | CAHN |
| >A> | AB |                   | 500MG | A070085 001 | Oct 15, 1985 | Apr | CAHN |

METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

METHYLPHENIDATE HYDROCHLORIDE

|     |     |                 |      |             |              |     |      |
|-----|-----|-----------------|------|-------------|--------------|-----|------|
| >D> | AB1 | ACTAVIS         | 20MG | A078458 001 | Dec 01, 2011 | Apr | CAHN |
| >D> | AB1 |                 | 30MG | A078458 002 | Dec 01, 2011 | Apr | CAHN |
| >D> | AB1 |                 | 40MG | A078458 003 | Dec 01, 2011 | Apr | CAHN |
| >A> | AB1 | WATSON LABS INC | 20MG | A078458 001 | Dec 01, 2011 | Apr | CAHN |
| >A> | AB1 |                 | 30MG | A078458 002 | Dec 01, 2011 | Apr | CAHN |
| >A> | AB1 |                 | 40MG | A078458 003 | Dec 01, 2011 | Apr | CAHN |

TABLET, EXTENDED RELEASE; ORAL

METHYLIN ER

MALLINCKRODT INC 10MG

A075629 001 May 09, 2000 Feb CTEC

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HYDROCHLORIDE

|     |    |                   |                |             |              |     |      |
|-----|----|-------------------|----------------|-------------|--------------|-----|------|
| >A> | AP | BD RX             | EQ 5MG BASE/ML | A091392 001 | Apr 19, 2013 | Apr | NEWA |
|     |    | @ TEVA PARENTERAL | EQ 5MG BASE/ML | A073135 001 | Nov 27, 1991 | Feb | DISC |

METOLAZONE

TABLET; ORAL

METOLAZONE

@ TEVA 2.5MG

A076600 001 Jan 06, 2004 Mar DISC

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

METOPROLOL SUCCINATE

@ NESHER PHARMS EQ 25MG TARTRATE

A077779 001 Mar 20, 2008 Feb DISC

METOPROLOL TARTRATE

INJECTABLE; INJECTION

METOPROLOL TARTRATE

|     |    |                     |        |             |              |     |      |
|-----|----|---------------------|--------|-------------|--------------|-----|------|
| >A> | AP | CLARIS LIFESCIENCES | 1MG/ML | A078950 001 | Apr 29, 2013 | Apr | NEWA |
|     |    | @ WATSON LABS       | 1MG/ML | A074032 001 | Dec 21, 1993 | Mar | DISC |

TABLET; ORAL

METOPROLOL TARTRATE

@ PRINSTON INC 50MG

A074453 001 Apr 27, 1995 Mar CAHN

@ 100MG

A074453 002 Apr 27, 1995 Mar CAHN

METRONIDAZOLE

TABLET; ORAL

METRONIDAZOLE

AB TEVA PHARMS USA 250MG

A070027 001 Nov 06, 1984 Mar CAHN

MIDAZOLAM HYDROCHLORIDE

## INJECTABLE; INJECTION

## MIDAZOLAM HYDROCHLORIDE

|     |                       |                |             |              |     |      |
|-----|-----------------------|----------------|-------------|--------------|-----|------|
| >A> | @ APOTEX INC          | EQ 1MG BASE/ML | A075637 001 | Oct 31, 2000 | Apr | DISC |
| >A> | @                     | EQ 5MG BASE/ML | A075637 002 | Oct 31, 2000 | Apr | DISC |
| >D> | @ CLARIS LIFESCIENCES | EQ 1MG BASE/ML | A075637 001 | Oct 31, 2000 | Apr | DISC |
|     | @                     | EQ 1MG BASE/ML | A075637 001 | Oct 31, 2000 | Jan | DISC |
| >D> | @                     | EQ 5MG BASE/ML | A075637 002 | Oct 31, 2000 | Apr | DISC |
|     | @                     | EQ 5MG BASE/ML | A075637 002 | Oct 31, 2000 | Jan | DISC |

## SYRUP; ORAL

## MIDAZOLAM HYDROCHLORIDE

|     |    |            |                |             |              |          |
|-----|----|------------|----------------|-------------|--------------|----------|
| >D> | AA | APOTEX INC | EQ 2MG BASE/ML | A077115 001 | Sep 09, 2005 | Apr DISC |
| >A> |    | @          | EQ 2MG BASE/ML | A077115 001 | Sep 09, 2005 | Apr DISC |

MILRINONE LACTATE

## INJECTABLE; INJECTION

## MILRINONE LACTATE

|     |              |                                                       |                                       |              |              |          |
|-----|--------------|-------------------------------------------------------|---------------------------------------|--------------|--------------|----------|
| >A> | @ APOTEX INC | EQ 1MG BASE/ML                                        | A076427 001                           | Sep 21, 2004 | Apr          | DISC     |
| >D> | AP           | CLARIS LIFESCIENCES                                   | EQ 1MG BASE/ML                        | A076427 001  | Sep 21, 2004 | Apr DISC |
|     |              | MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER |                                       |              |              |          |
| >A> | @ APOTEX INC | EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)                 | A077151 001                           | Jul 20, 2005 | Apr          | DISC     |
| >D> | AP           | CLARIS LIFESCIENCES                                   | EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML) | A077151 001  | Jul 20, 2005 | Apr DISC |

MINOCYCLINE HYDROCHLORIDE

## CAPSULE; ORAL

## MINOCYCLINE HYDROCHLORIDE

|     |    |        |               |             |              |          |
|-----|----|--------|---------------|-------------|--------------|----------|
| >A> | AB | CARACO | EQ 50MG BASE  | A090867 001 | May 13, 2013 | Apr NEWA |
| >A> | AB |        | EQ 75MG BASE  | A090867 002 | May 13, 2013 | Apr NEWA |
| >A> | AB |        | EQ 100MG BASE | A090867 003 | May 13, 2013 | Apr NEWA |

## TABLET, EXTENDED RELEASE; ORAL

## SOLODYN

|     |    |         |               |             |              |          |
|-----|----|---------|---------------|-------------|--------------|----------|
| >D> | AB | MEDICIS | EQ 45MG BASE  | N050808 001 | May 08, 2006 | Apr DISC |
| >A> |    | @       | EQ 45MG BASE  | N050808 001 | May 08, 2006 | Apr DISC |
| >D> |    |         | EQ 55MG BASE  | N050808 008 | Aug 27, 2010 | Apr CRLD |
| >A> | +  |         | EQ 55MG BASE  | N050808 008 | Aug 27, 2010 | Apr CRLD |
| >D> |    |         | EQ 80MG BASE  | N050808 007 | Aug 27, 2010 | Apr CRLD |
| >A> | +  |         | EQ 80MG BASE  | N050808 007 | Aug 27, 2010 | Apr CRLD |
| >D> | AB | +       | EQ 135MG BASE | N050808 003 | May 08, 2006 | Apr DISC |
| >A> |    | @       | EQ 135MG BASE | N050808 003 | May 08, 2006 | Apr DISC |

MIPOMERSEN SODIUM

## SOLUTION; SUBCUTANEOUS

## KYNAMRO

|   |              |                     |             |              |     |      |
|---|--------------|---------------------|-------------|--------------|-----|------|
| + | GENZYME CORP | 200MG/ML (200MG/ML) | N203568 001 | Jan 29, 2013 | Jan | NEWA |
|---|--------------|---------------------|-------------|--------------|-----|------|

MITOXANTRONE HYDROCHLORIDE

## INJECTABLE; INJECTION

## MITOXANTRONE HYDROCHLORIDE

|    |                    |                                    |             |              |     |      |
|----|--------------------|------------------------------------|-------------|--------------|-----|------|
| AP | ONCO THERAPIES LTD | EQ 20MG BASE/10ML (EQ 2MG BASE/ML) | A201014 001 | Dec 11, 2012 | Mar | CAIN |
|----|--------------------|------------------------------------|-------------|--------------|-----|------|

MOMETASONE FUROATE

CREAM; TOPICAL

ELOCON

|     |    |                   |      |             |              |     |      |
|-----|----|-------------------|------|-------------|--------------|-----|------|
| >A> | AB | MERCK SHARP DOHME | 0.1% | N019625 002 | Apr 19, 2013 | Apr | NEWA |
|-----|----|-------------------|------|-------------|--------------|-----|------|

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

KADIAN

|     |       |                   |       |             |              |     |      |
|-----|-------|-------------------|-------|-------------|--------------|-----|------|
| >D> | +     | ACTAVIS ELIZABETH | 10MG  | N020616 008 | Apr 20, 2007 | Apr | CAHN |
| >D> | AB1   |                   | 20MG  | N020616 001 | Jul 03, 1996 | Apr | CAHN |
| >D> | AB1   |                   | 30MG  | N020616 004 | Mar 09, 2001 | Apr | CAHN |
| >D> |       |                   | 40MG  | N020616 009 | Jul 09, 2012 | Apr | CAHN |
| >D> | AB1   |                   | 50MG  | N020616 002 | Jul 03, 1996 | Apr | CAHN |
| >D> | AB1   |                   | 60MG  | N020616 005 | Mar 09, 2001 | Apr | CAHN |
| >D> |       |                   | 70MG  | N020616 010 | Jul 09, 2012 | Apr | CAHN |
| >D> | AB1   |                   | 80MG  | N020616 006 | Oct 27, 2006 | Apr | CAHN |
| >D> | AB1 + |                   | 100MG | N020616 003 | Jul 03, 1996 | Apr | CAHN |
| >D> |       |                   | 130MG | N020616 011 | Jul 09, 2012 | Apr | CAHN |
| >D> |       |                   | 150MG | N020616 012 | Jul 09, 2012 | Apr | CAHN |
| >D> | +     |                   | 200MG | N020616 007 | Feb 27, 2007 | Apr | CAHN |
| >A> | +     | WATSON LABS INC   | 10MG  | N020616 008 | Apr 20, 2007 | Apr | CAHN |
| >A> | AB1   |                   | 20MG  | N020616 001 | Jul 03, 1996 | Apr | CAHN |
| >A> | AB1   |                   | 30MG  | N020616 004 | Mar 09, 2001 | Apr | CAHN |
| >A> |       |                   | 40MG  | N020616 009 | Jul 09, 2012 | Apr | CAHN |
| >A> | AB1   |                   | 50MG  | N020616 002 | Jul 03, 1996 | Apr | CAHN |
| >A> | AB1   |                   | 60MG  | N020616 005 | Mar 09, 2001 | Apr | CAHN |
| >A> |       |                   | 70MG  | N020616 010 | Jul 09, 2012 | Apr | CAHN |
| >A> | AB1   |                   | 80MG  | N020616 006 | Oct 27, 2006 | Apr | CAHN |
| >A> | AB1 + |                   | 100MG | N020616 003 | Jul 03, 1996 | Apr | CAHN |
| >A> |       |                   | 130MG | N020616 011 | Jul 09, 2012 | Apr | CAHN |
| >A> |       |                   | 150MG | N020616 012 | Jul 09, 2012 | Apr | CAHN |
| >A> | +     |                   | 200MG | N020616 007 | Feb 27, 2007 | Apr | CAHN |

MORPHINE SULFATE

|     |     |               |       |             |              |     |      |
|-----|-----|---------------|-------|-------------|--------------|-----|------|
| >D> | AB  | PAR PHARM INC | 20MG  | A200812 001 | Nov 10, 2011 | Apr | CTEC |
| >A> | AB1 |               | 20MG  | A200812 001 | Nov 10, 2011 | Apr | CTEC |
| >D> | AB  |               | 30MG  | A200812 002 | Nov 10, 2011 | Apr | CTEC |
| >A> | AB1 |               | 30MG  | A200812 002 | Nov 10, 2011 | Apr | CTEC |
| >D> | AB  |               | 50MG  | A200812 003 | Nov 10, 2011 | Apr | CTEC |
| >A> | AB1 |               | 50MG  | A200812 003 | Nov 10, 2011 | Apr | CTEC |
| >D> | AB  |               | 60MG  | A200812 004 | Nov 10, 2011 | Apr | CTEC |
| >A> | AB1 |               | 60MG  | A200812 004 | Nov 10, 2011 | Apr | CTEC |
| >D> | AB  |               | 80MG  | A200812 005 | Nov 10, 2011 | Apr | CTEC |
| >A> | AB1 |               | 80MG  | A200812 005 | Nov 10, 2011 | Apr | CTEC |
| >D> | AB  |               | 100MG | A200812 006 | Nov 10, 2011 | Apr | CTEC |
| >A> | AB1 |               | 100MG | A200812 006 | Nov 10, 2011 | Apr | CTEC |

MUPIROCIN CALCIUM

CREAM; TOPICAL

BACTROBAN

|    |   |                 |            |             |              |     |      |
|----|---|-----------------|------------|-------------|--------------|-----|------|
| AB | + | GLAXOSMITHKLINE | EQ 2% BASE | N050746 001 | Dec 11, 1997 | Jan | CFTG |
|----|---|-----------------|------------|-------------|--------------|-----|------|

MUPIROCIN

|    |  |                   |            |             |              |     |      |
|----|--|-------------------|------------|-------------|--------------|-----|------|
| AB |  | GLENMARK GENERICS | EQ 2% BASE | A201587 001 | Jan 24, 2013 | Jan | NEWA |
|----|--|-------------------|------------|-------------|--------------|-----|------|

MYCOPHENOLATE MOFETIL

CAPSULE; ORAL

MYCOPHENOLATE MOFETIL

|     |    |                     |       |         |     |              |     |      |
|-----|----|---------------------|-------|---------|-----|--------------|-----|------|
| >A> | AB | ACCORD HLTHCARE     | 250MG | A090253 | 001 | May 04, 2009 | Apr | CAHN |
| >D> | AB | ACCORD HLTHCARE INC | 250MG | A090253 | 001 | May 04, 2009 | Apr | CAHN |

NABUMETONE

TABLET; ORAL

NABUMETONE

|     |    |                    |       |         |     |              |     |      |
|-----|----|--------------------|-------|---------|-----|--------------|-----|------|
| >D> | AB | DR REDDYS LABS LTD | 500MG | A078420 | 001 | Sep 24, 2008 | Apr | DISC |
| >A> |    | @                  | 500MG | A078420 | 001 | Sep 24, 2008 | Apr | DISC |
| >D> | AB |                    | 750MG | A078420 | 002 | Sep 24, 2008 | Apr | DISC |
| >A> |    | @                  | 750MG | A078420 | 002 | Sep 24, 2008 | Apr | DISC |
|     |    | @ PROSAM LABS      | 500MG | A079093 | 001 | Feb 27, 2009 | Mar | DISC |
|     |    | @                  | 750MG | A079093 | 002 | Feb 27, 2009 | Mar | DISC |

NALTREXONE HYDROCHLORIDE

TABLET; ORAL

NALTREXONE HYDROCHLORIDE

|     |    |        |      |         |     |              |     |      |
|-----|----|--------|------|---------|-----|--------------|-----|------|
| >D> | AB | SANDOZ | 50MG | A075434 | 001 | Mar 08, 2000 | Apr | DISC |
| >A> |    | @      | 50MG | A075434 | 001 | Mar 08, 2000 | Apr | DISC |

NAPROXEN

TABLET; ORAL

NAPROXEN

|     |    |                      |       |         |     |              |     |      |
|-----|----|----------------------|-------|---------|-----|--------------|-----|------|
| >A> | AB | WEST WARD PHARM CORP | 250MG | A076494 | 001 | Jan 14, 2004 | Apr | CAHN |
| >A> | AB |                      | 375MG | A076494 | 002 | Jan 14, 2004 | Apr | CAHN |
| >A> | AB |                      | 500MG | A076494 | 003 | Jan 14, 2004 | Apr | CAHN |
| >D> | AB | WESTWARD             | 250MG | A076494 | 001 | Jan 14, 2004 | Apr | CAHN |
| >D> | AB |                      | 375MG | A076494 | 002 | Jan 14, 2004 | Apr | CAHN |
| >D> | AB |                      | 500MG | A076494 | 003 | Jan 14, 2004 | Apr | CAHN |

NARATRIPTAN HYDROCHLORIDE

TABLET; ORAL

AMERGE

|    |   |                     |               |         |     |              |     |      |
|----|---|---------------------|---------------|---------|-----|--------------|-----|------|
| AB |   | GLAXOSMITHKLINE LLC | EQ 1MG BASE   | N020763 | 002 | Feb 10, 1998 | Mar | CAHN |
| AB | + |                     | EQ 2.5MG BASE | N020763 | 001 | Feb 10, 1998 | Mar | CAHN |

NEOMYCIN SULFATE

POWDER; FOR RX COMPOUNDING

NEO-RX

|                |      |         |     |  |  |  |     |      |
|----------------|------|---------|-----|--|--|--|-----|------|
| @ X GEN PHARMS | 100% | A061579 | 001 |  |  |  | Mar | DISC |
|----------------|------|---------|-----|--|--|--|-----|------|

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE

|     |    |                   |      |         |     |              |     |      |
|-----|----|-------------------|------|---------|-----|--------------|-----|------|
| >D> |    | ACTAVIS ELIZABETH | 20MG | A072556 | 001 | Sep 20, 1990 | Apr | CTEC |
| >A> | AB |                   | 20MG | A072556 | 001 | Sep 20, 1990 | Apr | CTEC |
| >D> | AB | CATALENT          | 10MG | A073250 | 001 | Oct 08, 1991 | Apr | DISC |
| >A> |    | @                 | 10MG | A073250 | 001 | Oct 08, 1991 | Apr | DISC |
| >A> | AB | EMCURE PHARMS USA | 10MG | A202644 | 001 | Apr 25, 2013 | Apr | NEWA |
| >A> | AB |                   | 20MG | A202644 | 002 | Apr 25, 2013 | Apr | NEWA |

NILUTAMIDE

TABLET; ORAL

NILANDRON

|     |                     |       |             |              |     |      |
|-----|---------------------|-------|-------------|--------------|-----|------|
| >A> | @ COVIS PHARMA SARL | 50MG  | N020169 001 | Sep 19, 1996 | Apr | CAHN |
| >A> | +                   | 150MG | N020169 002 | Apr 30, 1999 | Apr | CAHN |
| >D> | @ SANOFI AVENTIS US | 50MG  | N020169 001 | Sep 19, 1996 | Apr | CAHN |
| >D> | +                   | 150MG | N020169 002 | Apr 30, 1999 | Apr | CAHN |

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

MACRODANTIN

|    |                |       |             |              |     |      |
|----|----------------|-------|-------------|--------------|-----|------|
|    | ALVOGEN INC    | 25MG  | N016620 003 |              | Mar | CTEC |
| AB |                | 25MG  | N016620 003 |              | Feb | CAHN |
| AB |                | 50MG  | N016620 001 |              | Feb | CAHN |
| AB | +              | 100MG | N016620 002 |              | Feb | CAHN |
|    | NITROFURANTOIN |       |             |              |     |      |
|    | @ WATSON LABS  | 25MG  | A073696 001 | Dec 31, 1992 | Mar | DISC |
|    | @              | 50MG  | A073696 002 | Dec 31, 1992 | Mar | DISC |
|    | @              | 100MG | A073696 003 | Dec 31, 1992 | Mar | DISC |

NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

MACROBID

|    |   |             |           |             |              |     |      |
|----|---|-------------|-----------|-------------|--------------|-----|------|
| AB | + | ALVOGEN INC | 75MG;25MG | N020064 001 | Dec 24, 1991 | Mar | CAHN |
|----|---|-------------|-----------|-------------|--------------|-----|------|

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

NITRO-DUR

|     |   |                   |          |             |              |     |      |
|-----|---|-------------------|----------|-------------|--------------|-----|------|
| AB1 | + | MERCK SHARP DOHME | 0.1MG/HR | N020145 001 | Apr 04, 1995 | Mar | CAHN |
| AB1 | + |                   | 0.2MG/HR | N020145 002 | Apr 04, 1995 | Mar | CAHN |
|     | + |                   | 0.3MG/HR | N020145 003 | Apr 04, 1995 | Mar | CAHN |
| AB1 | + |                   | 0.4MG/HR | N020145 004 | Apr 04, 1995 | Mar | CAHN |
| AB1 | + |                   | 0.6MG/HR | N020145 005 | Apr 04, 1995 | Mar | CAHN |
|     | + |                   | 0.8MG/HR | N020145 006 | Apr 04, 1995 | Mar | CAHN |

NIZATIDINE

CAPSULE; ORAL

NIZATIDINE

|  |              |       |             |              |     |      |
|--|--------------|-------|-------------|--------------|-----|------|
|  | @ APOTEX INC | 150MG | A076383 001 | Jan 23, 2003 | Feb | DISC |
|  | @            | 300MG | A076383 002 | Jan 23, 2003 | Feb | DISC |

NORETHINDRONE

TABLET; ORAL-28

JENCYCLA

|     |     |           |        |             |              |     |      |
|-----|-----|-----------|--------|-------------|--------------|-----|------|
| >D> | AB  | LUPIN LTD | 0.35MG | A091323 001 | Mar 28, 2013 | Apr | CTEC |
| >A> | AB2 |           | 0.35MG | A091323 001 | Mar 28, 2013 | Apr | CTEC |
|     | AB  |           | 0.35MG | A091323 001 | Mar 28, 2013 | Mar | NEWA |

NYSTATIN

SUSPENSION; ORAL

NILSTAT

|  |                     |                  |             |  |     |      |
|--|---------------------|------------------|-------------|--|-----|------|
|  | @ GLENMARK GENERICS | 100,000 UNITS/ML | N050299 001 |  | Feb | DISC |
|--|---------------------|------------------|-------------|--|-----|------|

OFLOXACIN

SOLUTION/DROPS; OPHTHALMIC

OFLOXACIN

|     |    |                    |      |         |     |              |     |      |
|-----|----|--------------------|------|---------|-----|--------------|-----|------|
| >A> | AT | ALTAIRE PHARMS INC | 0.3% | A202692 | 001 | Apr 29, 2013 | Apr | NEWA |
| >A> |    | @ APOTEX INC       | 0.3% | A076513 | 001 | May 14, 2004 | Apr | DISC |
| >D> | AT | NOVEX              | 0.3% | A076513 | 001 | May 14, 2004 | Apr | DISC |

OMEPRAZOLE; SODIUM BICARBONATE

FOR SUSPENSION; ORAL

|     |    |                                   |                           |         |     |              |     |      |
|-----|----|-----------------------------------|---------------------------|---------|-----|--------------|-----|------|
| >A> |    | OMEPRAZOLE AND SODIUM BICARBONATE |                           |         |     |              |     |      |
| >A> | AB | PAR PHARM                         | 20MG/PACKET;1.68GM/PACKET | A079182 | 001 | Apr 19, 2013 | Apr | NEWA |
| >A> | AB |                                   | 40MG/PACKET;1.68GM/PACKET | A079182 | 002 | Apr 19, 2013 | Apr | NEWA |
|     |    | ZEGERID                           |                           |         |     |              |     |      |
| >D> |    | SANTARUS                          | 20MG/PACKET;1.68GM/PACKET | N021636 | 001 | Jun 15, 2004 | Apr | CFTG |
| >A> | AB |                                   | 20MG/PACKET;1.68GM/PACKET | N021636 | 001 | Jun 15, 2004 | Apr | CFTG |
| >D> | +  |                                   | 40MG/PACKET;1.68GM/PACKET | N021636 | 002 | Dec 21, 2004 | Apr | CFTG |
| >A> | AB | +                                 | 40MG/PACKET;1.68GM/PACKET | N021636 | 002 | Dec 21, 2004 | Apr | CFTG |

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

|     |    |                                                             |                   |         |     |              |     |      |
|-----|----|-------------------------------------------------------------|-------------------|---------|-----|--------------|-----|------|
| >D> | AP | APOTEX                                                      | EQ 2MG BASE/ML    | A077368 | 001 | Dec 26, 2006 | Apr | DISC |
| >A> |    | @ APOTEX INC                                                | EQ 2MG BASE/ML    | A077368 | 001 | Dec 26, 2006 | Apr | DISC |
|     | AP | CLARIS LIFESCIENCES                                         | 2MG/ML            | A078288 | 001 | Feb 22, 2013 | Feb | NEWA |
|     |    | @ LUITPOLD                                                  | EQ 2MG BASE/ML    | A077582 | 001 | Dec 26, 2006 | Mar | DISC |
|     |    | @ PLIVA HRVATSKA DOO                                        | EQ 2MG BASE/ML    | A077544 | 001 | Dec 26, 2006 | Feb | DISC |
|     |    | ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER |                   |         |     |              |     |      |
|     |    | @ CLARIS LIFESCIENCES                                       | EQ 0.64MG BASE/ML | A078308 | 001 | Mar 17, 2008 | Jan | DISC |
|     |    | @ HOSPIRA                                                   | EQ 0.64MG BASE/ML | A077348 | 001 | Feb 01, 2007 | Jan | DISC |
|     |    | ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE                 |                   |         |     |              |     |      |
| >D> | AP | APOTEX INC                                                  | EQ 2MG BASE/ML    | A077343 | 001 | Dec 26, 2006 | Apr | DISC |
| >A> |    | @                                                           | EQ 2MG BASE/ML    | A077343 | 001 | Dec 26, 2006 | Apr | DISC |
|     | AP | CLARIS LIFESCIENCES                                         | 2MG/ML            | A078287 | 001 | Feb 22, 2013 | Feb | NEWA |
|     |    | @ LUITPOLD                                                  | EQ 2MG BASE/ML    | A077387 | 001 | Dec 26, 2006 | Mar | DISC |

OSPEMIFENE

TABLET; ORAL

OSPHENA

|   |              |      |         |     |              |     |      |
|---|--------------|------|---------|-----|--------------|-----|------|
| + | SHIONOGI INC | 60MG | N203505 | 001 | Feb 26, 2013 | Feb | NEWA |
|---|--------------|------|---------|-----|--------------|-----|------|

OXACILLIN SODIUM

INJECTABLE; INJECTION

OXACILLIN SODIUM

|    |                      |                   |         |     |              |     |      |
|----|----------------------|-------------------|---------|-----|--------------|-----|------|
| AP | AUROBINDO PHARMA LTD | EQ 1GM BASE/VIAL  | A201539 | 001 | Jan 18, 2013 | Jan | NEWA |
| AP |                      | EQ 2GM BASE/VIAL  | A201539 | 002 | Jan 18, 2013 | Jan | NEWA |
| AP |                      | EQ 10GM BASE/VIAL | A201538 | 001 | Jan 18, 2013 | Jan | NEWA |

OXAPROZIN

TABLET; ORAL

OXAPROZIN

|   |        |       |         |     |              |     |      |
|---|--------|-------|---------|-----|--------------|-----|------|
| @ | CARACO | 600MG | A075844 | 001 | Jan 03, 2002 | Jan | DISC |
|---|--------|-------|---------|-----|--------------|-----|------|

OXCARBAZEPINE

## TABLET; ORAL

## OXCARBAZEPINE

|                   |       |             |              |     |      |
|-------------------|-------|-------------|--------------|-----|------|
| @ TEVA PHARMS USA | 150MG | A078005 001 | Dec 11, 2007 | Mar | DISC |
| @                 | 300MG | A078005 002 | Dec 11, 2007 | Mar | DISC |
| @                 | 600MG | A078005 003 | Dec 11, 2007 | Mar | DISC |

OXYBUTYNIN CHLORIDE

## SYRUP; ORAL

## OXYBUTYNIN CHLORIDE

|     |              |         |             |              |     |      |
|-----|--------------|---------|-------------|--------------|-----|------|
| >A> | @ APOTEX INC | 5MG/5ML | A074997 001 | Oct 15, 1997 | Apr | DISC |
| >D> | AA NOVEX     | 5MG/5ML | A074997 001 | Oct 15, 1997 | Apr | DISC |

## TABLET; ORAL

## OXYBUTYNIN CHLORIDE

|    |                 |     |             |              |     |      |
|----|-----------------|-----|-------------|--------------|-----|------|
| AB | TEVA PHARMS USA | 5MG | A071655 001 | Nov 14, 1988 | Mar | CAHN |
|----|-----------------|-----|-------------|--------------|-----|------|

OXYCODONE HYDROCHLORIDE

## TABLET; ORAL

## OXYCODONE HYDROCHLORIDE

|                 |      |             |              |     |      |
|-----------------|------|-------------|--------------|-----|------|
| @ NESHER PHARMS | 5MG  | A077290 001 | Dec 08, 2005 | Mar | DISC |
| @               | 10MG | A077290 002 | Dec 08, 2005 | Mar | DISC |
| @               | 15MG | A077290 003 | Dec 08, 2005 | Mar | DISC |
| @               | 20MG | A077290 004 | Dec 08, 2005 | Mar | DISC |
| @               | 30MG | A077290 005 | Dec 08, 2005 | Mar | DISC |

OXYMORPHONE HYDROCHLORIDE

## TABLET; ORAL

## OXYMORPHONE HYDROCHLORIDE

|     |                     |      |             |              |     |      |
|-----|---------------------|------|-------------|--------------|-----|------|
| AB  | AVANTHI INC         | 5MG  | A203601 001 | Jan 30, 2013 | Jan | NEWA |
| AB  |                     | 10MG | A203601 002 | Jan 30, 2013 | Jan | NEWA |
| >A> | AB MALLINCKRODT INC | 5MG  | A202321 001 | Apr 25, 2013 | Apr | NEWA |
| >A> | AB                  | 10MG | A202321 002 | Apr 25, 2013 | Apr | NEWA |

## TABLET, EXTENDED RELEASE; ORAL

## OXYMORPHONE HYDROCHLORIDE

|     |                      |       |             |              |     |      |
|-----|----------------------|-------|-------------|--------------|-----|------|
| >D> | AB ACTAVIS           | 7.5MG | A079046 001 | Dec 13, 2010 | Apr | CAHN |
| >D> | AB                   | 15MG  | A079046 002 | Dec 13, 2010 | Apr | CAHN |
| >A> | AB ACTAVIS ELIZABETH | 7.5MG | A079046 001 | Dec 13, 2010 | Apr | CAHN |
| >A> | AB                   | 15MG  | A079046 002 | Dec 13, 2010 | Apr | CAHN |

OXYTOCIN

## INJECTABLE; INJECTION

## OXYTOCIN

|    |                    |                                 |             |              |     |      |
|----|--------------------|---------------------------------|-------------|--------------|-----|------|
| AP | HIKMA FARMACEUTICA | 10USP UNITS/ML (10USP UNITS/ML) | A200219 001 | Feb 13, 2013 | Jan | NEWA |
|----|--------------------|---------------------------------|-------------|--------------|-----|------|

PACLITAXEL

## INJECTABLE; INJECTION

## PACLITAXEL

|     |                        |        |             |              |     |      |
|-----|------------------------|--------|-------------|--------------|-----|------|
| >A> | @ ACCORD HLTHCARE      | 6MG/ML | A075436 001 | Nov 12, 2004 | Apr | DISC |
| >D> | AP ACCORD HLTHCARE INC | 6MG/ML | A075436 001 | Nov 12, 2004 | Apr | DISC |
|     | TAXOL                  |        |             |              |     |      |
| >D> | @ HQ SPCLT PHARMA      | 6MG/ML | N020262 001 | Dec 29, 1992 | Apr | CMFD |
| >A> | AP                     | 6MG/ML | N020262 001 | Dec 29, 1992 | Apr | CMFD |
|     | @                      | 6MG/ML | N020262 001 | Dec 29, 1992 | Jan | CAHN |

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION  
PAMIDRONATE DISODIUM

|    |                 |                    |             |              |     |      |
|----|-----------------|--------------------|-------------|--------------|-----|------|
| AP | TEVA PHARMS USA | 30MG/10ML (3MG/ML) | A076153 001 | Mar 27, 2002 | Mar | CAHN |
| AP |                 | 90MG/10ML (9MG/ML) | A076153 002 | Mar 27, 2002 | Mar | CAHN |

PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

CAPSULE, DELAYED RELEASE; ORAL  
CREON

|        |                                                   |             |              |     |      |
|--------|---------------------------------------------------|-------------|--------------|-----|------|
| ABBVIE | 180,000USP UNITS;36,000USP UNITS;114,000USP UNITS | N020725 005 | Mar 14, 2013 | Mar | NEWA |
|--------|---------------------------------------------------|-------------|--------------|-----|------|

PANCURONIUM BROMIDE

INJECTABLE; INJECTION  
PANCURONIUM BROMIDE

|    |   |                 |        |             |              |     |      |
|----|---|-----------------|--------|-------------|--------------|-----|------|
| AP | + | TEVA PHARMS USA | 2MG/ML | A072760 001 | Jul 31, 1990 | Mar | CAHN |
|----|---|-----------------|--------|-------------|--------------|-----|------|

PAROXETINE HYDROCHLORIDE

SUSPENSION; ORAL  
PAROXETINE HYDROCHLORIDE

|     |    |            |                  |             |              |     |      |
|-----|----|------------|------------------|-------------|--------------|-----|------|
| >D> | AB | APOTEX INC | EQ 10MG BASE/5ML | A077395 001 | Dec 05, 2006 | Apr | DISC |
| >A> |    | @          | EQ 10MG BASE/5ML | A077395 001 | Dec 05, 2006 | Apr | DISC |

PEGINESATIDE ACETATE

SOLUTION; INTRAVENOUS, SUBCUTANEOUS  
OMONTYS

|                           |   |                   |                                       |             |              |     |      |
|---------------------------|---|-------------------|---------------------------------------|-------------|--------------|-----|------|
| >D>                       | + | AFFYMAX           | EQ 10MG BASE/ML (EQ 10MG BASE/ML)     | N202799 007 | Mar 27, 2012 | Apr | CAHN |
| >D>                       | + |                   | EQ 20MG BASE/2ML (EQ 10MG BASE/ML)    | N202799 008 | Mar 27, 2012 | Apr | CAHN |
| >A>                       | + | TAKEDA PHARMS USA | EQ 10MG BASE/ML (EQ 10MG BASE/ML)     | N202799 007 | Mar 27, 2012 | Apr | CAHN |
| >A>                       | + |                   | EQ 20MG BASE/2ML (EQ 10MG BASE/ML)    | N202799 008 | Mar 27, 2012 | Apr | CAHN |
| OMONTYS PRESERVATIVE FREE |   |                   |                                       |             |              |     |      |
| >D>                       | + | AFFYMAX           | EQ 1MG BASE/0.5ML (EQ 1MG BASE/0.5ML) | N202799 001 | Mar 27, 2012 | Apr | CAHN |
| >D>                       | + |                   | EQ 2MG BASE/0.5ML (EQ 2MG BASE/0.5ML) | N202799 002 | Mar 27, 2012 | Apr | CAHN |
| >D>                       | + |                   | EQ 3MG BASE/0.5ML (EQ 3MG BASE/0.5ML) | N202799 003 | Mar 27, 2012 | Apr | CAHN |
| >D>                       | + |                   | EQ 4MG BASE/0.5ML (EQ 4MG BASE/0.5ML) | N202799 004 | Mar 27, 2012 | Apr | CAHN |
| >D>                       | + |                   | EQ 5MG BASE/0.5ML (EQ 5MG BASE/0.5ML) | N202799 005 | Mar 27, 2012 | Apr | CAHN |
| >D>                       | + |                   | EQ 6MG BASE/0.5ML (EQ 6MG BASE/0.5ML) | N202799 006 | Mar 27, 2012 | Apr | CAHN |
| >A>                       | + | TAKEDA PHARMS USA | EQ 1MG BASE/0.5ML (EQ 1MG BASE/0.5ML) | N202799 001 | Mar 27, 2012 | Apr | CAHN |
| >A>                       | + |                   | EQ 2MG BASE/0.5ML (EQ 2MG BASE/0.5ML) | N202799 002 | Mar 27, 2012 | Apr | CAHN |
| >A>                       | + |                   | EQ 3MG BASE/0.5ML (EQ 3MG BASE/0.5ML) | N202799 003 | Mar 27, 2012 | Apr | CAHN |
| >A>                       | + |                   | EQ 4MG BASE/0.5ML (EQ 4MG BASE/0.5ML) | N202799 004 | Mar 27, 2012 | Apr | CAHN |
| >A>                       | + |                   | EQ 5MG BASE/0.5ML (EQ 5MG BASE/0.5ML) | N202799 005 | Mar 27, 2012 | Apr | CAHN |
| >A>                       | + |                   | EQ 6MG BASE/0.5ML (EQ 6MG BASE/0.5ML) | N202799 006 | Mar 27, 2012 | Apr | CAHN |

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

PHENYLEPHRINE HYDROCHLORIDE

PARAGON BIOTECK 2.5%

N203510 001 Mar 21, 2013 Mar NEWA

+ 10%

N203510 002 Mar 21, 2013 Mar NEWA

PHENYTOIN SODIUM

INJECTABLE; INJECTION

PHENYTOIN SODIUM

@ HOSPIRA 50MG/ML

A089744 001 Dec 18, 1987 Mar DISC

PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL

PIOGLITAZONE HYDROCHLORIDE

|    |                      |              |             |              |     |      |
|----|----------------------|--------------|-------------|--------------|-----|------|
| AB | ACCORD HLTHCARE      | EQ 15MG BASE | A200044 001 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 30MG BASE | A200044 002 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 45MG BASE | A200044 003 | Feb 13, 2013 | Jan | NEWA |
| AB | AUROBINDO PHARMA LTD | EQ 15MG BASE | A200268 001 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 30MG BASE | A200268 002 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 45MG BASE | A200268 003 | Feb 13, 2013 | Jan | NEWA |
| AB | DR REDDYS LABS LTD   | EQ 15MG BASE | A078383 001 | Mar 12, 2013 | Mar | NEWA |
| AB |                      | EQ 30MG BASE | A078383 002 | Mar 12, 2013 | Mar | NEWA |
| AB |                      | EQ 45MG BASE | A078383 003 | Mar 12, 2013 | Mar | NEWA |
| AB | MACLEODS PHARMS LTD  | EQ 15MG BASE | A202467 001 | Feb 06, 2013 | Jan | NEWA |
| AB |                      | EQ 30MG BASE | A202467 002 | Feb 06, 2013 | Jan | NEWA |
| AB |                      | EQ 45MG BASE | A202467 003 | Feb 06, 2013 | Jan | NEWA |
| AB | SANDOZ               | EQ 15MG BASE | A078670 001 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 30MG BASE | A078670 002 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 45MG BASE | A078670 003 | Feb 13, 2013 | Jan | NEWA |
| AB | SYNTHON PHARMS       | EQ 15MG BASE | A078472 001 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 30MG BASE | A078472 002 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 45MG BASE | A078472 003 | Feb 13, 2013 | Jan | NEWA |
| AB | TORRENT PHARMS LTD   | EQ 15MG BASE | A091298 001 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 30MG BASE | A091298 002 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 45MG BASE | A091298 003 | Feb 13, 2013 | Jan | NEWA |
| AB | ZYDUS PHARMS USA INC | EQ 15MG BASE | A202456 001 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 30MG BASE | A202456 002 | Feb 13, 2013 | Jan | NEWA |
| AB |                      | EQ 45MG BASE | A202456 003 | Feb 13, 2013 | Jan | NEWA |

POLYMYXIN B SULFATE

POWDER; FOR RX COMPOUNDING

POLY-RX

@ X GEN PHARMS 100,000,000 UNITS/BOT

A061578 001 Mar DISC

POMALIDOMIDE

CAPSULE; ORAL

POMALYST

CELGENE 1MG

N204026 001 Feb 08, 2013 Feb NEWA

2MG

N204026 002 Feb 08, 2013 Feb NEWA

3MG

N204026 003 Feb 08, 2013 Feb NEWA

+ 4MG

N204026 004 Feb 08, 2013 Feb NEWA

POTASSIUM CHLORIDECAPSULE, EXTENDED RELEASE; ORAL  
POTASSIUM CHLORIDE

|    |               |       |         |     |              |     |      |
|----|---------------|-------|---------|-----|--------------|-----|------|
| AB | AMNEAL PHARMS | 10MEQ | A202128 | 001 | Feb 22, 2013 | Feb | NEWA |
|----|---------------|-------|---------|-----|--------------|-----|------|

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET; ORAL

PRAMIPEXOLE DIHYDROCHLORIDE

|    |                    |         |         |     |              |     |      |
|----|--------------------|---------|---------|-----|--------------|-----|------|
| AB | ACTAVIS GRP PTC    | 0.125MG | A091254 | 001 | Nov 30, 2010 | Mar | CAHN |
| AB |                    | 0.25MG  | A091254 | 002 | Nov 30, 2010 | Mar | CAHN |
| AB |                    | 0.5MG   | A091254 | 003 | Nov 30, 2010 | Mar | CAHN |
| AB |                    | 0.75MG  | A091254 | 004 | Nov 30, 2010 | Mar | CAHN |
| AB |                    | 1MG     | A091254 | 005 | Nov 30, 2010 | Mar | CAHN |
| AB |                    | 1.5MG   | A091254 | 006 | Nov 30, 2010 | Mar | CAHN |
| AB | SUN PHARM INDS INC | 0.125MG | A091683 | 001 | Mar 27, 2013 | Mar | NEWA |
| AB |                    | 0.25MG  | A091683 | 002 | Mar 27, 2013 | Mar | NEWA |
| AB |                    | 0.5MG   | A091683 | 003 | Mar 27, 2013 | Mar | NEWA |
| AB |                    | 0.75MG  | A091683 | 004 | Mar 27, 2013 | Mar | NEWA |
| AB |                    | 1MG     | A091683 | 005 | Mar 27, 2013 | Mar | NEWA |
| AB |                    | 1.5MG   | A091683 | 006 | Mar 27, 2013 | Mar | NEWA |

PRAMLINTIDE ACETATE

INJECTABLE; SUBCUTANEOUS

SYMLIN

|   |               |                                      |         |     |              |     |      |
|---|---------------|--------------------------------------|---------|-----|--------------|-----|------|
|   | AMYLIN PHARMS | EQ 1.5MG BASE/1.5ML (EQ 1MG BASE/ML) | N021332 | 002 | Sep 25, 2007 | Jan | CAHN |
|   |               | EQ 2.7MG BASE/2.7ML (EQ 1MG BASE/ML) | N021332 | 003 | Sep 25, 2007 | Jan | CAHN |
| + |               | EQ 3MG BASE/5ML (EQ 600MCG BASE/ML)  | N021332 | 001 | Mar 16, 2005 | Jan | CAHN |

PREDNISOLONE

SYRUP; ORAL

PREDNISOLONE

|     |    |            |          |         |     |              |     |      |
|-----|----|------------|----------|---------|-----|--------------|-----|------|
| >D> | AA | APOTEX INC | 5MG/5ML  | A040570 | 001 | Aug 25, 2005 | Apr | DISC |
| >A> |    | @          | 5MG/5ML  | A040570 | 001 | Aug 25, 2005 | Apr | DISC |
| >D> | AA |            | 15MG/5ML | A040571 | 001 | Aug 25, 2005 | Apr | DISC |
| >A> |    | @          | 15MG/5ML | A040571 | 001 | Aug 25, 2005 | Apr | DISC |

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL

PREDNISOLONE SODIUM PHOSPHATE

|   |             |                  |         |     |              |     |      |
|---|-------------|------------------|---------|-----|--------------|-----|------|
| @ | PHARM ASSOC | EQ 5MG BASE/5ML  | A076123 | 001 | Dec 23, 2002 | Mar | DISC |
| @ | WE PHARMS   | EQ 15MG BASE/5ML | A075250 | 001 | Jul 12, 2002 | Mar | DISC |

TABLET, ORALLY DISINTEGRATING; ORAL

ORAPRED ODT

|    |                  |                               |         |     |              |     |      |
|----|------------------|-------------------------------|---------|-----|--------------|-----|------|
| AB | SHIONOGI INC     | EQ 10MG BASE                  | N021959 | 001 | Jun 01, 2006 | Mar | CFTG |
| AB |                  | EQ 15MG BASE                  | N021959 | 002 | Jun 01, 2006 | Mar | CFTG |
| AB | +                | EQ 30MG BASE                  | N021959 | 003 | Jun 01, 2006 | Mar | CFTG |
|    |                  | PREDNISOLONE SODIUM PHOSPHATE |         |     |              |     |      |
| AB | MYLAN PHARMS INC | EQ 10MG BASE                  | A202179 | 001 | Apr 10, 2013 | Mar | NEWA |
| AB |                  | EQ 15MG BASE                  | A202179 | 002 | Apr 10, 2013 | Mar | NEWA |
| AB |                  | EQ 30MG BASE                  | A202179 | 003 | Apr 10, 2013 | Mar | NEWA |

PRIMIDONE

TABLET; ORAL

PRIMIDONE

|     |    |                    |       |             |              |     |      |
|-----|----|--------------------|-------|-------------|--------------|-----|------|
| >D> | AB | DR REDDYS LABS LTD | 50MG  | A040862 001 | Oct 03, 2008 | Apr | DISC |
| >A> |    | @                  | 50MG  | A040862 001 | Oct 03, 2008 | Apr | DISC |
| >D> | AB |                    | 250MG | A040862 002 | Oct 03, 2008 | Apr | DISC |
| >A> |    | @                  | 250MG | A040862 002 | Oct 03, 2008 | Apr | DISC |

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROMETHAZINE HYDROCHLORIDE

|    |   |                 |         |             |              |     |      |
|----|---|-----------------|---------|-------------|--------------|-----|------|
| AP | + | TEVA PHARMS USA | 25MG/ML | A040454 001 | Aug 22, 2002 | Mar | CAHN |
| AP | + |                 | 50MG/ML | A040454 002 | Aug 22, 2002 | Mar | CAHN |

PROPOFOL

INJECTABLE; INJECTION

PROPOFOL

|    |  |                 |         |             |              |     |      |
|----|--|-----------------|---------|-------------|--------------|-----|------|
| AB |  | TEVA PHARMS USA | 10MG/ML | A075102 001 | Jan 04, 1999 | Mar | CAHN |
|----|--|-----------------|---------|-------------|--------------|-----|------|

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

PROPRANOLOL HYDROCHLORIDE

|    |  |           |       |             |              |     |      |
|----|--|-----------|-------|-------------|--------------|-----|------|
| AB |  | GLATT AIR | 60MG  | A078065 001 | Jan 26, 2007 | Feb | CAHN |
| AB |  |           | 80MG  | A078065 002 | Jan 26, 2007 | Feb | CAHN |
| AB |  |           | 120MG | A078065 003 | Jan 26, 2007 | Feb | CAHN |
| AB |  |           | 160MG | A078065 004 | Jan 26, 2007 | Feb | CAHN |

PROTRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

VIVACTIL

@ TEVA WOMENS

@

5MG

10MG

|             |  |     |      |
|-------------|--|-----|------|
| N016012 001 |  | Mar | CAHN |
| N016012 002 |  | Mar | CAHN |

PYRIMETHAMINE

TABLET; ORAL

DARAPRIM

|     |   |               |      |             |  |     |      |
|-----|---|---------------|------|-------------|--|-----|------|
| >A> | + | AMEDRA PHARMS | 25MG | N008578 001 |  | Apr | CAHN |
| >D> | + | COREPHARMA    | 25MG | N008578 001 |  | Apr | CAHN |

QUETIAPINE FUMARATE

TABLET; ORAL

QUETIAPINE FUMARATE

|     |    |                     |               |             |              |     |      |
|-----|----|---------------------|---------------|-------------|--------------|-----|------|
| >A> | AB | ACCORD HLTHCARE     | EQ 25MG BASE  | A202152 001 | Mar 27, 2012 | Apr | CAHN |
| >A> | AB |                     | EQ 50MG BASE  | A202152 002 | Mar 27, 2012 | Apr | CAHN |
| >A> | AB |                     | EQ 100MG BASE | A202152 003 | Mar 27, 2012 | Apr | CAHN |
| >A> | AB |                     | EQ 200MG BASE | A202152 004 | Mar 27, 2012 | Apr | CAHN |
| >A> | AB |                     | EQ 300MG BASE | A202152 005 | Mar 27, 2012 | Apr | CAHN |
| >A> | AB |                     | EQ 400MG BASE | A202152 006 | Mar 27, 2012 | Apr | CAHN |
| >D> | AB | ACCORD HLTHCARE INC | EQ 25MG BASE  | A202152 001 | Mar 27, 2012 | Apr | CAHN |
| >D> | AB |                     | EQ 50MG BASE  | A202152 002 | Mar 27, 2012 | Apr | CAHN |
| >D> | AB |                     | EQ 100MG BASE | A202152 003 | Mar 27, 2012 | Apr | CAHN |
| >D> | AB |                     | EQ 200MG BASE | A202152 004 | Mar 27, 2012 | Apr | CAHN |
| >D> | AB |                     | EQ 300MG BASE | A202152 005 | Mar 27, 2012 | Apr | CAHN |
| >D> | AB |                     | EQ 400MG BASE | A202152 006 | Mar 27, 2012 | Apr | CAHN |

## TABLET; ORAL

## QUETIAPINE FUMARATE

|    |                |               |             |              |     |      |
|----|----------------|---------------|-------------|--------------|-----|------|
| AB | ACTAVIS PHARMA | EQ 25MG BASE  | A201762 001 | Feb 27, 2013 | Feb | NEWA |
| AB |                | EQ 50MG BASE  | A201762 002 | Feb 27, 2013 | Feb | NEWA |
| AB |                | EQ 100MG BASE | A201762 003 | Feb 27, 2013 | Feb | NEWA |
| AB |                | EQ 150MG BASE | A201762 004 | Feb 27, 2013 | Feb | NEWA |
| AB |                | EQ 200MG BASE | A201762 005 | Feb 27, 2013 | Feb | NEWA |
| AB |                | EQ 300MG BASE | A201762 006 | Feb 27, 2013 | Feb | NEWA |
| AB |                | EQ 400MG BASE | A201762 007 | Feb 27, 2013 | Feb | NEWA |
| AB | ALKEM LABS LTD | EQ 25MG BASE  | A201504 001 | Feb 12, 2013 | Jan | NEWA |
| AB |                | EQ 50MG BASE  | A201504 002 | Feb 12, 2013 | Jan | NEWA |
| AB |                | EQ 100MG BASE | A201504 003 | Feb 12, 2013 | Jan | NEWA |
| AB |                | EQ 150MG BASE | A201504 004 | Feb 12, 2013 | Jan | NEWA |
| AB |                | EQ 200MG BASE | A201504 005 | Feb 12, 2013 | Jan | NEWA |
| AB |                | EQ 300MG BASE | A201504 006 | Feb 12, 2013 | Jan | NEWA |
| AB |                | EQ 400MG BASE | A201504 007 | Feb 12, 2013 | Jan | NEWA |

QUINAPRIL HYDROCHLORIDE

## TABLET; ORAL

## QUINAPRIL HYDROCHLORIDE

|     |                         |              |             |              |     |      |
|-----|-------------------------|--------------|-------------|--------------|-----|------|
|     | @ APOTEX INC            | EQ 5MG BASE  | A076240 001 | Jan 26, 2006 | Mar | DISC |
|     | @                       | EQ 10MG BASE | A076240 002 | Jan 26, 2006 | Mar | DISC |
|     | @                       | EQ 20MG BASE | A076240 003 | Jan 26, 2006 | Mar | DISC |
|     | @                       | EQ 40MG BASE | A076240 004 | Jan 26, 2006 | Mar | DISC |
| >A> | AB AUROBINDO PHARMA LTD | EQ 5MG BASE  | A202725 001 | Apr 29, 2013 | Apr | NEWA |
| >A> | AB                      | EQ 10MG BASE | A202725 002 | Apr 29, 2013 | Apr | NEWA |
| >A> | AB                      | EQ 20MG BASE | A202725 003 | Apr 29, 2013 | Apr | NEWA |
| >A> | AB                      | EQ 40MG BASE | A202725 004 | Apr 29, 2013 | Apr | NEWA |

RABEPRAZOLE SODIUM

## CAPSULE, DELAYED RELEASE; ORAL

## ACIPHEX SPRINKLE

|  |           |      |             |              |     |      |
|--|-----------|------|-------------|--------------|-----|------|
|  | EISAI INC | 5MG  | N204736 001 | Mar 26, 2013 | Mar | NEWA |
|  | +         | 10MG | N204736 002 | Mar 26, 2013 | Mar | NEWA |

RANITIDINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## RANITIDINE HYDROCHLORIDE

|    |                      |         |             |              |     |      |
|----|----------------------|---------|-------------|--------------|-----|------|
| AP | ZYDUS PHARMS USA INC | 25MG/ML | A091534 001 | Feb 22, 2013 | Feb | NEWA |
|----|----------------------|---------|-------------|--------------|-----|------|

## SYRUP; ORAL

## RANITIDINE HYDROCHLORIDE

|     |                       |                 |             |              |     |      |
|-----|-----------------------|-----------------|-------------|--------------|-----|------|
| >D> | AA APOTEX             | EQ 15MG BASE/ML | A077602 001 | Sep 17, 2007 | Apr | DISC |
| >A> | @ APOTEX INC          | EQ 15MG BASE/ML | A077602 001 | Sep 17, 2007 | Apr | DISC |
| >A> | AA BIO PHARM INC      | EQ 15MG BASE/ML | A090102 001 | May 26, 2009 | Apr | CAHN |
| >A> | AA CARACO             | EQ 15MG BASE/ML | A091091 001 | Sep 20, 2011 | Apr | CAHN |
| >D> | AA DR REDDYS LABS LTD | EQ 15MG BASE/ML | A090102 001 | May 26, 2009 | Apr | CAHN |
| >D> | AA SUN PHARM INDS INC | EQ 15MG BASE/ML | A091091 001 | Sep 20, 2011 | Apr | CAHN |

## TABLET; ORAL

## RANITIDINE HYDROCHLORIDE

|  |                   |               |             |              |     |      |
|--|-------------------|---------------|-------------|--------------|-----|------|
|  | @ WATSON LABS     | EQ 150MG BASE | A074864 001 | Oct 20, 1997 | Jan | DISC |
|  | @                 | EQ 300MG BASE | A074864 002 | Oct 20, 1997 | Jan | DISC |
|  | @ WATSON LABS INC | EQ 150MG BASE | A077426 001 | Dec 19, 2005 | Mar | DISC |
|  | @                 | EQ 300MG BASE | A077426 002 | Dec 19, 2005 | Mar | DISC |

RILUZOLE

TABLET; ORAL

RILUTEK

|     |    |   |                   |      |         |     |         |      |     |      |
|-----|----|---|-------------------|------|---------|-----|---------|------|-----|------|
| >A> | AB | + | COVIS PHARMA SARL | 50MG | N020599 | 001 | Dec 12, | 1995 | Apr | CAHN |
| >D> | AB | + | SANOFI AVENTIS US | 50MG | N020599 | 001 | Dec 12, | 1995 | Apr | CAHN |

RIMANTADINE HYDROCHLORIDE

TABLET; ORAL

RIMANTADINE HYDROCHLORIDE

@ COREPHARMA

100MG

A075916 001 Nov 02, 2001 Feb DISC

RISPERIDONE

TABLET, ORALLY DISINTEGRATING; ORAL

RISPERIDONE

|    |                    |        |         |     |         |      |     |      |
|----|--------------------|--------|---------|-----|---------|------|-----|------|
| AB | MYLAN PHARMS INC   | 0.25MG | A091537 | 006 | Feb 12, | 2013 | Feb | NEWA |
| AB | PAR PHARM          | 0.25MG | A077494 | 001 | Apr 30, | 2009 | Feb | CTEC |
| AB | SUN PHARM INDS LTD | 0.5MG  | A078464 | 001 | Apr 08, | 2013 | Mar | NEWA |
| AB |                    | 1MG    | A078464 | 002 | Apr 08, | 2013 | Mar | NEWA |
| AB |                    | 2MG    | A078464 | 003 | Apr 08, | 2013 | Mar | NEWA |
| AB |                    | 3MG    | A078464 | 004 | Apr 08, | 2013 | Mar | NEWA |
| AB |                    | 4MG    | A078464 | 005 | Apr 08, | 2013 | Mar | NEWA |

RIVASTIGMINE TARTRATE

CAPSULE; ORAL

RIVASTIGMINE TARTRATE

|     |    |            |               |         |     |         |      |     |      |
|-----|----|------------|---------------|---------|-----|---------|------|-----|------|
| >A> | AB | APOTEX INC | EQ 1.5MG BASE | A091072 | 001 | May 16, | 2013 | Apr | NEWA |
| >A> | AB |            | EQ 3MG BASE   | A091072 | 002 | May 16, | 2013 | Apr | NEWA |
| >A> | AB |            | EQ 4.5MG BASE | A091072 | 003 | May 16, | 2013 | Apr | NEWA |
| >A> | AB |            | EQ 6MG BASE   | A091072 | 004 | May 16, | 2013 | Apr | NEWA |

RIZATRIPTAN BENZOATE

TABLET; ORAL

RIZATRIPTAN BENZOATE

|    |           |              |         |     |         |      |     |      |
|----|-----------|--------------|---------|-----|---------|------|-----|------|
| AB | CIPLA LTD | EQ 5MG BASE  | A077526 | 001 | Mar 26, | 2013 | Mar | NEWA |
| AB |           | EQ 10MG BASE | A077526 | 002 | Mar 26, | 2013 | Mar | NEWA |

ROCURONIUM BROMIDE

INJECTABLE; INJECTION

ZEMURON

@ ORGANON USA INC

|    |   |                      |         |     |         |      |     |      |
|----|---|----------------------|---------|-----|---------|------|-----|------|
|    |   | 10MG/ML (10MG/ML)    | N020214 | 002 | Mar 17, | 1994 | Jan | CAHN |
| AP | + | 50MG/5ML (10MG/ML)   | N020214 | 001 | Mar 17, | 1994 | Jan | CAHN |
| AP | + | 100MG/10ML (10MG/ML) | N020214 | 003 | Mar 17, | 1994 | Jan | CAHN |

ROPINIROLE HYDROCHLORIDE

TABLET; ORAL

REQUIP

|    |   |                     |                |         |     |         |      |     |      |
|----|---|---------------------|----------------|---------|-----|---------|------|-----|------|
| AB | + | GLAXOSMITHKLINE LLC | EQ 0.25MG BASE | N020658 | 001 | Sep 19, | 1997 | Mar | CAHN |
| AB |   |                     | EQ 0.5MG BASE  | N020658 | 002 | Sep 19, | 1997 | Mar | CAHN |
| AB |   |                     | EQ 1MG BASE    | N020658 | 003 | Sep 19, | 1997 | Mar | CAHN |
| AB |   |                     | EQ 2MG BASE    | N020658 | 004 | Sep 19, | 1997 | Mar | CAHN |
| AB |   |                     | EQ 3MG BASE    | N020658 | 006 | Jan 27, | 1999 | Mar | CAHN |
| AB |   |                     | EQ 4MG BASE    | N020658 | 007 | Jan 27, | 1999 | Mar | CAHN |
| AB |   |                     | EQ 5MG BASE    | N020658 | 005 | Sep 19, | 1997 | Mar | CAHN |

## TABLET, EXTENDED RELEASE; ORAL

## REQUIP XL

|    |   |                     |              |         |     |              |     |      |
|----|---|---------------------|--------------|---------|-----|--------------|-----|------|
| AB | + | GLAXOSMITHKLINE LLC | EQ 2MG BASE  | N022008 | 001 | Jun 13, 2008 | Mar | CAHN |
|    |   | @                   | EQ 3MG BASE  | N022008 | 002 | Jun 13, 2008 | Mar | CAHN |
| AB |   |                     | EQ 4MG BASE  | N022008 | 003 | Jun 13, 2008 | Mar | CAHN |
| AB |   |                     | EQ 6MG BASE  | N022008 | 006 | Apr 10, 2009 | Mar | CAHN |
| AB |   |                     | EQ 8MG BASE  | N022008 | 004 | Jun 13, 2008 | Mar | CAHN |
| AB |   |                     | EQ 12MG BASE | N022008 | 005 | Oct 31, 2008 | Mar | CAHN |

## ROPINIROLE HYDROCHLORIDE

|     |    |                   |              |         |     |              |     |      |
|-----|----|-------------------|--------------|---------|-----|--------------|-----|------|
| >D> | AB | ACTAVIS           | EQ 2MG BASE  | A090869 | 001 | May 17, 2012 | Apr | CAHN |
| >D> | AB |                   | EQ 4MG BASE  | A090869 | 002 | May 17, 2012 | Apr | CAHN |
| >D> | AB |                   | EQ 6MG BASE  | A090869 | 003 | May 17, 2012 | Apr | CAHN |
| >D> | AB |                   | EQ 8MG BASE  | A090869 | 004 | May 17, 2012 | Apr | CAHN |
| >D> | AB |                   | EQ 12MG BASE | A090869 | 005 | May 17, 2012 | Apr | CAHN |
| >A> | AB | ACTAVIS ELIZABETH | EQ 2MG BASE  | A090869 | 001 | May 17, 2012 | Apr | CAHN |
| >A> | AB |                   | EQ 4MG BASE  | A090869 | 002 | May 17, 2012 | Apr | CAHN |
| >A> | AB |                   | EQ 6MG BASE  | A090869 | 003 | May 17, 2012 | Apr | CAHN |
| >A> | AB |                   | EQ 8MG BASE  | A090869 | 004 | May 17, 2012 | Apr | CAHN |
| >A> | AB |                   | EQ 12MG BASE | A090869 | 005 | May 17, 2012 | Apr | CAHN |
| >A> | AB | ALEMBIC LTD       | EQ 2MG BASE  | A202786 | 001 | Apr 22, 2013 | Apr | NEWA |
| >A> | AB |                   | EQ 4MG BASE  | A202786 | 002 | Apr 22, 2013 | Apr | NEWA |
| >A> | AB |                   | EQ 6MG BASE  | A202786 | 003 | Apr 22, 2013 | Apr | NEWA |
| >A> | AB |                   | EQ 8MG BASE  | A202786 | 004 | Apr 22, 2013 | Apr | NEWA |
| >A> | AB |                   | EQ 12MG BASE | A202786 | 005 | Apr 22, 2013 | Apr | NEWA |

ROSIGLITAZONE MALEATE

## TABLET; ORAL

## AVANDIA

|    |   |            |             |         |     |              |     |      |
|----|---|------------|-------------|---------|-----|--------------|-----|------|
| AB |   | SB PHARMCO | EQ 2MG BASE | N021071 | 002 | May 25, 1999 | Jan | CFTG |
| AB |   |            | EQ 4MG BASE | N021071 | 003 | May 25, 1999 | Jan | CFTG |
| AB | + |            | EQ 8MG BASE | N021071 | 004 | May 25, 1999 | Jan | CFTG |

## ROSIGLITAZONE MALEATE

|    |  |      |             |         |     |              |     |      |
|----|--|------|-------------|---------|-----|--------------|-----|------|
| AB |  | TEVA | EQ 2MG BASE | A076747 | 001 | Jan 25, 2013 | Jan | NEWA |
| AB |  |      | EQ 4MG BASE | A076747 | 002 | Jan 25, 2013 | Jan | NEWA |
| AB |  |      | EQ 8MG BASE | A076747 | 003 | Jan 25, 2013 | Jan | NEWA |

SAQUINAVIR MESYLATE

## TABLET; ORAL

## INVIRASE

|   |                  |               |         |     |              |     |      |
|---|------------------|---------------|---------|-----|--------------|-----|------|
| + | HOFFMAN LA ROCHE | EQ 500MG BASE | N021785 | 001 | Dec 17, 2004 | Feb | CAHN |
|---|------------------|---------------|---------|-----|--------------|-----|------|

SELEGILINE HYDROCHLORIDE

## TABLET; ORAL

## SELEGILINE HYDROCHLORIDE

|   |                 |     |         |     |              |     |      |
|---|-----------------|-----|---------|-----|--------------|-----|------|
| @ | DAVA PHARMS INC | 5MG | A074641 | 001 | Aug 02, 1996 | Jan | DISC |
|---|-----------------|-----|---------|-----|--------------|-----|------|

SERTRALINE HYDROCHLORIDE

## TABLET; ORAL

## SERTRALINE HYDROCHLORIDE

|     |    |                    |               |         |     |              |     |      |
|-----|----|--------------------|---------------|---------|-----|--------------|-----|------|
| >D> | AB | DR REDDYS LABS LTD | EQ 25MG BASE  | A076442 | 001 | Apr 30, 2007 | Apr | DISC |
| >A> |    | @                  | EQ 25MG BASE  | A076442 | 001 | Apr 30, 2007 | Apr | DISC |
| >D> | AB |                    | EQ 50MG BASE  | A076442 | 002 | Apr 30, 2007 | Apr | DISC |
| >A> |    | @                  | EQ 50MG BASE  | A076442 | 002 | Apr 30, 2007 | Apr | DISC |
| >D> | AB |                    | EQ 100MG BASE | A076442 | 003 | Apr 30, 2007 | Apr | DISC |
| >A> |    | @                  | EQ 100MG BASE | A076442 | 003 | Apr 30, 2007 | Apr | DISC |

SILDENAFIL CITRATE

## TABLET; ORAL

## SILDENAFIL CITRATE

|     |    |                 |              |             |              |     |      |
|-----|----|-----------------|--------------|-------------|--------------|-----|------|
| >A> | AB | ACTAVIS GRP PTC | EQ 20MG BASE | A200149 001 | Feb 25, 2013 | Apr | CAHN |
| >D> | AB | ACTAVIS PHARMA  | EQ 20MG BASE | A200149 001 | Feb 25, 2013 | Apr | CAHN |
|     | AB |                 | EQ 20MG BASE | A200149 001 | Feb 25, 2013 | Feb | NEWA |
|     | AB | AMNEAL PHARMS   | EQ 20MG BASE | A202025 001 | Feb 28, 2013 | Feb | NEWA |

SODIUM CHLORIDE

## INJECTABLE; INJECTION

## SODIUM CHLORIDE 0.9%

## MEDEFIL INC

18MG/2ML (9MG/ML)

N202832 002 Jan 06, 2012 Mar NEWA

22.5MG/2.5ML (9MG/ML)

N202832 003 Jan 06, 2012 Mar NEWA

27MG/3ML (9MG/ML)

N202832 004 Jan 06, 2012 Mar NEWA

45MG/5ML (9MG/ML)

N202832 005 Jan 06, 2012 Mar NEWA

90MG/10ML (9MG/ML)

N202832 006 Jan 06, 2012 Mar NEWA

## SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

## MEDEFIL INC

9MG/ML (9MG/ML)

N202832 001 Jan 06, 2012 Mar CPOT

## SOLUTION; IRRIGATION

## SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

## @ BAXTER HLTHCARE

450MG/100ML

N017864 001 Jan DISC

SODIUM PHENYLBUTYRATE

## POWDER; ORAL

## BUPHENYL

|    |   |         |                 |             |              |     |      |
|----|---|---------|-----------------|-------------|--------------|-----|------|
| AB | + | MEDICIS | 3GM/TEASPOONFUL | N020573 001 | Apr 30, 1996 | Mar | CFTG |
|----|---|---------|-----------------|-------------|--------------|-----|------|

## SODIUM PHENYLBUTYRATE

|    |  |                     |                 |             |              |     |      |
|----|--|---------------------|-----------------|-------------|--------------|-----|------|
| AB |  | SIGMAPHARM LABS LLC | 3GM/TEASPOONFUL | A202819 001 | Mar 22, 2013 | Mar | NEWA |
|----|--|---------------------|-----------------|-------------|--------------|-----|------|

SODIUM POLYSTYRENE SULFONATE

## POWDER; ORAL, RECTAL

## KAYEXALATE

|     |    |   |                   |             |             |     |      |
|-----|----|---|-------------------|-------------|-------------|-----|------|
| >A> | AA | + | COVIS PHARMA SARL | 453.6GM/BOT | N011287 001 | Apr | CAHN |
|-----|----|---|-------------------|-------------|-------------|-----|------|

|     |    |   |                   |             |             |     |      |
|-----|----|---|-------------------|-------------|-------------|-----|------|
| >D> | AA | + | SANOFI AVENTIS US | 453.6GM/BOT | N011287 001 | Apr | CAHN |
|-----|----|---|-------------------|-------------|-------------|-----|------|

## SUSPENSION; ORAL, RECTAL

## SODIUM POLYSTYRENE SULFONATE

## @ ROXANE

15GM/60ML

A089049 001 Nov 17, 1986 Mar DISC

STAVUDINE

## CAPSULE; ORAL

## STAVUDINE

|     |    |                     |      |             |              |     |      |
|-----|----|---------------------|------|-------------|--------------|-----|------|
| >D> | AB | HETERO DRUGS        | 15MG | A078957 001 | Dec 29, 2008 | Apr | CAHN |
| >D> | AB |                     | 20MG | A078957 002 | Dec 29, 2008 | Apr | CAHN |
| >D> | AB |                     | 30MG | A078957 003 | Dec 29, 2008 | Apr | CAHN |
| >D> | AB |                     | 40MG | A078957 004 | Dec 29, 2008 | Apr | CAHN |
| >A> | AB | HETERO LABS LTD III | 15MG | A078957 001 | Dec 29, 2008 | Apr | CAHN |
| >A> | AB |                     | 20MG | A078957 002 | Dec 29, 2008 | Apr | CAHN |
| >A> | AB |                     | 30MG | A078957 003 | Dec 29, 2008 | Apr | CAHN |
| >A> | AB |                     | 40MG | A078957 004 | Dec 29, 2008 | Apr | CAHN |

STREPTOZOCIN

## INJECTABLE; INJECTION

## ZANOSAR

|     |   |                 |          |             |              |     |      |
|-----|---|-----------------|----------|-------------|--------------|-----|------|
| >D> | + | TEVA PARENTERAL | 1GM/VIAL | N050577 001 | May 07, 1982 | Apr | CAHN |
|-----|---|-----------------|----------|-------------|--------------|-----|------|

|                                       |    |                                   |                                     |         |     |                       |
|---------------------------------------|----|-----------------------------------|-------------------------------------|---------|-----|-----------------------|
|                                       |    | INJECTABLE; INJECTION             |                                     |         |     |                       |
|                                       |    | ZANOSAR                           |                                     |         |     |                       |
| >A>                                   | +  | TEVA PHARMS USA                   | 1GM/VIAL                            | N050577 | 001 | May 07, 1982 Apr CAHN |
| <u>SULFACETAMIDE SODIUM</u>           |    |                                   |                                     |         |     |                       |
|                                       |    | LOTION; TOPICAL                   |                                     |         |     |                       |
|                                       |    | KLARON                            |                                     |         |     |                       |
| AB                                    | +  | VALEANT BERMUDA                   | 10%                                 | N019931 | 001 | Dec 23, 1996 Feb CAHN |
| <u>SULFAMETHOXAZOLE; TRIMETHOPRIM</u> |    |                                   |                                     |         |     |                       |
|                                       |    | INJECTABLE; INJECTION             |                                     |         |     |                       |
|                                       |    | SULFAMETHOXAZOLE AND TRIMETHOPRIM |                                     |         |     |                       |
|                                       | +  | TEVA PHARMS USA                   | 80MG/ML;16MG/ML                     | A073303 | 001 | Oct 31, 1991 Mar CAHN |
|                                       |    | TABLET; ORAL                      |                                     |         |     |                       |
|                                       |    | SULFAMETHOPRIM                    |                                     |         |     |                       |
|                                       | @  | NOVEL LABS INC                    | 400MG;80MG                          | A070022 | 001 | Feb 15, 1985 Mar DISC |
|                                       |    | SULFAMETHOPRIM-DS                 |                                     |         |     |                       |
|                                       | @  | NOVEL LABS INC                    | 800MG;160MG                         | A070032 | 001 | Feb 15, 1985 Mar DISC |
| <u>SULINDAC</u>                       |    |                                   |                                     |         |     |                       |
|                                       |    | TABLET; ORAL                      |                                     |         |     |                       |
|                                       |    | SULINDAC                          |                                     |         |     |                       |
| >D>                                   |    | @ HERITAGE PHARMS INC             | 150MG                               | A073262 | 002 | Sep 06, 1991 Apr CMFD |
| >A>                                   | AB |                                   | 150MG                               | A073262 | 002 | Sep 06, 1991 Apr CMFD |
| >D>                                   |    | @                                 | 200MG                               | A073262 | 001 | Sep 06, 1991 Apr CMFD |
| >A>                                   | AB |                                   | 200MG                               | A073262 | 001 | Sep 06, 1991 Apr CMFD |
| <u>SUMATRIPTAN SUCCINATE</u>          |    |                                   |                                     |         |     |                       |
|                                       |    | INJECTABLE; SUBCUTANEOUS          |                                     |         |     |                       |
|                                       |    | SUMATRIPTAN SUCCINATE             |                                     |         |     |                       |
| >A>                                   | AP | AUROBINDO PHARMA LTD              | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | A202758 | 001 | Apr 23, 2013 Apr NEWA |
|                                       | AP | SAGENT AGILA                      | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | A090641 | 001 | Jul 28, 2010 Feb CAHN |
|                                       | AP | TEVA PHARMS USA                   | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | A077907 | 001 | Feb 06, 2009 Mar CAHN |
|                                       |    | SYSTEM; IONTOPHORESIS             |                                     |         |     |                       |
|                                       |    | ZECUITY                           |                                     |         |     |                       |
|                                       | +  | NUPATHE                           | EQ 6.5MG BASE/4HR                   | N202278 | 001 | Jan 17, 2013 Jan NEWA |
| <u>TAMSULOSIN HYDROCHLORIDE</u>       |    |                                   |                                     |         |     |                       |
|                                       |    | CAPSULE; ORAL                     |                                     |         |     |                       |
|                                       |    | TAMSULOSIN HYDROCHLORIDE          |                                     |         |     |                       |
| >A>                                   | AB | AUROBINDO PHARMA LTD              | 0.4MG                               | A202433 | 001 | Apr 30, 2013 Apr NEWA |
| <u>TECHNETIUM TC-99M TILMANOCEPT</u>  |    |                                   |                                     |         |     |                       |
|                                       |    | INJECTABLE; INJECTION             |                                     |         |     |                       |
|                                       |    | LYMPHOSEEK KIT                    |                                     |         |     |                       |
|                                       | +  | NAVIDEA BIOPHARMS                 | N/A                                 | N202207 | 001 | Mar 13, 2013 Mar NEWA |
| <u>TENIPOSIDE</u>                     |    |                                   |                                     |         |     |                       |
|                                       |    | INJECTABLE; INJECTION             |                                     |         |     |                       |
|                                       |    | VUMON                             |                                     |         |     |                       |
| >D>                                   | +  | BRISTOL MYERS SQUIBB              | 10MG/ML                             | N020119 | 001 | Jul 14, 1992 Apr CAHN |
| >A>                                   | +  | CORDEN PHARMA                     | 10MG/ML                             | N020119 | 001 | Jul 14, 1992 Apr CAHN |

TERBUTALINE SULFATE

INJECTABLE; INJECTION

TERBUTALINE SULFATE

@ TEVA PHARMS USA

1MG/ML

A076853 001 Jul 20, 2004 Mar CAHN

TESTOSTERONE

GEL; TRANSDERMAL

TESTOSTERONE

PERRIGO ISRAEL

25MG/2.5GM PACKET

N203098 002 Jan 31, 2013 Jan NEWA

50MG/5GM PACKET

N203098 003 Jan 31, 2013 Jan NEWA

GEL, METERED; TRANSDERMAL

TESTOSTERONE

PERRIGO ISRAEL

12.5MG/1.25GM ACTUATION

N203098 001 Jan 31, 2013 Jan NEWA

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

DELATESTRYL

AO + ENDO PHARMS

200MG/ML

N009165 003

Jan CAHN

@

200MG/ML

N009165 001

Jan CAHN

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

THEOPHYLLINE

AB + TEVA PHARMS

450MG

A081236 001 Nov 09, 1992 Mar CAHN

THIOGUANINE

TABLET; ORAL

THIOGUANINE

+ ASPEN GLOBAL INC

40MG

N012429 001

Mar CAHN

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

TIMOLOL MALEATE

&gt;D&gt; AT APOTEX INC

EQ 0.25% BASE

A075411 001 Sep 08, 2000 Apr DISC

&gt;A&gt; @

EQ 0.25% BASE

A075411 001 Sep 08, 2000 Apr DISC

&gt;D&gt; AT

EQ 0.5% BASE

A075412 001 Sep 08, 2000 Apr DISC

&gt;A&gt; @

EQ 0.5% BASE

A075412 001 Sep 08, 2000 Apr DISC

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC

TIMOPTIC-XE

AB + VALEANT PHARMS LLC

EQ 0.25% BASE

N020330 001 Nov 04, 1993 Jan CAHN

AB +

EQ 0.5% BASE

N020330 002 Nov 04, 1993 Jan CAHN

TIZANIDINE HYDROCHLORIDE

TABLET; ORAL

TIZANIDINE HYDROCHLORIDE

@ MYLAN PHARMS INC

EQ 2MG BASE

A076282 001 Dec 16, 2003 Feb DISC

@

EQ 4MG BASE

A076282 002 Dec 16, 2003 Feb DISC

TOBRAMYCIN

POWDER; INHALATION

TOBI PODHALER

+ NOVARTIS

28MG

N201688 001 Mar 22, 2013 Mar NEWA

SOLUTION/DROPS; OPHTHALMICTOBRAMYCIN

|     |    |              |      |         |     |         |      |     |      |
|-----|----|--------------|------|---------|-----|---------|------|-----|------|
| >A> |    | @ APOTEX INC | 0.3% | A065087 | 001 | Feb 25, | 2002 | Apr | DISC |
| >D> | AT | NOVEX        | 0.3% | A065087 | 001 | Feb 25, | 2002 | Apr | DISC |

TOLAZAMIDETABLET; ORALTOLAZAMIDE

|  |  |                  |       |         |     |         |      |     |      |
|--|--|------------------|-------|---------|-----|---------|------|-----|------|
|  |  | MYLAN PHARMS INC | 250MG | A070259 | 001 | Jan 02, | 1986 | Mar | CTEC |
|  |  | +                | 500MG | A070259 | 003 | Mar 17, | 1986 | Mar | CTEC |
|  |  | @ WATSON LABS    | 250MG | A070514 | 001 | Jan 09, | 1986 | Mar | DISC |
|  |  | @                | 500MG | A070515 | 001 | Jan 09, | 1986 | Mar | DISC |

TOPIRAMATETABLET; ORALTOPAMAX

|     |    |   |                |       |         |     |         |      |     |      |
|-----|----|---|----------------|-------|---------|-----|---------|------|-----|------|
| >D> | AB | + | JANSSEN PHARMS | 25MG  | N020505 | 004 | Dec 24, | 1996 | Apr | CRLD |
| >A> | AB |   |                | 25MG  | N020505 | 004 | Dec 24, | 1996 | Apr | CRLD |
| >D> | AB |   |                | 100MG | N020505 | 001 | Dec 24, | 1996 | Apr | CRLD |
| >A> | AB | + |                | 100MG | N020505 | 001 | Dec 24, | 1996 | Apr | CRLD |

TOPIRAMATE

|  |    |  |                    |       |         |     |         |      |     |      |
|--|----|--|--------------------|-------|---------|-----|---------|------|-----|------|
|  | AB |  | ACTIVIS TOTOWA LLC | 25MG  | A078637 | 001 | Feb 27, | 2013 | Feb | NEWA |
|  | AB |  |                    | 50MG  | A078637 | 002 | Feb 27, | 2013 | Feb | NEWA |
|  | AB |  |                    | 100MG | A078637 | 003 | Feb 27, | 2013 | Feb | NEWA |
|  | AB |  |                    | 200MG | A078637 | 004 | Feb 27, | 2013 | Feb | NEWA |
|  | AB |  | UNICHEM LABS LTD   | 200MG | A090162 | 004 | Feb 19, | 2013 | Feb | NEWA |

TORSEMIDETABLET; ORALTORSEMIDE

|     |    |  |                     |       |         |     |         |      |     |      |
|-----|----|--|---------------------|-------|---------|-----|---------|------|-----|------|
| >D> | AB |  | HETERO DRUGS        | 5MG   | A079234 | 001 | Jan 27, | 2009 | Apr | CAHN |
| >D> | AB |  |                     | 10MG  | A079234 | 002 | Jan 27, | 2009 | Apr | CAHN |
| >D> | AB |  |                     | 20MG  | A079234 | 003 | Jan 27, | 2009 | Apr | CAHN |
| >D> | AB |  |                     | 100MG | A079234 | 004 | Jan 27, | 2009 | Apr | CAHN |
| >A> | AB |  | HETERO LABS LTD III | 5MG   | A079234 | 001 | Jan 27, | 2009 | Apr | CAHN |
| >A> | AB |  |                     | 10MG  | A079234 | 002 | Jan 27, | 2009 | Apr | CAHN |
| >A> | AB |  |                     | 20MG  | A079234 | 003 | Jan 27, | 2009 | Apr | CAHN |
| >A> | AB |  |                     | 100MG | A079234 | 004 | Jan 27, | 2009 | Apr | CAHN |

TRAMADOL HYDROCHLORIDETABLET; ORALTRAMADOL HYDROCHLORIDE

|     |    |  |                     |      |         |     |         |      |     |      |
|-----|----|--|---------------------|------|---------|-----|---------|------|-----|------|
| >A> | AB |  | ACCORD HLTHCARE INC | 50MG | A202390 | 001 | May 16, | 2013 | Apr | NEWA |
|     | AB |  | CSPC OUYI PHARM CO  | 50MG | A091498 | 001 | Mar 29, | 2013 | Mar | NEWA |

TABLET, EXTENDED RELEASE; ORALRYZOLT

|  |  |                 |       |         |     |         |      |     |      |
|--|--|-----------------|-------|---------|-----|---------|------|-----|------|
|  |  | @ PURDUE PHARMA | 100MG | N021745 | 001 | Dec 30, | 2008 | Jan | DISC |
|  |  | @               | 200MG | N021745 | 002 | Dec 30, | 2008 | Jan | DISC |
|  |  | @               | 300MG | N021745 | 003 | Dec 30, | 2008 | Jan | DISC |

TRAMADOL HYDROCHLORIDE

|     |     |  |                   |       |         |     |         |      |     |      |
|-----|-----|--|-------------------|-------|---------|-----|---------|------|-----|------|
| >D> | AB2 |  | ACTAVIS           | 100MG | A091609 | 001 | Jun 27, | 2012 | Apr | CAHN |
| >D> | AB2 |  |                   | 200MG | A091609 | 002 | Jun 27, | 2012 | Apr | CAHN |
| >D> | AB2 |  |                   | 300MG | A091609 | 003 | Jun 27, | 2012 | Apr | CAHN |
| >A> | AB2 |  | ACTAVIS ELIZABETH | 100MG | A091609 | 001 | Jun 27, | 2012 | Apr | CAHN |
| >A> | AB2 |  |                   | 200MG | A091609 | 002 | Jun 27, | 2012 | Apr | CAHN |
| >A> | AB2 |  |                   | 300MG | A091609 | 003 | Jun 27, | 2012 | Apr | CAHN |

TABLET, EXTENDED RELEASE; ORAL  
TRAMADOL HYDROCHLORIDE

|       |                   |       |         |     |              |     |      |
|-------|-------------------|-------|---------|-----|--------------|-----|------|
| AB1   | PAR PHARM INC     | 100MG | A078783 | 001 | Nov 13, 2009 | Feb | CRLD |
| AB2 + | SUN PHARMA GLOBAL | 100MG | A091607 | 001 | Dec 30, 2011 | Feb | CRLD |

TRANDOLAPRIL

TABLET; ORAL

TRANDOLAPRIL

|     |    |                    |     |         |     |              |     |      |
|-----|----|--------------------|-----|---------|-----|--------------|-----|------|
| >D> | AB | DR REDDYS LABS LTD | 1MG | A078493 | 001 | Aug 25, 2008 | Apr | DISC |
| >A> |    | @                  | 1MG | A078493 | 001 | Aug 25, 2008 | Apr | DISC |
| >D> | AB |                    | 2MG | A078493 | 002 | Aug 25, 2008 | Apr | DISC |
| >A> |    | @                  | 2MG | A078493 | 002 | Aug 25, 2008 | Apr | DISC |
| >D> | AB |                    | 4MG | A078493 | 003 | Aug 25, 2008 | Apr | DISC |
| >A> |    | @                  | 4MG | A078493 | 003 | Aug 25, 2008 | Apr | DISC |

TRAVOPROST

SOLUTION/DROPS; OPHTHALMIC

TRAVOPROST

|           |        |         |     |              |     |      |
|-----------|--------|---------|-----|--------------|-----|------|
| PAR PHARM | 0.004% | A091340 | 001 | Mar 01, 2013 | Feb | NEWA |
|-----------|--------|---------|-----|--------------|-----|------|

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HYDROCHLORIDE

|    |                 |       |         |     |              |     |      |
|----|-----------------|-------|---------|-----|--------------|-----|------|
| AB | TEVA PHARMS USA | 50MG  | A071523 | 001 | Dec 11, 1987 | Mar | CAHN |
| AB |                 | 100MG | A071524 | 001 | Dec 11, 1987 | Mar | CAHN |

TRETINOIN

GEL; TOPICAL

ATRALIN

|     |   |                    |       |         |     |              |     |      |
|-----|---|--------------------|-------|---------|-----|--------------|-----|------|
| >A> | + | DOW PHARM          | 0.05% | N022070 | 001 | Jul 26, 2007 | Apr | CAHN |
| >D> | + | DOW PHARM SCIENCES | 0.05% | N022070 | 001 | Jul 26, 2007 | Apr | CAHN |

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

KENALOG

|     |    |   |           |        |         |     |     |      |
|-----|----|---|-----------|--------|---------|-----|-----|------|
| >D> | AT | + | APOTHECON | 0.025% | N011601 | 003 | Apr | DISC |
| >A> |    |   | @         | 0.025% | N011601 | 003 | Apr | DISC |
| >D> | AT | + |           | 0.1%   | N011601 | 006 | Apr | DISC |
| >A> |    |   | @         | 0.1%   | N011601 | 006 | Apr | DISC |

TRACET

|     |    |      |        |         |     |     |      |
|-----|----|------|--------|---------|-----|-----|------|
| >D> | AT | TEVA | 0.025% | A084908 | 001 | Apr | DISC |
| >A> |    | @    | 0.025% | A084908 | 001 | Apr | DISC |
| >D> | AT |      | 0.5%   | A084908 | 003 | Apr | DISC |
| >A> |    | @    | 0.5%   | A084908 | 003 | Apr | DISC |

TRIAMCINOLONE ACETONIDE

|     |    |                |        |         |     |     |      |
|-----|----|----------------|--------|---------|-----|-----|------|
| >D> | AT | FOUGERA PHARMS | 0.025% | A085692 | 001 | Apr | CRLD |
| >A> | AT | +              | 0.025% | A085692 | 001 | Apr | CRLD |
| >D> | AT |                | 0.1%   | A085692 | 003 | Apr | CRLD |
| >A> | AT | +              | 0.1%   | A085692 | 003 | Apr | CRLD |
| >D> | AT | TARO           | 0.025% | A086277 | 001 | Apr | DISC |
| >A> |    | @              | 0.025% | A086277 | 001 | Apr | DISC |
| >D> | AT |                | 0.1%   | A086276 | 001 | Apr | DISC |
| >A> |    | @              | 0.1%   | A086276 | 001 | Apr | DISC |
| >D> | AT |                | 0.5%   | A086275 | 001 | Apr | DISC |
| >A> |    | @              | 0.5%   | A086275 | 001 | Apr | DISC |

## LOTION; TOPICAL

## TRIAMCINOLONE ACETONIDE

|     |    |   |                      |        |         |     |              |     |      |
|-----|----|---|----------------------|--------|---------|-----|--------------|-----|------|
| >D> | AT | + | MORTON GROVE         | 0.025% | A088450 | 001 | Apr 01, 1985 | Apr | CAHN |
| >A> | AT |   | VERSAPHARM INC       | 0.025% | A202374 | 001 | May 08, 2013 | Apr | NEWA |
| >A> | AT |   |                      | 0.1%   | A202374 | 002 | May 08, 2013 | Apr | NEWA |
| >A> | AT | + | WOCKHARDT EU OPERATN | 0.025% | A088450 | 001 | Apr 01, 1985 | Apr | CAHN |

## OINTMENT; TOPICAL

## KENALOG

|     |    |   |           |        |         |     |  |     |      |
|-----|----|---|-----------|--------|---------|-----|--|-----|------|
| >D> | AT |   | APOTHECON | 0.025% | N011600 | 003 |  | Apr | DISC |
| >A> |    | @ |           | 0.025% | N011600 | 003 |  | Apr | DISC |
| >D> | AT |   |           | 0.1%   | N011600 | 001 |  | Apr | DISC |
| >A> |    | @ |           | 0.1%   | N011600 | 001 |  | Apr | DISC |

URSODIOL

## TABLET; ORAL

## URSODIOL

|     |    |   |                 |       |         |     |              |     |      |
|-----|----|---|-----------------|-------|---------|-----|--------------|-----|------|
|     | AB |   | PAR PHARM       | 250MG | A202540 | 001 | Feb 14, 2013 | Feb | NEWA |
|     | AB |   |                 | 500MG | A202540 | 002 | Feb 14, 2013 | Feb | NEWA |
| >D> | AB |   | TEVA PHARMS     | 250MG | A079184 | 001 | May 13, 2009 | Apr | DISC |
| >D> | AB |   |                 | 500MG | A079184 | 002 | May 13, 2009 | Apr | DISC |
| >A> |    | @ | TEVA PHARMS USA | 250MG | A079184 | 001 | May 13, 2009 | Apr | DISC |
| >A> |    | @ |                 | 500MG | A079184 | 002 | May 13, 2009 | Apr | DISC |

VALACYCLOVIR HYDROCHLORIDE

## TABLET; ORAL

## VALACYCLOVIR HYDROCHLORIDE

|  |    |  |                 |               |         |     |              |     |      |
|--|----|--|-----------------|---------------|---------|-----|--------------|-----|------|
|  | AB |  | ACTAVIS GRP PTC | EQ 500MG BASE | A090370 | 001 | Mar 16, 2011 | Mar | CAHN |
|  | AB |  |                 | EQ 1GM BASE   | A090370 | 002 | Mar 16, 2011 | Mar | CAHN |

VALPROIC ACID

## CAPSULE; ORAL

## VALPROIC ACID

|  |    |  |                    |       |         |     |              |     |      |
|--|----|--|--------------------|-------|---------|-----|--------------|-----|------|
|  | AB |  | SUN PHARM INDS LTD | 250MG | A091037 | 001 | Feb 22, 2013 | Feb | NEWA |
|--|----|--|--------------------|-------|---------|-----|--------------|-----|------|

VECURONIUM BROMIDE

## INJECTABLE; INJECTION

## VECURONIUM BROMIDE

|     |    |  |                 |           |         |     |              |     |      |
|-----|----|--|-----------------|-----------|---------|-----|--------------|-----|------|
| >D> | AP |  | TEVA PARENTERAL | 10MG/VIAL | A074688 | 001 | Aug 25, 1999 | Apr | CAHN |
| >D> | AP |  |                 | 20MG/VIAL | A074688 | 002 | Aug 25, 1999 | Apr | CAHN |
| >A> | AP |  | TEVA PHARMS USA | 10MG/VIAL | A074688 | 001 | Aug 25, 1999 | Apr | CAHN |
| >A> | AP |  |                 | 20MG/VIAL | A074688 | 002 | Aug 25, 1999 | Apr | CAHN |

VERAPAMIL HYDROCHLORIDE

## INJECTABLE; INJECTION

## VERAPAMIL HYDROCHLORIDE

|   |                 |          |
|---|-----------------|----------|
| @ | INTL MEDICATION | 2.5MG/ML |
|---|-----------------|----------|

|         |     |              |     |      |
|---------|-----|--------------|-----|------|
| A070451 | 001 | Dec 16, 1985 | Mar | DISC |
|---------|-----|--------------|-----|------|

VERTEPORFIN

## INJECTABLE; INJECTION

## VISUDYNE

|   |                    |           |
|---|--------------------|-----------|
| + | VALEANT PHARMS INC | 15MG/VIAL |
|---|--------------------|-----------|

|         |     |              |     |      |
|---------|-----|--------------|-----|------|
| N021119 | 001 | Apr 12, 2000 | Jan | CAHN |
|---------|-----|--------------|-----|------|

VINCRIStINE SULFATE

## INJECTABLE; INJECTION

## VINCRIStINE SULFATE PFS

|     |    |                 |        |             |              |     |      |
|-----|----|-----------------|--------|-------------|--------------|-----|------|
| >D> | AP | TEVA PARENTERAL | 1MG/ML | A075493 001 | Sep 01, 1999 | Apr | CAHN |
| >A> | AP | TEVA PHARMS USA | 1MG/ML | A075493 001 | Sep 01, 1999 | Apr | CAHN |

VINORELBINE TARTRATE

## INJECTABLE; INJECTION

## VINORELBINE TARTRATE

|     |    |                 |                 |             |              |     |      |
|-----|----|-----------------|-----------------|-------------|--------------|-----|------|
| >D> | AP | TEVA PARENTERAL | EQ 10MG BASE/ML | A076028 001 | Feb 03, 2003 | Apr | CAHN |
| >A> | AP | TEVA PHARMS USA | EQ 10MG BASE/ML | A076028 001 | Feb 03, 2003 | Apr | CAHN |

WARFARIN SODIUM

## TABLET; ORAL

## WARFARIN SODIUM

|    |               |       |             |              |     |      |
|----|---------------|-------|-------------|--------------|-----|------|
| AB | AMNEAL PHARMS | 1MG   | A202202 001 | Mar 04, 2013 | Feb | NEWA |
| AB |               | 2MG   | A202202 002 | Mar 04, 2013 | Feb | NEWA |
| AB |               | 2.5MG | A202202 003 | Mar 04, 2013 | Feb | NEWA |
| AB |               | 3MG   | A202202 004 | Mar 04, 2013 | Feb | NEWA |
| AB |               | 4MG   | A202202 005 | Mar 04, 2013 | Feb | NEWA |
| AB |               | 5MG   | A202202 006 | Mar 04, 2013 | Feb | NEWA |
| AB |               | 6MG   | A202202 007 | Mar 04, 2013 | Feb | NEWA |
| AB |               | 7.5MG | A202202 008 | Mar 04, 2013 | Feb | NEWA |
| AB |               | 10MG  | A202202 009 | Mar 04, 2013 | Feb | NEWA |

ZALEPLON

## CAPSULE; ORAL

## SONATA

|     |    |             |      |             |              |     |      |
|-----|----|-------------|------|-------------|--------------|-----|------|
| >D> | AB | KING PHARMS | 5MG  | N020859 001 | Aug 13, 1999 | Apr | CAHN |
| >D> | AB | +           | 10MG | N020859 002 | Aug 13, 1999 | Apr | CAHN |
| >A> | AB | PFIZER      | 5MG  | N020859 001 | Aug 13, 1999 | Apr | CAHN |
| >A> | AB | +           | 10MG | N020859 002 | Aug 13, 1999 | Apr | CAHN |

ZIDOVUDINE

## TABLET; ORAL

## RETROVIR

|     |    |   |                |       |             |              |     |      |
|-----|----|---|----------------|-------|-------------|--------------|-----|------|
| >D> | AB | + | VIIIV HLTHCARE | 300MG | N020518 002 | Oct 04, 1996 | Apr | DISC |
| >A> |    | @ |                | 300MG | N020518 002 | Oct 04, 1996 | Apr | DISC |

## ZIDOVUDINE

|     |    |                   |                     |             |              |              |      |      |
|-----|----|-------------------|---------------------|-------------|--------------|--------------|------|------|
|     | AB | HEC PHARM USA INC | 300MG               | A202058 001 | Oct 07, 2011 | Feb          | CMFD |      |
|     |    | @                 | 300MG               | A202058 001 | Oct 07, 2011 | Jan          | DISC |      |
| >D> | AB | HETERO DRUGS LTD  | 300MG               | A090092 001 | Apr 25, 2008 | Apr          | CRLD |      |
| >A> | AB | +                 | HETERO LABS LTD III | 300MG       | A090092 001  | Apr 25, 2008 | Apr  | CRLD |

ZOLEDRONIC ACID

## INJECTABLE; INJECTION

## ZOLEDRONIC ACID

|    |                    |                   |             |              |     |      |
|----|--------------------|-------------------|-------------|--------------|-----|------|
| AP | DR REDDYS LABS LTD | EQ 5MG BASE/100ML | A091363 001 | Mar 29, 2013 | Mar | NEWA |
| AP | EMCURE PHARMS LTD  | EQ 5MG BASE/100ML | A201801 001 | Mar 29, 2013 | Mar | NEWA |

## INJECTABLE; IV (INFUSION)

## RECLAST

|    |   |          |                   |             |              |     |      |
|----|---|----------|-------------------|-------------|--------------|-----|------|
| AP | + | NOVARTIS | EQ 5MG BASE/100ML | N021817 001 | Apr 16, 2007 | Mar | CTEC |
|----|---|----------|-------------------|-------------|--------------|-----|------|

## ZOLEDRONIC ACID

|    |             |                 |             |              |     |      |
|----|-------------|-----------------|-------------|--------------|-----|------|
| AP | ACTAVIS INC | EQ 4MG BASE/5ML | A202472 001 | Mar 04, 2013 | Feb | NEWA |
|----|-------------|-----------------|-------------|--------------|-----|------|

## INJECTABLE; IV (INFUSION)

## ZOLEDRONIC ACID

|     |    |                    |                   |         |     |              |     |      |
|-----|----|--------------------|-------------------|---------|-----|--------------|-----|------|
| >A> | AP | AGILA SPECLTS      | EQ 4MG BASE/5ML   | A202650 | 001 | Mar 04, 2013 | Feb | NEWA |
|     | AP | DR REDDYS LABS LTD | EQ 4MG BASE/5ML   | A091186 | 001 | Mar 04, 2013 | Feb | NEWA |
|     | AP | EMCURE PHARMS LTD  | EQ 4MG BASE/5ML   | A201783 | 001 | Mar 12, 2013 | Mar | NEWA |
|     | AP | HOSPIRA INC        | EQ 5MG BASE/100ML | A202837 | 001 | Apr 05, 2013 | Mar | NEWA |
|     | AP | PHARMACEUTICS      | EQ 4MG BASE/5ML   | A091170 | 001 | Mar 04, 2013 | Feb | NEWA |
|     | AP | PHARMS             | EQ 4MG BASE/5ML   | A202571 | 001 | May 07, 2013 | Apr | NEWA |
|     | +  | SUN PHARMA GLOBAL  | EQ 4MG BASE/VIAL  | A090018 | 001 | Mar 04, 2013 | Feb | NEWA |
|     | AP |                    | EQ 4MG BASE/5ML   | A202746 | 001 | Mar 04, 2013 | Feb | NEWA |
|     |    | ZOMETA             |                   |         |     |              |     |      |
| AP  | +  | NOVARTIS           | EQ 4MG BASE/5ML   | N021223 | 002 | Mar 07, 2003 | Feb | CFTG |

## ZOLMITRIPTAN

## TABLET; ORAL

|     |                                     |                      |       |         |     |              |     |      |
|-----|-------------------------------------|----------------------|-------|---------|-----|--------------|-----|------|
| >A> | ZOLMITRIPTAN                        |                      |       |         |     |              |     |      |
| >A> | AB                                  | APOTEX INC           | 2.5MG | A202078 | 001 | May 14, 2013 | Apr | NEWA |
| >A> | AB                                  |                      | 5MG   | A202078 | 002 | May 14, 2013 | Apr | NEWA |
| >A> | AB                                  | GLENMARK GENERICS    | 2.5MG | A201779 | 001 | May 14, 2013 | Apr | NEWA |
| >A> | AB                                  |                      | 5MG   | A201779 | 002 | May 14, 2013 | Apr | NEWA |
| >A> | AB                                  | MYLAN PHARMS INC     | 2.5MG | A203186 | 001 | May 14, 2013 | Apr | NEWA |
| >A> | AB                                  |                      | 5MG   | A203186 | 002 | May 14, 2013 | Apr | NEWA |
|     | ZOMIG                               |                      |       |         |     |              |     |      |
| >D> |                                     | IPR                  | 2.5MG | N020768 | 001 | Nov 25, 1997 | Apr | CFTG |
| >A> | AB                                  |                      | 2.5MG | N020768 | 001 | Nov 25, 1997 | Apr | CFTG |
| >D> | +                                   |                      | 5MG   | N020768 | 002 | Nov 25, 1997 | Apr | CFTG |
| >A> | AB                                  | +                    | 5MG   | N020768 | 002 | Nov 25, 1997 | Apr | CFTG |
|     | TABLET, ORALLY DISINTEGRATING; ORAL |                      |       |         |     |              |     |      |
| >A> | ZOLMITRIPTAN                        |                      |       |         |     |              |     |      |
| >A> | AB                                  | APOTEX INC           | 2.5MG | A202476 | 001 | May 14, 2013 | Apr | NEWA |
| >A> | AB                                  |                      | 5MG   | A202476 | 002 | May 14, 2013 | Apr | NEWA |
| >A> | AB                                  | GLENMARK GENERICS    | 2.5MG | A202560 | 001 | May 14, 2013 | Apr | NEWA |
| >A> | AB                                  |                      | 5MG   | A202560 | 002 | May 14, 2013 | Apr | NEWA |
| >A> | AB                                  | ZYDUS PHARMS USA INC | 2.5MG | A202890 | 001 | May 15, 2013 | Apr | NEWA |
| >A> | AB                                  |                      | 5MG   | A202890 | 002 | May 15, 2013 | Apr | NEWA |
|     | ZOMIG-ZMT                           |                      |       |         |     |              |     |      |
| >D> |                                     | ASTRAZENECA          | 2.5MG | N021231 | 001 | Feb 13, 2001 | Apr | CFTG |
| >A> | AB                                  |                      | 2.5MG | N021231 | 001 | Feb 13, 2001 | Apr | CFTG |
| >D> | +                                   |                      | 5MG   | N021231 | 002 | Sep 17, 2001 | Apr | CFTG |
| >A> | AB                                  | +                    | 5MG   | N021231 | 002 | Sep 17, 2001 | Apr | CFTG |

## ZOLPIDEM TARTRATE

## TABLET; ORAL

|                                |    |                    |        |         |     |              |     |      |
|--------------------------------|----|--------------------|--------|---------|-----|--------------|-----|------|
| ZOLPIDEM TARTRATE              |    |                    |        |         |     |              |     |      |
| >D>                            | AB | DR REDDYS LABS LTD | 5MG    | A077985 | 001 | Apr 23, 2007 | Apr | DISC |
| >A>                            |    | @                  | 5MG    | A077985 | 001 | Apr 23, 2007 | Apr | DISC |
| >D>                            | AB |                    | 10MG   | A077985 | 002 | Apr 23, 2007 | Apr | DISC |
| >A>                            |    | @                  | 10MG   | A077985 | 002 | Apr 23, 2007 | Apr | DISC |
| TABLET, EXTENDED RELEASE; ORAL |    |                    |        |         |     |              |     |      |
| ZOLPIDEM TARTRATE              |    |                    |        |         |     |              |     |      |
| >A>                            | AB | ACTAVIS ELIZABETH  | 6.25MG | A078179 | 002 | Oct 13, 2010 | Apr | CAHN |
| >A>                            | AB |                    | 12.5MG | A078179 | 001 | Jun 06, 2011 | Apr | CAHN |
| >D>                            | AB | ACTAVIS S ATLANTIC | 6.25MG | A078179 | 002 | Oct 13, 2010 | Apr | CAHN |
| >D>                            | AB |                    | 12.5MG | A078179 | 001 | Jun 06, 2011 | Apr | CAHN |
|                                | AB | WATSON LABS INC FL | 6.25MG | A090153 | 001 | Mar 25, 2013 | Mar | NEWA |
|                                | AB |                    | 12.5MG | A090153 | 002 | Mar 25, 2013 | Mar | NEWA |

ZONISAMIDE

CAPSULE; ORAL

ZONISAMIDE

|                      |       |             |              |     |      |
|----------------------|-------|-------------|--------------|-----|------|
| @ COREPHARMA         | 25MG  | A077876 001 | Feb 21, 2007 | Feb | DISC |
| @                    | 50MG  | A077876 002 | Feb 21, 2007 | Feb | DISC |
| @                    | 100MG | A077876 003 | Feb 21, 2007 | Feb | DISC |
| @ DR REDDYS LABS LTD | 25MG  | A077645 002 | Sep 29, 2006 | Mar | DISC |
| @                    | 50MG  | A077645 003 | Sep 29, 2006 | Mar | DISC |
| @                    | 100MG | A077645 001 | Dec 22, 2005 | Mar | DISC |

OTC DRUG PRODUCT LIST - 33RD EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

2-1

ASPIRIN

CAPSULE; ORAL

ASPIRIN

|  |              |       |             |              |     |      |
|--|--------------|-------|-------------|--------------|-----|------|
|  | + PLX PHARMA | 325MG | N203697 001 | Jan 14, 2013 | Jan | NEWA |
|--|--------------|-------|-------------|--------------|-----|------|

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

|     |        |         |             |              |     |      |
|-----|--------|---------|-------------|--------------|-----|------|
| >D> | APOTEX | 5MG/5ML | A090188 002 | Apr 22, 2008 | Apr | DISC |
|-----|--------|---------|-------------|--------------|-----|------|

|     |              |         |             |              |     |      |
|-----|--------------|---------|-------------|--------------|-----|------|
| >A> | @ APOTEX INC | 5MG/5ML | A090188 002 | Apr 22, 2008 | Apr | DISC |
|-----|--------------|---------|-------------|--------------|-----|------|

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

|     |        |         |             |              |     |      |
|-----|--------|---------|-------------|--------------|-----|------|
| >D> | APOTEX | 5MG/5ML | A090188 001 | Apr 22, 2008 | Apr | DISC |
|-----|--------|---------|-------------|--------------|-----|------|

|     |              |         |             |              |     |      |
|-----|--------------|---------|-------------|--------------|-----|------|
| >A> | @ APOTEX INC | 5MG/5ML | A090188 001 | Apr 22, 2008 | Apr | DISC |
|-----|--------------|---------|-------------|--------------|-----|------|

TABLET, CHEWABLE; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

|     |        |      |             |              |     |      |
|-----|--------|------|-------------|--------------|-----|------|
| >D> | SANDOZ | 10MG | A078692 002 | Feb 14, 2008 | Apr | CRLD |
|-----|--------|------|-------------|--------------|-----|------|

|     |   |      |             |              |     |      |
|-----|---|------|-------------|--------------|-----|------|
| >A> | + | 10MG | A078692 002 | Feb 14, 2008 | Apr | CRLD |
|-----|---|------|-------------|--------------|-----|------|

CHILDREN'S ZYRTEC ALLERGY

|     |               |     |             |              |     |      |
|-----|---------------|-----|-------------|--------------|-----|------|
| >D> | + MCNEIL CONS | 5MG | N021621 003 | Nov 16, 2007 | Apr | DISC |
|-----|---------------|-----|-------------|--------------|-----|------|

|     |   |     |             |              |     |      |
|-----|---|-----|-------------|--------------|-----|------|
| >A> | @ | 5MG | N021621 003 | Nov 16, 2007 | Apr | DISC |
|-----|---|-----|-------------|--------------|-----|------|

+

|  |   |      |             |              |     |      |
|--|---|------|-------------|--------------|-----|------|
|  | @ | 10MG | N021621 004 | Nov 16, 2007 | Feb | DISC |
|--|---|------|-------------|--------------|-----|------|

CHILDREN'S ZYRTEC HIVES RELIEF

|     |               |     |             |              |     |      |
|-----|---------------|-----|-------------|--------------|-----|------|
| >D> | + MCNEIL CONS | 5MG | N021621 005 | Nov 16, 2007 | Apr | DISC |
|-----|---------------|-----|-------------|--------------|-----|------|

|     |   |     |             |              |     |      |
|-----|---|-----|-------------|--------------|-----|------|
| >A> | @ | 5MG | N021621 005 | Nov 16, 2007 | Apr | DISC |
|-----|---|-----|-------------|--------------|-----|------|

+

|  |   |      |             |              |     |      |
|--|---|------|-------------|--------------|-----|------|
|  | @ | 10MG | N021621 006 | Nov 16, 2007 | Feb | DISC |
|--|---|------|-------------|--------------|-----|------|

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL

DYNA-HEX

|     |                   |       |             |              |     |      |
|-----|-------------------|-------|-------------|--------------|-----|------|
| >A> | BAJAJ MEDICAL LLC | 0.75% | N020111 001 | Sep 11, 1997 | Apr | CAHN |
|-----|-------------------|-------|-------------|--------------|-----|------|

|     |         |       |             |              |     |      |
|-----|---------|-------|-------------|--------------|-----|------|
| >D> | XTTRIUM | 0.75% | N020111 001 | Sep 11, 1997 | Apr | CAHN |
|-----|---------|-------|-------------|--------------|-----|------|

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SWAB; TOPICAL

PREVANTICS MAXI SWABSTICK

|   |            |                   |             |              |     |      |
|---|------------|-------------------|-------------|--------------|-----|------|
| + | PROF DSPLS | 3.15%;70% (5.1ML) | N021524 003 | Jun 03, 2005 | Mar | CTNA |
|---|------------|-------------------|-------------|--------------|-----|------|

PREVANTICS SWAB

|   |            |                 |             |              |     |      |
|---|------------|-----------------|-------------|--------------|-----|------|
| + | PROF DSPLS | 3.15%;70% (1ML) | N021524 001 | Jun 03, 2005 | Mar | CTNA |
|---|------------|-----------------|-------------|--------------|-----|------|

PREVANTICS SWABSTICK

|   |            |                   |             |              |     |      |
|---|------------|-------------------|-------------|--------------|-----|------|
| + | PROF DSPLS | 3.15%;70% (1.6ML) | N021524 002 | Jun 03, 2005 | Mar | CTNA |
|---|------------|-------------------|-------------|--------------|-----|------|

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

DEXBROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE

|  |             |           |             |              |     |      |
|--|-------------|-----------|-------------|--------------|-----|------|
|  | AVANTHI INC | 6MG;120MG | A078648 001 | Feb 27, 2013 | Feb | NEWA |
|--|-------------|-----------|-------------|--------------|-----|------|

FEXOFENADINE HYDROCHLORIDE

TABLET, ORALLY DISINTEGRATING; ORAL

CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY

|  |                    |      |             |              |     |      |
|--|--------------------|------|-------------|--------------|-----|------|
|  | DR REDDYS LABS LTD | 30MG | A202978 001 | Jan 18, 2013 | Jan | NEWA |
|--|--------------------|------|-------------|--------------|-----|------|

TABLET, ORALLY DISINTEGRATING; ORAL  
 CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES  
 DR REDDYS LABS LTD 30MG

A202978 002 Jan 18, 2013 Jan NEWA

#### KETOTIFEN FUMARATE

SOLUTION/DROPS; OPHTHALMIC  
 KETOTIFEN FUMARATE

>D> APOTEX INC EQ 0.025% BASE  
 >A> @ EQ 0.025% BASE

A077354 001 May 09, 2006 Apr DISC  
 A077354 001 May 09, 2006 Apr DISC

#### LEVONORGESTREL

TABLET; ORAL  
 LEVONORGESTREL

LUPIN LTD 0.75MG  
 AB NOVEL LABS INC 1.5MG  
 PLAN B ONE-STEP  
 >D> + DURAMED 1.5MG  
 >A> + TEVA BRANDED PHARM 1.5MG

A091328 001 Jan 23, 2013 Jan NEWA  
 A202508 001 Feb 22, 2013 Feb NEWA  
 N021998 001 Jul 10, 2009 Apr CAHN  
 N021998 001 Jul 10, 2009 Apr CAHN

#### LORATADINE

SYRUP; ORAL  
 LORATADINE

>D> APOTEX INC 1MG/ML  
 >A> @ 1MG/ML

A075565 001 Oct 05, 2004 Apr DISC  
 A075565 001 Oct 05, 2004 Apr DISC

#### LORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL  
 LORATADINE AND PSEUDOEPHEDRINE SULFATE  
 @ WATSON LABS INC FL 5MG;120MG

A076208 001 Jan 28, 2004 Feb DISC

#### MICONAZOLE NITRATE

CREAM; VAGINAL  
 MICONAZOLE NITRATE  
 APHENA PHARMA MD 2%

A074366 001 Feb 22, 1996 Jan CAHN

#### MINOXIDIL

SOLUTION; TOPICAL  
 MINOXIDIL (FOR MEN)

>D> NOVEX 2%  
 >A> @ 2%

A074924 001 Apr 29, 1998 Apr DISC  
 A074924 001 Apr 29, 1998 Apr DISC

MINOXIDIL (FOR WOMEN)

>A> @ APOTEX INC 2%  
 >D> NOVEX 2%

A074924 002 Apr 29, 1998 Apr DISC  
 A074924 002 Apr 29, 1998 Apr DISC

MINOXIDIL EXTRA STRENGTH (FOR MEN)

>A> @ APOTEX INC 5%  
 >D> NOVEX 5%

A075839 001 Oct 01, 2001 Apr DISC  
 A075839 001 Oct 01, 2001 Apr DISC

#### NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC  
 NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE  
 AKORN INC 0.025%;0.3%

A202795 001 Jan 24, 2013 Jan NEWA

OXYBUTYNIN

FILM, EXTENDED RELEASE; TRANSDERMAL  
OXYTROL FOR WOMEN

+ MSD CONSUMER 3.9MG/24HR N202211 001 Jan 25, 2013 Jan NEWA

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL  
POLYETHYLENE GLYCOL 3350  
PAR PHARM

17GM/SCOOPFUL

A079214 001 Jan 31, 2013 Jan NEWA

RANITIDINE HYDROCHLORIDE

TABLET; ORAL  
RANITIDINE HYDROCHLORIDE  
@ WATSON LABS

EQ 75MG BASE

A075212 001 Jan 14, 2000 Mar DISC

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

**CUMULATIVE SUPPLEMENT NUMBER 04 APRIL 2013**

NO APRIL 2013 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 APRIL 2013 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST - 33RD EDITION

A - 1

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                             | PATENT NO | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|---------------------------------------------|-----------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ACETYLCYSTEINE - ACETADOTE</u>           |           |                              |                 |                               |                        |                                   |
| N021539 001                                 | 8399445   | Aug 24, 2025                 | U-1373          |                               |                        |                                   |
| <u>ACYCLOVIR - SITAVIG</u>                  |           |                              |                 |                               |                        |                                   |
| N203791 001                                 |           |                              |                 |                               | >A> NP                 | Apr 12, 2016                      |
| <u>ADAPALENE; BENZOYL PEROXIDE - EPIDUO</u> |           |                              |                 |                               |                        |                                   |
| N022320 001                                 |           |                              |                 |                               | NPP                    | Feb 01, 2016                      |
| <u>ALOGLIPTIN BENZOATE - NESINA</u>         |           |                              |                 |                               |                        |                                   |
| N022271 001                                 | 6150383   | Jun 19, 2016                 | U-1330          |                               | NCE                    | Jan 25, 2018                      |
|                                             | 6211205   | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                             | 6303640   | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                             | 6303661   | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                             | 6329404   | Jun 19, 2016                 | DP U-1334       |                               |                        |                                   |
|                                             | 6890898   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                             | 7078381   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                             | 7459428   | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                             | 7807689   | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                             | 8173663   | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                             | 8288539   | Mar 15, 2025                 | DS              |                               |                        |                                   |
| <u>ALOGLIPTIN BENZOATE - NESINA</u>         |           |                              |                 |                               |                        |                                   |
| N022271 002                                 | 6150383   | Jun 19, 2016                 | U-1330          |                               | NCE                    | Jan 25, 2018                      |
|                                             | 6211205   | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                             | 6303640   | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                             | 6303661   | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                             | 6329404   | Jun 19, 2016                 | DP U-1334       |                               |                        |                                   |
|                                             | 6890898   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                             | 7078381   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                             | 7459428   | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                             | 7807689   | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                             | 8173663   | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                             | 8288539   | Mar 15, 2025                 | DS              |                               |                        |                                   |
| <u>ALOGLIPTIN BENZOATE - NESINA</u>         |           |                              |                 |                               |                        |                                   |
| N022271 003                                 | 6150383   | Jun 19, 2016                 | U-1330          |                               | NCE                    | Jan 25, 2018                      |
|                                             | 6211205   | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                             | 6303640   | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                             | 6303661   | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                             | 6329404   | Jun 19, 2016                 | DP U-1334       |                               |                        |                                   |
|                                             | 6890898   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                             | 7078381   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                             | 7459428   | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                             | 7807689   | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                             | 8173663   | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                             | 8288539   | Mar 15, 2025                 | DS              |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                              | PATENT NO | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|--------------------------------------------------------------|-----------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE - KAZANO</u> |           |                              |                 |                               |                        |                                   |
| N203414 001                                                  | 5965584   | Jun 19, 2016                 | U-1339          |                               | NCE                    | Jan 25, 2018                      |
|                                                              | 6150383   | Jun 19, 2016                 | U-1330          |                               | NC                     | Jan 25, 2016                      |
|                                                              | 6150384   | Jun 19, 2016                 | U-1340          |                               |                        |                                   |
|                                                              | 6166042   | Jun 19, 2016                 | U-1341          |                               |                        |                                   |
|                                                              | 6166043   | Jun 19, 2016                 | U-1342          |                               |                        |                                   |
|                                                              | 6172090   | Jun 19, 2016                 | U-1343          |                               |                        |                                   |
|                                                              | 6211205   | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                                              | 6303640   | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                                              | 6303661   | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                                              | 6329404   | Jun 19, 2016                 | U-1334          |                               |                        |                                   |
|                                                              | 6890898   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                              | 7078381   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                              | 7459428   | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                                              | 7807689   | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                                              | 8173663   | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                                              | 8288539   | Mar 15, 2025                 | DS              |                               |                        |                                   |
| <u>ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE - KAZANO</u> |           |                              |                 |                               |                        |                                   |
| N203414 002                                                  | 5965584   | Jun 19, 2016                 | U-1339          |                               | NCE                    | Jan 25, 2018                      |
|                                                              | 6150383   | Jun 19, 2016                 | U-1330          |                               | NC                     | Jan 25, 2016                      |
|                                                              | 6150384   | Jun 19, 2016                 | U-1340          |                               |                        |                                   |
|                                                              | 6166042   | Jun 19, 2016                 | U-1341          |                               |                        |                                   |
|                                                              | 6166043   | Jun 19, 2016                 | U-1342          |                               |                        |                                   |
|                                                              | 6172090   | Jun 19, 2016                 | U-1343          |                               |                        |                                   |
|                                                              | 6211205   | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                                              | 6303640   | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                                              | 6303661   | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                                              | 6329404   | Jun 19, 2016                 | U-1334          |                               |                        |                                   |
|                                                              | 6890898   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                              | 7078381   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                              | 7459428   | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                                              | 7807689   | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                                              | 8173663   | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                                              | 8288539   | Mar 15, 2025                 | DS              |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                                | PATENT NO | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|----------------------------------------------------------------|-----------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u> |           |                              |                 |                               |                        |                                   |
| N022426 001                                                    | 5965584   | Jun 19, 2016                 | DP U-1339       |                               | NCE                    | Jan 25, 2018                      |
|                                                                | 6150383   | Jun 19, 2016                 | U-1330          |                               | NC                     | Jan 25, 2016                      |
|                                                                | 6150384   | Jun 19, 2016                 | U-1340          |                               |                        |                                   |
|                                                                | 6166042   | Jun 19, 2016                 | U-1341          |                               |                        |                                   |
|                                                                | 6166043   | Jun 19, 2016                 | U-1342          |                               |                        |                                   |
|                                                                | 6172090   | Jun 19, 2016                 | U-1343          |                               |                        |                                   |
|                                                                | 6211205   | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                                                | 6271243   | Jun 19, 2016                 | U-1344          |                               |                        |                                   |
|                                                                | 6303640   | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                                                | 6303661   | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                                                | 6329404   | Jun 19, 2016                 | DP U-1334       |                               |                        |                                   |
|                                                                | 6890898   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7078381   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7459428   | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                                                | 7807689   | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                                                | 8173663   | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                                                | 8288539   | Mar 15, 2025                 | DS              |                               |                        |                                   |
| <u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u> |           |                              |                 |                               |                        |                                   |
| N022426 002                                                    | 5965584   | Jun 19, 2016                 | DP U-1339       |                               | NCE                    | Jan 25, 2018                      |
|                                                                | 6150383   | Jun 19, 2016                 | U-1330          |                               | NC                     | Jan 25, 2016                      |
|                                                                | 6150384   | Jun 19, 2016                 | U-1340          |                               |                        |                                   |
|                                                                | 6166042   | Jun 19, 2016                 | U-1341          |                               |                        |                                   |
|                                                                | 6166043   | Jun 19, 2016                 | U-1342          |                               |                        |                                   |
|                                                                | 6172090   | Jun 19, 2016                 | U-1343          |                               |                        |                                   |
|                                                                | 6211205   | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                                                | 6271243   | Jun 19, 2016                 | U-1344          |                               |                        |                                   |
|                                                                | 6303640   | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                                                | 6303661   | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                                                | 6329404   | Jun 19, 2016                 | DP U-1334       |                               |                        |                                   |
|                                                                | 6890898   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7078381   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7459428   | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                                                | 7807689   | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                                                | 8173663   | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                                                | 8288539   | Mar 15, 2025                 | DS              |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                                | PATENT NO | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|----------------------------------------------------------------|-----------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u> |           |                              |                 |                               |                        |                                   |
| N022426 003                                                    | 5965584   | Jun 19, 2016                 | DP U-1339       |                               | NCE                    | Jan 25, 2018                      |
|                                                                | 6150383   | Jun 19, 2016                 | U-1330          |                               | NC                     | Jan 25, 2016                      |
|                                                                | 6150384   | Jun 19, 2016                 | U-1340          |                               |                        |                                   |
|                                                                | 6166042   | Jun 19, 2016                 | U-1341          |                               |                        |                                   |
|                                                                | 6166043   | Jun 19, 2016                 | U-1342          |                               |                        |                                   |
|                                                                | 6172090   | Jun 19, 2016                 | U-1343          |                               |                        |                                   |
|                                                                | 6211205   | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                                                | 6271243   | Jun 19, 2016                 | U-1344          |                               |                        |                                   |
|                                                                | 6303640   | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                                                | 6303661   | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                                                | 6329404   | Jun 19, 2016                 | DP U-1334       |                               |                        |                                   |
|                                                                | 6890898   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7078381   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7459428   | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                                                | 7807689   | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                                                | 8173663   | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                                                | 8288539   | Mar 15, 2025                 | DS              |                               |                        |                                   |
| <u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u> |           |                              |                 |                               |                        |                                   |
| N022426 004                                                    | 5965584   | Jun 19, 2016                 | DP U-1339       |                               | NCE                    | Jan 25, 2018                      |
|                                                                | 6150383   | Jun 19, 2016                 | U-1330          |                               | NC                     | Jan 25, 2016                      |
|                                                                | 6150384   | Jun 19, 2016                 | U-1340          |                               |                        |                                   |
|                                                                | 6166042   | Jun 19, 2016                 | U-1341          |                               |                        |                                   |
|                                                                | 6166043   | Jun 19, 2016                 | U-1342          |                               |                        |                                   |
|                                                                | 6172090   | Jun 19, 2016                 | U-1343          |                               |                        |                                   |
|                                                                | 6211205   | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                                                | 6271243   | Jun 19, 2016                 | U-1344          |                               |                        |                                   |
|                                                                | 6303640   | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                                                | 6303661   | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                                                | 6329404   | Jun 19, 2016                 | DP U-1334       |                               |                        |                                   |
|                                                                | 6890898   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7078381   | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7459428   | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                                                | 7807689   | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                                                | 8173663   | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                                                | 8288539   | Mar 15, 2025                 | DS              |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                                | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|----------------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u> |             |                              |                 |                               |                        |                                   |
| N022426 005                                                    | 5965584     | Jun 19, 2016                 | DP U-1339       |                               | NCE                    | Jan 25, 2018                      |
|                                                                | 6150383     | Jun 19, 2016                 | U-1330          |                               | NC                     | Jan 25, 2016                      |
|                                                                | 6150384     | Jun 19, 2016                 | U-1340          |                               |                        |                                   |
|                                                                | 6166042     | Jun 19, 2016                 | U-1341          |                               |                        |                                   |
|                                                                | 6166043     | Jun 19, 2016                 | U-1342          |                               |                        |                                   |
|                                                                | 6172090     | Jun 19, 2016                 | U-1343          |                               |                        |                                   |
|                                                                | 6211205     | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                                                | 6271243     | Jun 19, 2016                 | U-1344          |                               |                        |                                   |
|                                                                | 6303640     | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                                                | 6303661     | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                                                | 6329404     | Jun 19, 2016                 | DP U-1334       |                               |                        |                                   |
|                                                                | 6890898     | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7078381     | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7459428     | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                                                | 7807689     | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                                                | 8173663     | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                                                | 8288539     | Mar 15, 2025                 | DS              |                               |                        |                                   |
| <u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u> |             |                              |                 |                               |                        |                                   |
| N022426 006                                                    | 5965584     | Jun 19, 2016                 | DP U-1339       |                               | NCE                    | Jan 25, 2018                      |
|                                                                | 6150383     | Jun 19, 2016                 | U-1330          |                               | NC                     | Jan 25, 2016                      |
|                                                                | 6150384     | Jun 19, 2016                 | U-1340          |                               |                        |                                   |
|                                                                | 6166042     | Jun 19, 2016                 | U-1341          |                               |                        |                                   |
|                                                                | 6166043     | Jun 19, 2016                 | U-1342          |                               |                        |                                   |
|                                                                | 6172090     | Jun 19, 2016                 | U-1343          |                               |                        |                                   |
|                                                                | 6211205     | Jun 19, 2016                 | U-1331          |                               |                        |                                   |
|                                                                | 6271243     | Jun 19, 2016                 | U-1344          |                               |                        |                                   |
|                                                                | 6303640     | Aug 09, 2016                 | U-1332          |                               |                        |                                   |
|                                                                | 6303661     | Apr 24, 2017                 | U-1333          |                               |                        |                                   |
|                                                                | 6329404     | Jun 19, 2016                 | DP U-1334       |                               |                        |                                   |
|                                                                | 6890898     | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7078381     | Feb 02, 2019                 | U-1335          |                               |                        |                                   |
|                                                                | 7459428     | Feb 02, 2019                 | U-1336          |                               |                        |                                   |
|                                                                | 7807689     | Jun 27, 2028                 | DS DP U-1337    |                               |                        |                                   |
|                                                                | 8173663     | Mar 15, 2025                 | U-1338          |                               |                        |                                   |
|                                                                | 8288539     | Mar 15, 2025                 | DS              |                               |                        |                                   |
| <u>AMBRISANTAN - LETAIRIS</u>                                  |             |                              |                 |                               |                        |                                   |
| N022081 001                                                    | >A> 8349843 | Oct 07, 2015                 | DS DP           |                               |                        |                                   |
| <u>AMBRISANTAN - LETAIRIS</u>                                  |             |                              |                 |                               |                        |                                   |
| N022081 002                                                    | >A> 8349843 | Oct 07, 2015                 | DS DP           |                               |                        |                                   |
| <u>AMOXICILLIN - MOXATAG</u>                                   |             |                              |                 |                               |                        |                                   |
| N050813 001                                                    | 8357394     | Dec 08, 2026                 | DP              |                               |                        |                                   |
| <u>APIXABAN - ELIQUIS</u>                                      |             |                              |                 |                               |                        |                                   |
| N202155 001                                                    | 6413980     | Dec 22, 2019                 | DS DP U-1200    |                               |                        |                                   |
|                                                                | 6967208     | Feb 03, 2023                 | DS DP U-1323    |                               |                        |                                   |
|                                                                | 6967208     | Feb 03, 2023                 | DS DP U-1200    |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                         | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|---------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>APIXABAN - ELIQUIS</u>                               |             |                              |                 |                               |                        |                                   |
| N202155 002                                             | 6413980     | Dec 22, 2019                 | DS DP U-1200    |                               |                        |                                   |
|                                                         | 6967208     | Feb 03, 2023                 | DS DP U-1323    |                               |                        |                                   |
|                                                         | 6967208     | Feb 03, 2023                 | DS DP U-1200    |                               |                        |                                   |
| <u>ARIPIRAZOLE - ABILIFY MAINTENA KIT</u>               |             |                              |                 |                               |                        |                                   |
| N202971 001                                             | >A> 5006528 | Apr 20, 2015                 | DS DP U-543     |                               | NDF                    | Feb 28, 2016                      |
|                                                         | >A> 7807680 | Oct 19, 2024                 | DP              |                               |                        |                                   |
|                                                         | >A> 8030313 | Oct 19, 2024                 | U-543           |                               |                        |                                   |
|                                                         | >A> 8338427 | Mar 15, 2025                 | DP U-543        |                               |                        |                                   |
|                                                         | >A> 8338428 | Aug 06, 2023                 | DP U-543        |                               |                        |                                   |
|                                                         | >A> 8399469 | Dec 29, 2023                 | DS              |                               |                        |                                   |
| <u>ARIPIRAZOLE - ABILIFY MAINTENA KIT</u>               |             |                              |                 |                               |                        |                                   |
| N202971 002                                             | >A> 5006528 | Apr 20, 2015                 | DS DP U-543     |                               | NDF                    | Feb 28, 2016                      |
|                                                         | >A> 7807680 | Oct 19, 2024                 | DP              |                               |                        |                                   |
|                                                         | >A> 8030313 | Oct 19, 2024                 | U-543           |                               |                        |                                   |
|                                                         | >A> 8338427 | Mar 15, 2025                 | DP U-543        |                               |                        |                                   |
|                                                         | >A> 8338428 | Aug 06, 2023                 | DP U-543        |                               |                        |                                   |
|                                                         | >A> 8399469 | Dec 29, 2023                 | DS              |                               |                        |                                   |
| <u>AZTREONAM - CAYSTON</u>                              |             |                              |                 |                               |                        |                                   |
| N050814 001                                             | >A> 8399496 | Dec 20, 2021                 | DP U-1377       |                               |                        |                                   |
| <u>BEDAQUILINE FUMARATE - SIRTURO</u>                   |             |                              |                 |                               |                        |                                   |
| N204384 001                                             | 7498343     | Oct 02, 2024                 | DS DP U-1321    |                               | ODE                    | Dec 28, 2019                      |
| <u>BEPOTASTINE BESILATE - BEPREVE</u>                   |             |                              |                 |                               |                        |                                   |
| N022288 001                                             | >A> 6780877 | Sep 09, 2019                 | DS DP           |                               |                        |                                   |
| <u>BESIFLOXACIN HYDROCHLORIDE - BESIVANCE</u>           |             |                              |                 |                               |                        |                                   |
| N022308 001                                             | >A> 8415342 | Nov 07, 2030                 | U-80            |                               |                        |                                   |
| <u>BOCEPREVIR - VICTRELIS</u>                           |             |                              |                 |                               |                        |                                   |
| N202258 001                                             |             |                              |                 |                               | M-126<br>NPP           | Feb 27, 2016<br>Feb 13, 2016      |
| <u>BRIMONIDINE TARTRATE; BRINZOLAMIDE - SIMBRINZA</u>   |             |                              |                 |                               |                        |                                   |
| N204251 001                                             |             |                              |                 |                               | >A> NC                 | Apr 19, 2016                      |
| <u>BRIMONIDINE TARTRATE; TIMOLOL MALEATE - COMBIGAN</u> |             |                              |                 |                               |                        |                                   |
| N021398 001                                             | 8354409     | Apr 19, 2022                 | DP U-1371       |                               |                        |                                   |
| <u>BROMFENAC SODIUM - PROLENSA</u>                      |             |                              |                 |                               |                        |                                   |
| N203168 001                                             | >A> 8129431 | Sep 11, 2025                 | DS DP           |                               | >A> NP                 | Apr 05, 2016                      |
| <u>BROMOCRIPTINE MESYLATE - CYCLOSET</u>                |             |                              |                 |                               |                        |                                   |
| N020866 001                                             | >A> 7888310 | Jul 25, 2023                 | U-976           |                               |                        |                                   |
|                                                         | >A> 7888310 | Jul 25, 2023                 | U-1379          |                               |                        |                                   |
|                                                         | >A> 8137992 | Jul 25, 2023                 | U-1380          |                               |                        |                                   |
|                                                         | >A> 8137993 | Jul 25, 2023                 | U-1379          |                               |                        |                                   |
|                                                         | >A> 8137994 | Jul 25, 2023                 | U-1379          |                               |                        |                                   |
|                                                         | >A> 8431155 | Apr 30, 2032                 | DP U-1379       |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                                                                   | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|---------------------------------------------------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>BUDESONIDE - UCERIS</u>                                                                        |             |                              |                 |                               |                        |                                   |
| N203634 001                                                                                       | 7410651     | Jun 09, 2020                 | DP U-1325       |                               | NDF                    | Jan 14, 2016                      |
|                                                                                                   | 7431943     | Jun 09, 2020                 | DP              |                               |                        |                                   |
|                                                                                                   | 8293273     | Jun 09, 2020                 | DP              |                               |                        |                                   |
|                                                                                                   | RE43799     | Jun 09, 2020                 | DP U-1325       |                               |                        |                                   |
| <u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>                                      |             |                              |                 |                               |                        |                                   |
| N021929 001                                                                                       | 8387615     | Nov 10, 2024                 | DP              |                               |                        |                                   |
| <u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>                                      |             |                              |                 |                               |                        |                                   |
| N021929 002                                                                                       | 8387615     | Nov 10, 2024                 | DP              |                               |                        |                                   |
| <u>CABOZANTINIB S-MALATE - COMETRIQ</u>                                                           |             |                              |                 |                               |                        |                                   |
| N203756 001                                                                                       |             |                              |                 |                               | ODE                    | Nov 29, 2019                      |
| <u>CABOZANTINIB S-MALATE - COMETRIQ</u>                                                           |             |                              |                 |                               |                        |                                   |
| N203756 002                                                                                       |             |                              |                 |                               | ODE                    | Nov 29, 2019                      |
| <u>CALCITONIN SALMON RECOMBINANT - FORTICAL</u>                                                   |             |                              |                 |                               |                        |                                   |
| N021406 001                                                                                       | >A> RE43580 | Feb 02, 2021                 | DP U-227        |                               |                        |                                   |
| <u>CANAGLIFLOZIN - INVOKANA</u>                                                                   |             |                              |                 |                               |                        |                                   |
| N204042 001                                                                                       | >A> 7943582 | Feb 26, 2029                 | DS DP U-493     |                               | NCE                    | Mar 29, 2018                      |
|                                                                                                   | >A> 7943788 | Jul 14, 2027                 | DS DP           |                               |                        |                                   |
|                                                                                                   | >A> 8222219 | Jul 30, 2024                 | U-493           |                               |                        |                                   |
| <u>CANAGLIFLOZIN - INVOKANA</u>                                                                   |             |                              |                 |                               |                        |                                   |
| N204042 002                                                                                       | >A> 7943582 | Feb 26, 2029                 | DS DP U-493     |                               | NCE                    | Mar 29, 2018                      |
|                                                                                                   | >A> 7943788 | Jul 14, 2027                 | DS DP           |                               |                        |                                   |
|                                                                                                   | >A> 8222219 | Jul 30, 2024                 | U-493           |                               |                        |                                   |
| <u>CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE - CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE</u> |             |                              |                 |                               |                        |                                   |
| A090704 003                                                                                       |             |                              |                 |                               | PC                     | Jun 02, 2013                      |
| <u>CARBINOXAMINE MALEATE - KARBINAL ER</u>                                                        |             |                              |                 |                               |                        |                                   |
| N022556 001                                                                                       | >A> 8062667 | Mar 29, 2029                 | DP              |                               |                        |                                   |
| <u>CELECOXIB - CELEBREX</u>                                                                       |             |                              |                 |                               |                        |                                   |
| N020998 001                                                                                       | RE44048     | Jun 02, 2015                 | U-247           |                               |                        |                                   |
|                                                                                                   | RE44048     | Jun 02, 2015                 | U-1352          |                               |                        |                                   |
|                                                                                                   | RE44048     | Jun 02, 2015                 | U-1351          |                               |                        |                                   |
|                                                                                                   | RE44048     | Jun 02, 2015                 | U-1350          |                               |                        |                                   |
|                                                                                                   | RE44048     | Jun 02, 2015                 | U-1349          |                               |                        |                                   |
|                                                                                                   | RE44048     | Jun 02, 2015                 | U-1348          |                               |                        |                                   |
|                                                                                                   | RE44048*PED | Dec 02, 2015                 |                 |                               |                        |                                   |
| <u>CELECOXIB - CELEBREX</u>                                                                       |             |                              |                 |                               |                        |                                   |
| N020998 002                                                                                       | RE44048     | Jun 02, 2015                 | U-247           |                               |                        |                                   |
|                                                                                                   | RE44048     | Jun 02, 2015                 | U-1352          |                               |                        |                                   |
|                                                                                                   | RE44048     | Jun 02, 2015                 | U-1351          |                               |                        |                                   |
|                                                                                                   | RE44048     | Jun 02, 2015                 | U-1350          |                               |                        |                                   |
|                                                                                                   | RE44048     | Jun 02, 2015                 | U-1349          |                               |                        |                                   |
|                                                                                                   | RE44048     | Jun 02, 2015                 | U-1348          |                               |                        |                                   |
|                                                                                                   | RE44048*PED | Dec 02, 2015                 |                 |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                                                          | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|------------------------------------------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>CELECOXIB - CELEBREX</u>                                                              |             |                              |                 |                               |                        |                                   |
| N020998 003                                                                              | RE44048     | Jun 02, 2015                 | U-247           |                               |                        |                                   |
|                                                                                          | RE44048     | Jun 02, 2015                 | U-1352          |                               |                        |                                   |
|                                                                                          | RE44048     | Jun 02, 2015                 | U-1351          |                               |                        |                                   |
|                                                                                          | RE44048     | Jun 02, 2015                 | U-1350          |                               |                        |                                   |
|                                                                                          | RE44048     | Jun 02, 2015                 | U-1349          |                               |                        |                                   |
|                                                                                          | RE44048     | Jun 02, 2015                 | U-1348          |                               |                        |                                   |
|                                                                                          | RE44048*PED | Dec 02, 2015                 |                 |                               |                        |                                   |
| <u>CELECOXIB - CELEBREX</u>                                                              |             |                              |                 |                               |                        |                                   |
| N020998 004                                                                              | RE44048     | Jun 02, 2015                 | U-247           |                               |                        |                                   |
|                                                                                          | RE44048     | Jun 02, 2015                 | U-1352          |                               |                        |                                   |
|                                                                                          | RE44048     | Jun 02, 2015                 | U-1351          |                               |                        |                                   |
|                                                                                          | RE44048     | Jun 02, 2015                 | U-1350          |                               |                        |                                   |
|                                                                                          | RE44048     | Jun 02, 2015                 | U-1349          |                               |                        |                                   |
|                                                                                          | RE44048     | Jun 02, 2015                 | U-1348          |                               |                        |                                   |
|                                                                                          | RE44048*PED | Dec 02, 2015                 |                 |                               |                        |                                   |
| <u>CICLESONIDE - ALVESCO</u>                                                             |             |                              |                 |                               |                        |                                   |
| N021658 002                                                                              | 8371292     | Aug 25, 2027                 | U-1355          |                               | M-125                  | Dec 17, 2015                      |
| <u>CICLESONIDE - ALVESCO</u>                                                             |             |                              |                 |                               |                        |                                   |
| N021658 003                                                                              | 8371292     | Aug 25, 2027                 | U-1355          |                               | M-125                  | Dec 17, 2015                      |
| <u>CICLESONIDE - OMNARIS</u>                                                             |             |                              |                 |                               |                        |                                   |
| N022004 001                                                                              | 8371292     | Aug 25, 2027                 | U-1356          |                               |                        |                                   |
|                                                                                          | 8383611     | Oct 20, 2020                 | DP              |                               |                        |                                   |
| <u>CICLESONIDE - ZETONNA</u>                                                             |             |                              |                 |                               |                        |                                   |
| N202129 001                                                                              | 8371292     | Aug 25, 2027                 | U-1357          |                               |                        |                                   |
| <u>CLOBAZAM - ONFI</u>                                                                   |             |                              |                 |                               |                        |                                   |
| N203993 001                                                                              |             |                              |                 |                               | ODE                    | Oct 21, 2018                      |
| <u>CLOBETASOL PROPIONATE - CLOBETASOL PROPIONATE</u>                                     |             |                              |                 |                               |                        |                                   |
| A201402 001                                                                              |             |                              |                 |                               | PC                     | Jul 31, 2013                      |
| <u>COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - STRIBILD</u> |             |                              |                 |                               |                        |                                   |
| N203100 001                                                                              | 7635704     | Oct 26, 2026                 | DS DP U-257     |                               |                        |                                   |
| <u>COLCHICINE - COLCRYS</u>                                                              |             |                              |                 |                               |                        |                                   |
| N022352 001                                                                              | >A> 8415395 | Oct 06, 2028                 | U-1007          |                               |                        |                                   |
|                                                                                          | >A> 8415396 | Oct 06, 2028                 | U-1007          |                               |                        |                                   |
| <u>CYSTEAMINE BITARTRATE - PROCYSBI</u>                                                  |             |                              |                 |                               |                        |                                   |
| N203389 001                                                                              |             |                              |                 |                               | >A> NDF                | Apr 30, 2016                      |
| <u>CYSTEAMINE BITARTRATE - PROCYSBI</u>                                                  |             |                              |                 |                               |                        |                                   |
| N203389 002                                                                              |             |                              |                 |                               | >A> NDF                | Apr 30, 2016                      |
| <u>DALFAMPRIDINE - AMPYRA</u>                                                            |             |                              |                 |                               |                        |                                   |
| N022250 001                                                                              | >A> 8354437 | Dec 22, 2026                 | U-1030          |                               |                        |                                   |
| <u>DARUNAVIR ETHANOLATE - PREZISTA</u>                                                   |             |                              |                 |                               |                        |                                   |
| N021976 001                                                                              |             |                              |                 |                               | D-135<br>PED           | Feb 01, 2016<br>Aug 01, 2016      |
| <u>DARUNAVIR ETHANOLATE - PREZISTA</u>                                                   |             |                              |                 |                               |                        |                                   |
| N021976 002                                                                              |             |                              |                 |                               | D-135<br>PED           | Feb 01, 2016<br>Aug 01, 2016      |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                 | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S)                     | EXCLUSIVITY<br>EXPIRATION<br>DATE                                                            |
|-------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|--------------------------------------------|----------------------------------------------------------------------------------------------|
| <u>DARUNAVIR ETHANOLATE - PREZISTA</u>          |             |                              |                 |                               |                                            |                                                                                              |
| N021976 003                                     |             |                              |                 |                               | D-135<br>PED                               | Feb 01, 2016<br>Aug 01, 2016                                                                 |
| <u>DARUNAVIR ETHANOLATE - PREZISTA</u>          |             |                              |                 |                               |                                            |                                                                                              |
| N021976 004                                     |             |                              |                 |                               | D-135<br>PED                               | Feb 01, 2016<br>Aug 01, 2016                                                                 |
| <u>DARUNAVIR ETHANOLATE - PREZISTA</u>          |             |                              |                 |                               |                                            |                                                                                              |
| N021976 005                                     |             |                              |                 |                               | D-135<br>PED                               | Feb 01, 2016<br>Aug 01, 2016                                                                 |
| <u>DARUNAVIR ETHANOLATE - PREZISTA</u>          |             |                              |                 |                               |                                            |                                                                                              |
| N021976 006                                     |             |                              |                 |                               | D-135<br>PED                               | Feb 01, 2016<br>Aug 01, 2016                                                                 |
| <u>DARUNAVIR ETHANOLATE - PREZISTA</u>          |             |                              |                 |                               |                                            |                                                                                              |
| N202895 001                                     |             |                              |                 |                               | D-135<br>PED                               | Feb 01, 2016<br>Aug 01, 2016                                                                 |
| <u>DEFERASIROX - EXJADE</u>                     |             |                              |                 |                               |                                            |                                                                                              |
| N021882 001                                     |             |                              |                 |                               | I-665                                      | Jan 23, 2016                                                                                 |
| <u>DEFERASIROX - EXJADE</u>                     |             |                              |                 |                               |                                            |                                                                                              |
| N021882 002                                     |             |                              |                 |                               | I-665                                      | Jan 23, 2016                                                                                 |
| <u>DEFERASIROX - EXJADE</u>                     |             |                              |                 |                               |                                            |                                                                                              |
| N021882 003                                     |             |                              |                 |                               | I-665                                      | Jan 23, 2016                                                                                 |
| <u>DESOXIMETASONE - TOPICORT</u>                |             |                              |                 |                               |                                            |                                                                                              |
| N204141 001                                     |             |                              |                 |                               | >A> NDF                                    | Apr 11, 2016                                                                                 |
| <u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>       |             |                              |                 |                               |                                            |                                                                                              |
| N021992 001                                     | 6673838     | Feb 11, 2022                 | DS DP U-860     |                               |                                            |                                                                                              |
|                                                 | 6673838     | Feb 11, 2022                 | DS DP U-1364    |                               |                                            |                                                                                              |
| <u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>       |             |                              |                 |                               |                                            |                                                                                              |
| N021992 002                                     | 6673838     | Feb 11, 2022                 | DS DP U-860     |                               |                                            |                                                                                              |
|                                                 | 6673838     | Feb 11, 2022                 | DS DP U-1364    |                               |                                            |                                                                                              |
| <u>DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX</u> |             |                              |                 |                               |                                            |                                                                                              |
| N021038 001                                     | 4910214     | Jul 15, 2013                 | DS DP U-421     |                               |                                            |                                                                                              |
|                                                 | 4910214*PED | Jan 15, 2014                 |                 |                               |                                            |                                                                                              |
|                                                 | 6716867     | Mar 31, 2019                 | U-572           |                               |                                            |                                                                                              |
|                                                 | 6716867*PED | Oct 01, 2019                 |                 |                               |                                            |                                                                                              |
| <u>DIFLUPREDNATE - DUREZOL</u>                  |             |                              |                 |                               |                                            |                                                                                              |
| N022212 001                                     | 6114319     | May 18, 2019                 | DP              |                               | I-653<br>M-127<br>ODE<br>PED<br>PED<br>PED | Jun 13, 2015<br>Mar 22, 2016<br>Jun 13, 2019<br>Dec 13, 2019<br>Sep 22, 2016<br>Dec 13, 2015 |
|                                                 | 6114319*PED | Nov 18, 2019                 |                 |                               |                                            |                                                                                              |
| <u>DIMETHYL FUMARATE - TECFIDERA</u>            |             |                              |                 |                               |                                            |                                                                                              |
| N204063 001                                     | >A> 6509376 | Oct 29, 2019                 | DP              |                               | NCE                                        | Mar 27, 2018                                                                                 |
|                                                 | >A> 7320999 | May 18, 2020                 | U-1384          |                               |                                            |                                                                                              |
|                                                 | >A> 7619001 | Apr 01, 2018                 | U-1384          |                               |                                            |                                                                                              |
|                                                 | >A> 7803840 | Apr 01, 2018                 | U-1385          |                               |                                            |                                                                                              |
|                                                 | >A> 8399514 | Feb 07, 2028                 | U-1384          |                               |                                            |                                                                                              |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                                      | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|----------------------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>DIMETHYL FUMARATE - TECFIDERA</u>                                 |             |                              |                 |                               |                        |                                   |
| N204063 002                                                          | >A> 6509376 | Oct 29, 2019                 | DP              |                               | NCE                    | Mar 27, 2018                      |
|                                                                      | >A> 7320999 | May 18, 2020                 | U-1384          |                               |                        |                                   |
|                                                                      | >A> 7619001 | Apr 01, 2018                 | U-1384          |                               |                        |                                   |
|                                                                      | >A> 7803840 | Apr 01, 2018                 | U-1385          |                               |                        |                                   |
|                                                                      | >A> 8399514 | Feb 07, 2028                 | U-1384          |                               |                        |                                   |
| <u>DOXYCYCLINE - ORACEA</u>                                          |             |                              |                 |                               |                        |                                   |
| N050805 001                                                          | >A> 8394405 | Dec 24, 2025                 | DP U-925        |                               |                        |                                   |
|                                                                      | 8394406     | Dec 24, 2025                 | DP U-925        |                               |                        |                                   |
| <u>DOXYCYCLINE HYCLATE - DORYX</u>                                   |             |                              |                 |                               |                        |                                   |
| N050795 005                                                          |             |                              |                 |                               | >A> D-136              | Apr 11, 2016                      |
|                                                                      |             |                              |                 |                               | >A> NS                 | Apr 11, 2016                      |
| <u>DOXYLAMINE SUCCINATE; PYRIDOXINE HYDROCHLORIDE - DICLEGIS</u>     |             |                              |                 |                               |                        |                                   |
| N021876 001                                                          | >A> 6340695 | Jun 21, 2021                 | DP U-1382       |                               | >A> NP                 | Apr 08, 2016                      |
|                                                                      | >A> 7560122 | Jan 25, 2019                 | DP              |                               |                        |                                   |
| <u>DRONEDARONE HYDROCHLORIDE - MULTAQ</u>                            |             |                              |                 |                               |                        |                                   |
| N022425 001                                                          | >A> 8410167 | Apr 16, 2029                 | U-1388          |                               |                        |                                   |
|                                                                      | >A> 8410167 | Apr 16, 2029                 | U-1387          |                               |                        |                                   |
| <u>DROSPIRENONE; ETHINYL ESTRADIOL - YAZ</u>                         |             |                              |                 |                               |                        |                                   |
| N021676 001                                                          | RE43916     | Jun 30, 2014                 | U-1326          |                               |                        |                                   |
| <u>DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - BEYAZ</u> |             |                              |                 |                               |                        |                                   |
| N022532 001                                                          | RE43916     | Jun 30, 2014                 | U-1326          |                               |                        |                                   |
| <u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>                           |             |                              |                 |                               |                        |                                   |
| N021427 001                                                          |             |                              |                 |                               | M-61<br>PED            | Oct 18, 2015<br>Apr 18, 2016      |
| <u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>                           |             |                              |                 |                               |                        |                                   |
| N021427 002                                                          |             |                              |                 |                               | M-61<br>PED            | Oct 18, 2015<br>Apr 18, 2016      |
| <u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>                           |             |                              |                 |                               |                        |                                   |
| N021427 004                                                          |             |                              |                 |                               | M-61<br>PED            | Oct 18, 2015<br>Apr 18, 2016      |
| <u>EFAVIRENZ - SUSTIVA</u>                                           |             |                              |                 |                               |                        |                                   |
| N020972 001                                                          | 5519021     | May 21, 2013                 | DS DP           |                               |                        |                                   |
|                                                                      | 5519021*PED | Nov 21, 2013                 |                 |                               |                        |                                   |
|                                                                      | 5663169     | Sep 02, 2014                 | U-257           |                               |                        |                                   |
|                                                                      | 5663169*PED | Mar 02, 2015                 |                 |                               |                        |                                   |
|                                                                      | 6238695     | Apr 06, 2019                 | DP              |                               |                        |                                   |
|                                                                      | 6238695*PED | Oct 06, 2019                 |                 |                               |                        |                                   |
|                                                                      | 6555133     | Apr 06, 2019                 | U-248           |                               |                        |                                   |
|                                                                      | 6555133*PED | Oct 06, 2019                 |                 |                               |                        |                                   |
|                                                                      | 6639071     | Feb 14, 2018                 | DS              |                               |                        |                                   |
|                                                                      | 6639071*PED | Aug 14, 2018                 |                 |                               |                        |                                   |
|                                                                      | 6939964     | Jan 20, 2018                 | DS              |                               |                        |                                   |
|                                                                      | 6939964*PED | Jul 20, 2018                 |                 |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO            | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|----------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>EFAVIRENZ - SUSTIVA</u> |             |                              |                 |                               |                        |                                   |
| N020972 002                | 5519021     | May 21, 2013                 | DS DP           |                               |                        |                                   |
|                            | 5519021*PED | Nov 21, 2013                 |                 |                               |                        |                                   |
|                            | 5663169     | Sep 02, 2014                 |                 |                               | U-257                  |                                   |
|                            | 5663169*PED | Mar 02, 2015                 |                 |                               |                        |                                   |
|                            | 6238695     | Apr 06, 2019                 | DP              |                               |                        |                                   |
|                            | 6238695*PED | Oct 06, 2019                 |                 |                               |                        |                                   |
|                            | 6555133     | Apr 06, 2019                 |                 |                               | U-248                  |                                   |
|                            | 6555133*PED | Oct 06, 2019                 |                 |                               |                        |                                   |
|                            | 6639071     | Feb 14, 2018                 | DS              |                               |                        |                                   |
|                            | 6639071*PED | Aug 14, 2018                 |                 |                               |                        |                                   |
|                            | 6939964     | Jan 20, 2018                 | DS              |                               |                        |                                   |
|                            | 6939964*PED | Jul 20, 2018                 |                 |                               |                        |                                   |
| <u>EFAVIRENZ - SUSTIVA</u> |             |                              |                 |                               |                        |                                   |
| N020972 003                | 5519021     | May 21, 2013                 | DS DP           |                               |                        |                                   |
|                            | 5519021*PED | Nov 21, 2013                 |                 |                               |                        |                                   |
|                            | 5663169     | Sep 02, 2014                 |                 |                               | U-257                  |                                   |
|                            | 5663169*PED | Mar 02, 2015                 |                 |                               |                        |                                   |
|                            | 6238695     | Apr 06, 2019                 | DP              |                               |                        |                                   |
|                            | 6238695*PED | Oct 06, 2019                 |                 |                               |                        |                                   |
|                            | 6555133     | Apr 06, 2019                 |                 |                               | U-248                  |                                   |
|                            | 6555133*PED | Oct 06, 2019                 |                 |                               |                        |                                   |
|                            | 6639071     | Feb 14, 2018                 | DS              |                               |                        |                                   |
|                            | 6639071*PED | Aug 14, 2018                 |                 |                               |                        |                                   |
|                            | 6939964     | Jan 20, 2018                 | DS              |                               |                        |                                   |
|                            | 6939964*PED | Jul 20, 2018                 |                 |                               |                        |                                   |
| <u>EFAVIRENZ - SUSTIVA</u> |             |                              |                 |                               |                        |                                   |
| N021360 001                | 5519021     | May 21, 2013                 |                 |                               |                        |                                   |
|                            | 5519021*PED | Nov 21, 2013                 |                 |                               |                        |                                   |
|                            | 5663169     | Sep 02, 2014                 |                 |                               |                        |                                   |
|                            | 5663169*PED | Mar 02, 2015                 |                 |                               |                        |                                   |
|                            | 6639071     | Feb 14, 2018                 | DS              |                               |                        |                                   |
|                            | 6639071*PED | Aug 14, 2018                 |                 |                               |                        |                                   |
|                            | 6939964     | Jan 20, 2018                 | DS              |                               |                        |                                   |
|                            | 6939964*PED | Jul 20, 2018                 |                 |                               |                        |                                   |
| <u>EFAVIRENZ - SUSTIVA</u> |             |                              |                 |                               |                        |                                   |
| N021360 002                | 5519021     | May 21, 2013                 | DS DP           |                               |                        |                                   |
|                            | 5519021*PED | Nov 21, 2013                 |                 |                               |                        |                                   |
|                            | 5663169     | Sep 02, 2014                 |                 |                               | U-248                  |                                   |
|                            | 5663169*PED | Mar 02, 2015                 |                 |                               |                        |                                   |
|                            | 6639071     | Feb 14, 2018                 | DS              |                               |                        |                                   |
|                            | 6639071*PED | Aug 14, 2018                 |                 |                               |                        |                                   |
|                            | 6939964     | Jan 20, 2018                 | DS              |                               |                        |                                   |
|                            | 6939964*PED | Jul 20, 2018                 |                 |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                                          | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|--------------------------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - ATRIPLA</u> |             |                              |                 |                               |                        |                                   |
| N021937 001                                                              | 5519021     | May 21, 2013                 | DS DP           |                               |                        |                                   |
|                                                                          | 5519021*PED | Nov 21, 2013                 |                 |                               |                        |                                   |
|                                                                          | 5663169     | Sep 02, 2014                 |                 | U-750                         |                        |                                   |
|                                                                          | 5663169     | Sep 02, 2014                 |                 | U-1170                        |                        |                                   |
|                                                                          | 5663169*PED | Mar 02, 2015                 |                 |                               |                        |                                   |
|                                                                          | 6639071     | Feb 14, 2018                 | DS              |                               |                        |                                   |
|                                                                          | 6639071*PED | Aug 14, 2018                 |                 |                               |                        |                                   |
|                                                                          | 6939964     | Jan 20, 2018                 | DS              |                               |                        |                                   |
|                                                                          | 6939964*PED | Jul 20, 2018                 |                 |                               |                        |                                   |
| <u>EPINEPHRINE - AUVI-Q</u>                                              |             |                              |                 |                               |                        |                                   |
| N201739 001                                                              | 7731686     | Jun 01, 2026                 | DP              |                               |                        |                                   |
|                                                                          | 7731690     | Jan 15, 2025                 | DP              |                               |                        |                                   |
|                                                                          | 7749194     | Oct 30, 2028                 | DP              |                               |                        |                                   |
|                                                                          | 7918823     | Nov 23, 2024                 | DP              |                               |                        |                                   |
|                                                                          | 7947017     | Mar 12, 2028                 | DP              |                               |                        |                                   |
|                                                                          | 8016788     | Mar 21, 2025                 | DP              |                               |                        |                                   |
|                                                                          | 8206360     | Feb 27, 2027                 | DP              |                               |                        |                                   |
|                                                                          | 8361029     | Nov 23, 2024                 | DP              |                               |                        |                                   |
| <u>EPINEPHRINE - AUVI-Q</u>                                              |             |                              |                 |                               |                        |                                   |
| N201739 002                                                              | 7731686     | Jun 01, 2026                 | DP              |                               |                        |                                   |
|                                                                          | 7731690     | Jan 15, 2025                 | DP              |                               |                        |                                   |
|                                                                          | 7749194     | Oct 30, 2028                 | DP              |                               |                        |                                   |
|                                                                          | 7918823     | Nov 23, 2024                 | DP              |                               |                        |                                   |
|                                                                          | 7947017     | Mar 12, 2028                 | DP              |                               |                        |                                   |
|                                                                          | 8016788     | Mar 21, 2025                 | DP              |                               |                        |                                   |
|                                                                          | 8206360     | Feb 27, 2027                 | DP              |                               |                        |                                   |
|                                                                          | 8361029     | Nov 23, 2024                 | DP              |                               |                        |                                   |
| <u>EPOPROSTENOL SODIUM - VELETRI</u>                                     |             |                              |                 |                               |                        |                                   |
| N022260 001                                                              | 8318802     | Mar 15, 2027                 | DP              |                               |                        |                                   |
| <u>EPOPROSTENOL SODIUM - VELETRI</u>                                     |             |                              |                 |                               |                        |                                   |
| N022260 002                                                              | 8318802     | Mar 15, 2027                 | DP              |                               |                        |                                   |
| <u>ESTRADIOL - MINIVELLE</u>                                             |             |                              |                 |                               |                        |                                   |
| N203752 001                                                              | 5646286     | Aug 12, 2014                 | DS DP           |                               |                        |                                   |
|                                                                          | 6024976     | Jan 07, 2014                 | DS DP           |                               |                        |                                   |
|                                                                          | 8231906     | May 24, 2030                 | DS DP           |                               |                        |                                   |
| <u>ESTRADIOL - MINIVELLE</u>                                             |             |                              |                 |                               |                        |                                   |
| N203752 002                                                              | 5646286     | Aug 12, 2014                 | DS DP           |                               |                        |                                   |
|                                                                          | 6024976     | Jan 07, 2014                 | DS DP           |                               |                        |                                   |
|                                                                          | 8231906     | May 24, 2030                 | DS DP           |                               |                        |                                   |
| <u>ESTRADIOL - MINIVELLE</u>                                             |             |                              |                 |                               |                        |                                   |
| N203752 003                                                              | 5646286     | Aug 12, 2014                 | DS DP           |                               |                        |                                   |
|                                                                          | 6024976     | Jan 07, 2014                 | DS DP           |                               |                        |                                   |
|                                                                          | 8231906     | May 24, 2030                 | DS DP           |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                                   | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|-------------------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ESTRADIOL - MINIVELLE</u>                                      |             |                              |                 |                               |                        |                                   |
| N203752 004                                                       | 5646286     | Aug 12, 2014                 | DS DP           |                               |                        |                                   |
|                                                                   | 6024976     | Jan 07, 2014                 | DS DP           |                               |                        |                                   |
|                                                                   | 8231906     | May 24, 2030                 | DS DP           |                               |                        |                                   |
| <u>ESZOPICLONE - LUNESTA</u>                                      |             |                              |                 |                               |                        |                                   |
| N021476 001                                                       |             |                              |                 |                               | M-61<br>PED            | Oct 10, 2015<br>Apr 10, 2016      |
| <u>ESZOPICLONE - LUNESTA</u>                                      |             |                              |                 |                               |                        |                                   |
| N021476 002                                                       |             |                              |                 |                               | M-61<br>PED            | Oct 10, 2015<br>Apr 10, 2016      |
| <u>ESZOPICLONE - LUNESTA</u>                                      |             |                              |                 |                               |                        |                                   |
| N021476 003                                                       |             |                              |                 |                               | M-61<br>PED            | Oct 10, 2015<br>Apr 10, 2016      |
| <u>ETHINYL ESTRADIOL; LEVONORGESTREL - QUARTETTE</u>              |             |                              |                 |                               |                        |                                   |
| N204061 001                                                       | >A> 8415332 | Mar 11, 2029                 | DP              |                               | NP                     | Mar 28, 2016                      |
| <u>ETHINYL ESTRADIOL; NORETHINDRONE ACETATE - MINASTRIN 24 FE</u> |             |                              |                 |                               |                        |                                   |
| N204426 001                                                       | >A> 5552394 | Jul 22, 2014                 | U-1             |                               |                        |                                   |
|                                                                   | >A> 6652880 | Mar 29, 2020                 | DP              |                               |                        |                                   |
| <u>EVEROLIMUS - AFINITOR</u>                                      |             |                              |                 |                               |                        |                                   |
| N022334 001                                                       | 8410131     | May 22, 2025                 | DS DP U-1368    |                               |                        |                                   |
|                                                                   | 8410131*PED | Nov 22, 2025                 |                 |                               |                        |                                   |
| <u>EVEROLIMUS - AFINITOR</u>                                      |             |                              |                 |                               |                        |                                   |
| N022334 002                                                       | 8410131     | May 22, 2025                 | DS DP U-1368    |                               |                        |                                   |
|                                                                   | 8410131*PED | Nov 22, 2025                 |                 |                               |                        |                                   |
| <u>EVEROLIMUS - AFINITOR</u>                                      |             |                              |                 |                               |                        |                                   |
| N022334 003                                                       | 8410131     | May 22, 2025                 | DS DP U-1368    |                               |                        |                                   |
|                                                                   | 8410131*PED | Nov 22, 2025                 |                 |                               |                        |                                   |
| <u>EVEROLIMUS - AFINITOR</u>                                      |             |                              |                 |                               |                        |                                   |
| N022334 004                                                       | 8410131     | May 22, 2025                 | DS DP U-1368    |                               |                        |                                   |
|                                                                   | 8410131*PED | Nov 22, 2025                 |                 |                               |                        |                                   |
| <u>EVEROLIMUS - ZORTRESS</u>                                      |             |                              |                 |                               |                        |                                   |
| N021560 001                                                       | 5665772     | Sep 09, 2019                 | DS DP U-1365    |                               | I-668                  | Feb 15, 2016                      |
|                                                                   | 5665772     | Sep 09, 2019                 | DS DP U-1049    |                               |                        |                                   |
|                                                                   | 5665772*PED | Mar 09, 2020                 |                 |                               |                        |                                   |
|                                                                   | 6004973     | Jul 12, 2016                 | DP U-1365       |                               |                        |                                   |
|                                                                   | 6004973     | Jul 12, 2016                 | DP U-1049       |                               |                        |                                   |
|                                                                   | 6004973*PED | Jan 12, 2017                 |                 |                               |                        |                                   |
|                                                                   | 6440990     | Sep 24, 2013                 | DP U-1365       |                               |                        |                                   |
|                                                                   | 6440990     | Sep 24, 2013                 | DP U-1049       |                               |                        |                                   |
|                                                                   | 6440990*PED | Mar 24, 2014                 |                 |                               |                        |                                   |
|                                                                   | 6455518     | Jul 29, 2017                 | U-1365          |                               |                        |                                   |
|                                                                   | 6455518     | Jul 29, 2017                 | U-1049          |                               |                        |                                   |
|                                                                   | 6455518*PED | Jan 29, 2018                 |                 |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                      | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|--------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| EVEROLIMUS - ZORTRESS                |             |                              |                 |                               |                        |                                   |
| N021560 002                          | 5665772     | Sep 09, 2019                 | DS DP U-1365    |                               | I-668                  | Feb 15, 2016                      |
|                                      | 5665772     | Sep 09, 2019                 | DS DP U-1049    |                               |                        |                                   |
|                                      | 5665772*PED | Mar 09, 2020                 |                 |                               |                        |                                   |
|                                      | 6004973     | Jul 12, 2016                 | DP U-1365       |                               |                        |                                   |
|                                      | 6004973     | Jul 12, 2016                 | DP U-1049       |                               |                        |                                   |
|                                      | 6004973*PED | Jan 12, 2017                 |                 |                               |                        |                                   |
|                                      | 6440990     | Sep 24, 2013                 | DP U-1365       |                               |                        |                                   |
|                                      | 6440990     | Sep 24, 2013                 | DP U-1049       |                               |                        |                                   |
|                                      | 6440990*PED | Mar 24, 2014                 |                 |                               |                        |                                   |
|                                      | 6455518     | Jul 29, 2017                 | U-1365          |                               |                        |                                   |
|                                      | 6455518     | Jul 29, 2017                 | U-1049          |                               |                        |                                   |
|                                      | 6455518*PED | Jan 29, 2018                 |                 |                               |                        |                                   |
| EVEROLIMUS - ZORTRESS                |             |                              |                 |                               |                        |                                   |
| N021560 003                          | 5665772     | Sep 09, 2019                 | DS DP U-1365    |                               | I-668                  | Feb 15, 2016                      |
|                                      | 5665772     | Sep 09, 2019                 | DS DP U-1049    |                               |                        |                                   |
|                                      | 5665772*PED | Mar 09, 2020                 |                 |                               |                        |                                   |
|                                      | 6004973     | Jul 12, 2016                 | DP U-1365       |                               |                        |                                   |
|                                      | 6004973     | Jul 12, 2016                 | DP U-1049       |                               |                        |                                   |
|                                      | 6004973*PED | Jan 12, 2017                 |                 |                               |                        |                                   |
|                                      | 6440990     | Sep 24, 2013                 | DP U-1365       |                               |                        |                                   |
|                                      | 6440990     | Sep 24, 2013                 | DP U-1049       |                               |                        |                                   |
|                                      | 6440990*PED | Mar 24, 2014                 |                 |                               |                        |                                   |
|                                      | 6455518     | Jul 29, 2017                 | U-1365          |                               |                        |                                   |
|                                      | 6455518     | Jul 29, 2017                 | U-1049          |                               |                        |                                   |
|                                      | 6455518*PED | Jan 29, 2018                 |                 |                               |                        |                                   |
| FEBUXOSTAT - ULORIC                  |             |                              |                 |                               |                        |                                   |
| N021856 001                          | 8372872     | Sep 08, 2031                 | U-1346          |                               |                        |                                   |
| FEBUXOSTAT - ULORIC                  |             |                              |                 |                               |                        |                                   |
| N021856 002                          | 8372872     | Sep 08, 2031                 | U-1346          |                               |                        |                                   |
| FESOTERODINE FUMARATE - TOVIAZ       |             |                              |                 |                               |                        |                                   |
| N022030 001                          | 8338478     | May 11, 2019                 | DS DP U-913     |                               |                        |                                   |
| FESOTERODINE FUMARATE - TOVIAZ       |             |                              |                 |                               |                        |                                   |
| N022030 002                          | 8338478     | May 11, 2019                 | DS DP U-913     |                               |                        |                                   |
| FLUTICASONE FUROATE - VERAMYST       |             |                              |                 |                               |                        |                                   |
| N022051 001                          | 8347879     | Apr 01, 2027                 | DP              |                               |                        |                                   |
| FOLLITROPIN ALFA/BETA - FOLLISTIM AQ |             |                              |                 |                               |                        |                                   |
| N021211 001                          | 5929028     | Jan 14, 2018                 | DP U-567        |                               |                        |                                   |
|                                      | 5929028     | Jan 14, 2018                 | DP U-1366       |                               |                        |                                   |
|                                      | 7563763     | Aug 23, 2019                 | U-993           |                               |                        |                                   |
|                                      | 7563763     | Aug 23, 2019                 | U-1367          |                               |                        |                                   |
|                                      | 7563763     | Aug 23, 2019                 | U-1183          |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                        | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|--------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>FOLLITROPIN ALFA/BETA - FOLLISTIM AQ</u>            |             |                              |                 |                               |                        |                                   |
| N021211 002                                            | 5929028     | Jan 14, 2018                 | DP U-567        |                               |                        |                                   |
|                                                        | 5929028     | Jan 14, 2018                 | DP U-1366       |                               |                        |                                   |
|                                                        | 7563763     | Aug 23, 2019                 | U-993           |                               |                        |                                   |
|                                                        | 7563763     | Aug 23, 2019                 | U-1367          |                               |                        |                                   |
|                                                        | 7563763     | Aug 23, 2019                 | U-1183          |                               |                        |                                   |
| <u>FOLLITROPIN ALFA/BETA - FOLLISTIM AQ</u>            |             |                              |                 |                               |                        |                                   |
| N021211 003                                            | 5929028     | Jan 14, 2018                 | DP U-567        |                               |                        |                                   |
|                                                        | 5929028     | Jan 14, 2018                 | DP U-1366       |                               |                        |                                   |
|                                                        | 7563763     | Aug 23, 2019                 | U-993           |                               |                        |                                   |
|                                                        | 7563763     | Aug 23, 2019                 | U-1367          |                               |                        |                                   |
|                                                        | 7563763     | Aug 23, 2019                 | U-1183          |                               |                        |                                   |
| <u>FOLLITROPIN ALFA/BETA - FOLLISTIM AQ</u>            |             |                              |                 |                               |                        |                                   |
| N021211 004                                            | 5929028     | Jan 14, 2018                 | DP U-567        |                               |                        |                                   |
|                                                        | 5929028     | Jan 14, 2018                 | DP U-1366       |                               |                        |                                   |
|                                                        | 7563763     | Aug 23, 2019                 | U-993           |                               |                        |                                   |
|                                                        | 7563763     | Aug 23, 2019                 | U-1367          |                               |                        |                                   |
|                                                        | 7563763     | Aug 23, 2019                 | U-1183          |                               |                        |                                   |
| <u>FOLLITROPIN ALFA/BETA - FOLLISTIM AQ</u>            |             |                              |                 |                               |                        |                                   |
| N021273 001                                            | 5767251     | Jun 16, 2015                 | DS              |                               |                        |                                   |
|                                                        | 5929028     | Jan 14, 2018                 | DP U-1366       |                               |                        |                                   |
| <u>FOLLITROPIN ALFA/BETA - FOLLISTIM AQ</u>            |             |                              |                 |                               |                        |                                   |
| N021273 002                                            | 5767251     | Jun 16, 2015                 | DS              |                               |                        |                                   |
|                                                        | 5929028     | Jan 14, 2018                 | DP U-1366       |                               |                        |                                   |
| <u>GABAPENTIN - GRALISE</u>                            |             |                              |                 |                               |                        |                                   |
| N022544 001                                            | 8333992     | Oct 25, 2022                 | DP U-1114       |                               |                        |                                   |
| <u>GABAPENTIN - GRALISE</u>                            |             |                              |                 |                               |                        |                                   |
| N022544 002                                            | 8333992     | Oct 25, 2022                 | DP U-1114       |                               |                        |                                   |
| <u>GADOFOSVESET TRISODIUM - ABLAVAR</u>                |             |                              |                 |                               |                        |                                   |
| N021711 001                                            | >A> 8394356 | Feb 01, 2015                 | U-1112          |                               |                        |                                   |
| <u>GADOFOSVESET TRISODIUM - ABLAVAR</u>                |             |                              |                 |                               |                        |                                   |
| N021711 002                                            | >A> 8394356 | Feb 01, 2015                 | U-1112          |                               |                        |                                   |
| <u>GADOTERATE MEGLUMINE - DOTAREM</u>                  |             |                              |                 |                               |                        |                                   |
| N204781 001                                            |             |                              |                 |                               | NCE                    | Mar 20, 2018                      |
| <u>GADOTERATE MEGLUMINE - DOTAREM</u>                  |             |                              |                 |                               |                        |                                   |
| N204781 002                                            |             |                              |                 |                               | NCE                    | Mar 20, 2018                      |
| <u>GADOTERATE MEGLUMINE - DOTAREM</u>                  |             |                              |                 |                               |                        |                                   |
| N204781 003                                            |             |                              |                 |                               | NCE                    | Mar 20, 2018                      |
| <u>GADOTERATE MEGLUMINE - DOTAREM</u>                  |             |                              |                 |                               |                        |                                   |
| N204781 004                                            |             |                              |                 |                               | NCE                    | Mar 20, 2018                      |
| <u>GADOXETATE DISODIUM - EOVI</u>                      |             |                              |                 |                               |                        |                                   |
| N022090 002                                            |             |                              |                 |                               | NCE                    | Jul 03, 2013                      |
| <u>GANIRELIX ACETATE - GANIRELIX ACETATE INJECTION</u> |             |                              |                 |                               |                        |                                   |
| N021057 001                                            | 6653286     | Jun 16, 2018                 | U-1354          |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                               | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|-----------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>GLATIRAMER ACETATE - COPAXONE</u>          |             |                              |                 |                               |                        |                                   |
| N020622 002                                   | 8367605     | May 24, 2014                 | DS              |                               |                        |                                   |
| <u>GLYCEROL PHENYLBUTYRATE - RAVICTI</u>      |             |                              |                 |                               |                        |                                   |
| N203284 001                                   | >A> 5968979 | Feb 07, 2015                 | DS DP U-1378    |                               | NE                     | Feb 01, 2016                      |
|                                               | >A> 8404215 | Mar 09, 2032                 | U-1383          |                               | >A> ODE                | Feb 01, 2020                      |
| <u>GLYCOPYRROLATE - ROBINUL</u>               |             |                              |                 |                               |                        |                                   |
| N012827 001                                   | >A> 7091236 | Apr 24, 2024                 | U-877           | Y                             |                        |                                   |
| <u>GLYCOPYRROLATE - ROBINUL FORTE</u>         |             |                              |                 |                               |                        |                                   |
| N012827 002                                   | >A> 7091236 | Apr 24, 2024                 | U-877           | Y                             |                        |                                   |
| <u>IBUPROFEN LYSINE - NEOPROFEN</u>           |             |                              |                 |                               |                        |                                   |
| N021903 001                                   | >A> 8415337 | Mar 02, 2032                 | DS DP           |                               |                        |                                   |
| <u>ICOSAPENT ETHYL - VASCEPA</u>              |             |                              |                 |                               |                        |                                   |
| N202057 001                                   | 8357677     | Feb 09, 2030                 | U-1287          |                               |                        |                                   |
|                                               | 8367652     | Feb 09, 2030                 | U-1287          |                               |                        |                                   |
|                                               | 8377920     | Feb 09, 2030                 | U-1287          |                               |                        |                                   |
|                                               | 8399446     | Feb 09, 2030                 | U-1287          |                               |                        |                                   |
|                                               | 8415335     | Feb 09, 2030                 | U-1287          |                               |                        |                                   |
|                                               | >A> 8426399 | Feb 09, 2030                 | U-1287          |                               |                        |                                   |
|                                               | >A> 8431560 | Feb 09, 2030                 | U-1287          |                               |                        |                                   |
|                                               | >A> 8440650 | Feb 09, 2030                 | U-1287          |                               |                        |                                   |
| <u>IMATINIB MESYLATE - GLEEVEC</u>            |             |                              |                 |                               |                        |                                   |
| N021588 001                                   | 7544799     | Jan 16, 2019                 | DS DP           | Y                             | I-666                  | Jan 25, 2016                      |
|                                               | RE43932     | Jan 16, 2019                 | DS DP           |                               | ODE                    | Jan 25, 2020                      |
|                                               | RE43932*PED | Jul 16, 2019                 |                 |                               |                        |                                   |
| <u>IMATINIB MESYLATE - GLEEVEC</u>            |             |                              |                 |                               |                        |                                   |
| N021588 002                                   | 7544799     | Jan 16, 2019                 | DS DP           | Y                             | I-666                  | Jan 25, 2016                      |
|                                               | RE43932     | Jan 16, 2019                 | DS DP           |                               | ODE                    | Jan 25, 2020                      |
|                                               | RE43932*PED | Jul 16, 2019                 |                 |                               |                        |                                   |
| <u>INDACATEROL MALEATE - ARCAPTA NEOHALER</u> |             |                              |                 |                               |                        |                                   |
| N022383 001                                   | >A> 8067437 | Jun 02, 2020                 | U-1168          |                               |                        |                                   |
| <u>INGENOL MEBUTATE - PICATO</u>              |             |                              |                 |                               |                        |                                   |
| N202833 001                                   | 8372827     | Dec 18, 2026                 | DS DP           |                               |                        |                                   |
|                                               | 8372828     | Dec 18, 2026                 | DS DP           |                               |                        |                                   |
|                                               | 8377919     | Dec 18, 2026                 | DS DP           |                               |                        |                                   |
| <u>INGENOL MEBUTATE - PICATO</u>              |             |                              |                 |                               |                        |                                   |
| N202833 002                                   | 8372827     | Dec 18, 2026                 | DS DP           |                               |                        |                                   |
|                                               | 8372828     | Dec 18, 2026                 | DS DP           |                               |                        |                                   |
|                                               | 8377919     | Dec 18, 2026                 | DS DP           |                               |                        |                                   |
| <u>IOBENGUANE SULFATE I-123 - ADREVIEW</u>    |             |                              |                 |                               |                        |                                   |
| N022290 001                                   |             |                              |                 |                               | I-669                  | Mar 20, 2016                      |
| <u>IRON SUCROSE - VENOFER</u>                 |             |                              |                 |                               |                        |                                   |
| N021135 005                                   |             |                              |                 |                               | NPP                    | Sep 21, 2015                      |
| <u>ISOTRETINOIN - ABSORICA</u>                |             |                              |                 |                               |                        |                                   |
| N021951 001                                   | 8367102     | Sep 21, 2021                 | U-1347          |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                                | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|----------------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ISOTRETINOIN - ABSORICA</u>                                 |             |                              |                 |                               |                        |                                   |
| N021951 002                                                    | 8367102     | Sep 21, 2021                 | U-1347          |                               |                        |                                   |
| <u>ISOTRETINOIN - ABSORICA</u>                                 |             |                              |                 |                               |                        |                                   |
| N021951 003                                                    | 8367102     | Sep 21, 2021                 | U-1347          |                               |                        |                                   |
| <u>ISOTRETINOIN - ABSORICA</u>                                 |             |                              |                 |                               |                        |                                   |
| N021951 004                                                    | 8367102     | Sep 21, 2021                 | U-1347          |                               |                        |                                   |
| <u>IVACAFTOR - KALYDECO</u>                                    |             |                              |                 |                               |                        |                                   |
| N203188 001                                                    | >A> 8410274 | Dec 28, 2026                 | DP              |                               |                        |                                   |
| <u>KETOROLAC TROMETHAMINE - ACULAR LS</u>                      |             |                              |                 |                               |                        |                                   |
| N021528 001                                                    | 8377982     | May 28, 2024                 | U-1363          |                               |                        |                                   |
|                                                                | 8377982*PED | Nov 28, 2024                 |                 |                               |                        |                                   |
| <u>LENALIDOMIDE - REVLIMID</u>                                 |             |                              |                 |                               |                        |                                   |
| N021880 001                                                    | 8404717     | Apr 11, 2023                 | U-1215          |                               |                        |                                   |
| <u>LENALIDOMIDE - REVLIMID</u>                                 |             |                              |                 |                               |                        |                                   |
| N021880 002                                                    | 8404717     | Apr 11, 2023                 | U-1215          |                               |                        |                                   |
| <u>LENALIDOMIDE - REVLIMID</u>                                 |             |                              |                 |                               |                        |                                   |
| N021880 003                                                    | 8404717     | Apr 11, 2023                 | U-1215          |                               |                        |                                   |
| <u>LENALIDOMIDE - REVLIMID</u>                                 |             |                              |                 |                               |                        |                                   |
| N021880 004                                                    | 8404717     | Apr 11, 2023                 | U-1215          |                               |                        |                                   |
| <u>LENALIDOMIDE - REVLIMID</u>                                 |             |                              |                 |                               |                        |                                   |
| N021880 005                                                    | 8404717     | Apr 11, 2023                 | U-1215          |                               |                        |                                   |
| <u>LEVALBUTEROL HYDROCHLORIDE - LEVALBUTEROL HYDROCHLORIDE</u> |             |                              |                 |                               |                        |                                   |
| A077756 001                                                    |             |                              |                 |                               | PC                     | Feb 16, 2013                      |
| <u>LEVALBUTEROL HYDROCHLORIDE - LEVALBUTEROL HYDROCHLORIDE</u> |             |                              |                 |                               |                        |                                   |
| A077756 002                                                    |             |                              |                 |                               | PC                     | Feb 16, 2013                      |
| <u>LEVALBUTEROL HYDROCHLORIDE - LEVALBUTEROL HYDROCHLORIDE</u> |             |                              |                 |                               |                        |                                   |
| A077756 003                                                    |             |                              |                 |                               | PC                     | Feb 16, 2013                      |
| <u>LEVOLEUCOVORIN CALCIUM - FUSILEV</u>                        |             |                              |                 |                               |                        |                                   |
| N020140 001                                                    | 6500829     | Mar 07, 2022                 | DS DP           |                               |                        |                                   |
| <u>LEVOLEUCOVORIN CALCIUM - FUSILEV</u>                        |             |                              |                 |                               |                        |                                   |
| N020140 002                                                    | 6500829     | Mar 07, 2022                 | DS DP           |                               |                        |                                   |
| <u>LEVOLEUCOVORIN CALCIUM - FUSILEV</u>                        |             |                              |                 |                               |                        |                                   |
| N020140 003                                                    | 6500829     | Mar 07, 2022                 | DS DP           |                               |                        |                                   |
| <u>LEVONORGESTREL - SKYLA</u>                                  |             |                              |                 |                               |                        |                                   |
| N203159 001                                                    | 5785053     | Dec 05, 2015                 | DP              |                               | NP                     | Jan 09, 2016                      |
|                                                                | 7252839     | Nov 13, 2023                 | DP              |                               |                        |                                   |
| <u>LOMITAPIDE MESYLATE - JUXTAPID</u>                          |             |                              |                 |                               |                        |                                   |
| N203858 001                                                    | 5712279     | Feb 21, 2015                 | DS              | U-1317                        | ODE                    | Dec 21, 2019                      |
|                                                                | 7932268     | Aug 19, 2027                 |                 | U-1316                        |                        |                                   |
| <u>LOMITAPIDE MESYLATE - JUXTAPID</u>                          |             |                              |                 |                               |                        |                                   |
| N203858 002                                                    | 5712279     | Feb 21, 2015                 | DS              | U-1317                        | ODE                    | Dec 21, 2019                      |
|                                                                | 7932268     | Aug 19, 2027                 |                 | U-1316                        |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                          | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>LOMITAPIDE MESYLATE - JUXTAPID</u>    |             |                              |                 |                               |                        |                                   |
| N203858 003                              | 5712279     | Feb 21, 2015                 | DS U-1317       |                               | ODE                    | Dec 21, 2019                      |
|                                          | 7932268     | Aug 19, 2027                 | U-1316          |                               |                        |                                   |
| <u>LOPINAVIR; RITONAVIR - KALETRA</u>    |             |                              |                 |                               |                        |                                   |
| N021906 001                              | 8025899     | Dec 14, 2027                 | DP              |                               |                        |                                   |
|                                          | 8025899*PED | Jun 14, 2028                 |                 |                               |                        |                                   |
|                                          | 8377952     | Oct 22, 2027                 | U-1372          |                               |                        |                                   |
|                                          | 8377952*PED | Apr 22, 2028                 |                 |                               |                        |                                   |
|                                          | 8399015     | Aug 25, 2024                 | DP              |                               |                        |                                   |
|                                          | 8399015*PED | Feb 25, 2025                 |                 |                               |                        |                                   |
| <u>LOPINAVIR; RITONAVIR - KALETRA</u>    |             |                              |                 |                               |                        |                                   |
| N021906 002                              | 8025899     | Dec 14, 2027                 | DP              |                               |                        |                                   |
|                                          | 8025899*PED | Jun 14, 2028                 |                 |                               |                        |                                   |
|                                          | 8377952     | Oct 22, 2027                 | U-1372          |                               |                        |                                   |
|                                          | 8377952*PED | Apr 22, 2028                 |                 |                               |                        |                                   |
|                                          | 8399015     | Aug 25, 2024                 | DP              |                               |                        |                                   |
|                                          | 8399015*PED | Feb 25, 2025                 |                 |                               |                        |                                   |
| <u>LOTEPREDNOL ETABONATE - LOTEMAX</u>   |             |                              |                 |                               |                        |                                   |
| N202872 001                              | 5800807     | Jan 29, 2017                 | DP              |                               |                        |                                   |
| <u>LOXAPINE - ADASUVE</u>                |             |                              |                 |                               |                        |                                   |
| N022549 001                              | 6716416     | May 20, 2022                 | DP              |                               |                        |                                   |
|                                          | 7052679     | Mar 20, 2022                 | DP              |                               |                        |                                   |
|                                          | 7078020     | Oct 26, 2021                 | DP U-1375       |                               |                        |                                   |
|                                          | 7090830     | Oct 26, 2021                 | DP              |                               |                        |                                   |
|                                          | 7458374     | Aug 18, 2024                 | DP              |                               |                        |                                   |
|                                          | 7537009     | Oct 26, 2021                 | DP              |                               |                        |                                   |
|                                          | 7585493     | Oct 26, 2021                 | DP              |                               |                        |                                   |
|                                          | 7601337     | Oct 26, 2021                 | DP              |                               |                        |                                   |
|                                          | 8074644     | Oct 26, 2021                 | DP              |                               |                        |                                   |
|                                          | 8173107     | Oct 26, 2021                 | DP              |                               |                        |                                   |
|                                          | 8235037     | Oct 26, 2021                 | DP              |                               |                        |                                   |
|                                          | 8387612     | Oct 23, 2026                 | DP              |                               |                        |                                   |
| <u>LUBIPROSTONE - AMITIZA</u>            |             |                              |                 |                               |                        |                                   |
| N021908 001                              | >A> 6414016 | Sep 05, 2020                 | U-717           |                               | >A> I-670              | Apr 19, 2016                      |
|                                          | >A> 6414016 | Sep 05, 2020                 | U-1392          |                               |                        |                                   |
|                                          | >A> 6982283 | Dec 04, 2022                 | U-1391          |                               |                        |                                   |
|                                          | >A> 8026393 | Oct 25, 2027                 | DP U-1391       |                               |                        |                                   |
|                                          | >A> 8071613 | Sep 05, 2020                 | U-1393          |                               |                        |                                   |
|                                          | >A> 8071613 | Sep 05, 2020                 | U-1203          |                               |                        |                                   |
|                                          | >A> 8097653 | Nov 14, 2022                 | U-1394          |                               |                        |                                   |
|                                          | >A> 8097653 | Nov 14, 2022                 | U-1214          |                               |                        |                                   |
|                                          | >A> 8389542 | Nov 14, 2022                 | DP U-1395       |                               |                        |                                   |
|                                          | >A> 8389542 | Nov 14, 2022                 | DP U-1345       |                               |                        |                                   |
| <u>LURASIDONE HYDROCHLORIDE - LATUDA</u> |             |                              |                 |                               |                        |                                   |
| N200603 001                              | >A> 5532372 | Jul 02, 2018                 | DS              |                               |                        |                                   |
| <u>LURASIDONE HYDROCHLORIDE - LATUDA</u> |             |                              |                 |                               |                        |                                   |
| N200603 002                              | >A> 5532372 | Jul 02, 2018                 | DS              |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                                                                                                                              | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>LURASIDONE HYDROCHLORIDE - LATUDA</u>                                                                                                                     |             |                              |                 |                               |                        |                                   |
| N200603 003                                                                                                                                                  | >A> 5532372 | Jul 02, 2018                 | DS              |                               |                        |                                   |
| <u>LURASIDONE HYDROCHLORIDE - LATUDA</u>                                                                                                                     |             |                              |                 |                               |                        |                                   |
| N200603 004                                                                                                                                                  | >A> 5532372 | Jul 02, 2018                 | DS              |                               |                        |                                   |
| <u>MAGNESIUM SULFATE; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; POTASSIUM SULFATE; SODIUM BICARBONATE;<br/>SODIUM CHLORIDE; SODIUM SULFATE - SUCLEAR</u> |             |                              |                 |                               |                        |                                   |
| N203595 001                                                                                                                                                  |             |                              |                 |                               | NC                     | Jan 18, 2016                      |
| <u>MEMANTINE HYDROCHLORIDE - NAMENDA XR</u>                                                                                                                  |             |                              |                 |                               |                        |                                   |
| N022525 001                                                                                                                                                  | >A> 8168209 | Nov 22, 2025                 | DP              |                               |                        |                                   |
|                                                                                                                                                              | >A> 8173708 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
|                                                                                                                                                              | >A> 8283379 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
|                                                                                                                                                              | >A> 8329752 | Nov 22, 2025                 | DP              |                               |                        |                                   |
|                                                                                                                                                              | >A> 8362085 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
| <u>MEMANTINE HYDROCHLORIDE - NAMENDA XR</u>                                                                                                                  |             |                              |                 |                               |                        |                                   |
| N022525 002                                                                                                                                                  | >A> 8168209 | Nov 22, 2025                 | DP              |                               |                        |                                   |
|                                                                                                                                                              | >A> 8173708 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
|                                                                                                                                                              | >A> 8283379 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
|                                                                                                                                                              | >A> 8329752 | Nov 22, 2025                 | DP              |                               |                        |                                   |
|                                                                                                                                                              | >A> 8362085 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
| <u>MEMANTINE HYDROCHLORIDE - NAMENDA XR</u>                                                                                                                  |             |                              |                 |                               |                        |                                   |
| N022525 003                                                                                                                                                  | >A> 8168209 | Nov 22, 2025                 | DP              |                               |                        |                                   |
|                                                                                                                                                              | >A> 8173708 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
|                                                                                                                                                              | >A> 8283379 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
|                                                                                                                                                              | >A> 8329752 | Nov 22, 2025                 | DP              |                               |                        |                                   |
|                                                                                                                                                              | >A> 8362085 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
| <u>MEMANTINE HYDROCHLORIDE - NAMENDA XR</u>                                                                                                                  |             |                              |                 |                               |                        |                                   |
| N022525 004                                                                                                                                                  | >A> 8168209 | Nov 22, 2025                 | DP              |                               |                        |                                   |
|                                                                                                                                                              | >A> 8173708 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
|                                                                                                                                                              | >A> 8283379 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
|                                                                                                                                                              | >A> 8329752 | Nov 22, 2025                 | DP              |                               |                        |                                   |
|                                                                                                                                                              | >A> 8362085 | Nov 22, 2025                 | U-539           |                               |                        |                                   |
| <u>MESALAMINE - DELZICOL</u>                                                                                                                                 |             |                              |                 |                               |                        |                                   |
| N204412 001                                                                                                                                                  | >A> 5541170 | Jul 30, 2013                 | DP U-141        |                               |                        |                                   |
|                                                                                                                                                              | >A> 5541171 | Jul 30, 2013                 | DP U-141        |                               |                        |                                   |
| <u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>                                                                                              |             |                              |                 |                               |                        |                                   |
| N022044 001                                                                                                                                                  | >A> 7459428 | Feb 02, 2019                 | U-1036          |                               |                        |                                   |
|                                                                                                                                                              | >A> 8414921 | Jul 21, 2028                 | DP U-1036       |                               |                        |                                   |
| <u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>                                                                                              |             |                              |                 |                               |                        |                                   |
| N022044 002                                                                                                                                                  | >A> 7459428 | Feb 02, 2019                 | U-1036          |                               |                        |                                   |
|                                                                                                                                                              | >A> 8414921 | Jul 21, 2028                 | DP U-1036       |                               |                        |                                   |
| <u>METHYLNALTREXONE BROMIDE - RELISTOR</u>                                                                                                                   |             |                              |                 |                               |                        |                                   |
| N021964 001                                                                                                                                                  | >A> 8420663 | Sep 30, 2029                 | U-1185          |                               |                        |                                   |
| <u>METHYLNALTREXONE BROMIDE - RELISTOR</u>                                                                                                                   |             |                              |                 |                               |                        |                                   |
| N021964 002                                                                                                                                                  | >A> 8420663 | Sep 30, 2029                 | U-1185          |                               |                        |                                   |
| <u>METHYLNALTREXONE BROMIDE - RELISTOR</u>                                                                                                                   |             |                              |                 |                               |                        |                                   |
| N021964 003                                                                                                                                                  | >A> 8420663 | Sep 30, 2029                 | U-1185          |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                      | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>METHYLPHENIDATE HYDROCHLORIDE - QUILLIVANT XR</u> |             |                              |                 |                               |                        |                                   |
| N202100 001                                          | 8062667     | Mar 29, 2029                 | DP              |                               |                        |                                   |
|                                                      | 8287903     | Feb 15, 2031                 | DP              |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - XIMINO</u>            |             |                              |                 |                               |                        |                                   |
| N201922 001                                          | >A> 5908838 | Feb 19, 2018                 | U-1376          |                               |                        |                                   |
|                                                      | >A> 7541347 | Apr 02, 2027                 | U-917           |                               |                        |                                   |
|                                                      | >A> 7544373 | Apr 02, 2027                 | DP              |                               |                        |                                   |
|                                                      | >A> 7790705 | Jun 24, 2025                 | U-124           |                               |                        |                                   |
|                                                      | >A> 7919483 | Mar 07, 2027                 | U-124           |                               |                        |                                   |
|                                                      | >A> 8252776 | Jun 24, 2025                 | U-124           |                               |                        |                                   |
|                                                      | >A> 8268804 | Jun 24, 2025                 | U-124           |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - XIMINO</u>            |             |                              |                 |                               |                        |                                   |
| N201922 003                                          | >A> 5908838 | Feb 19, 2018                 | U-1376          |                               |                        |                                   |
|                                                      | >A> 7541347 | Apr 02, 2027                 | U-917           |                               |                        |                                   |
|                                                      | >A> 7544373 | Apr 02, 2027                 | DP              |                               |                        |                                   |
|                                                      | >A> 7790705 | Jun 24, 2025                 | U-124           |                               |                        |                                   |
|                                                      | >A> 7919483 | Mar 07, 2027                 | U-124           |                               |                        |                                   |
|                                                      | >A> 8252776 | Jun 24, 2025                 | U-124           |                               |                        |                                   |
|                                                      | >A> 8268804 | Jun 24, 2025                 | U-124           |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - XIMINO</u>            |             |                              |                 |                               |                        |                                   |
| N201922 005                                          | >A> 5908838 | Feb 19, 2018                 | U-1376          |                               |                        |                                   |
|                                                      | >A> 7541347 | Apr 02, 2027                 | U-917           |                               |                        |                                   |
|                                                      | >A> 7544373 | Apr 02, 2027                 | DP              |                               |                        |                                   |
|                                                      | >A> 7790705 | Jun 24, 2025                 | U-124           |                               |                        |                                   |
|                                                      | >A> 7919483 | Mar 07, 2027                 | U-124           |                               |                        |                                   |
|                                                      | >A> 8252776 | Jun 24, 2025                 | U-124           |                               |                        |                                   |
|                                                      | >A> 8268804 | Jun 24, 2025                 | U-124           |                               |                        |                                   |
| <u>MIPOMERSEN SODIUM - KYNAMRO</u>                   |             |                              |                 |                               |                        |                                   |
| N203568 001                                          | 5914396     | Jun 22, 2016                 | DS              |                               | NCE                    | Jan 29, 2018                      |
|                                                      | 6166197     | Dec 26, 2017                 | DS              |                               | ODE                    | Jan 29, 2020                      |
|                                                      | 6222025     | Mar 06, 2015                 | DS              |                               |                        |                                   |
|                                                      | 6451991     | Feb 11, 2017                 | DS              |                               |                        |                                   |
|                                                      | 7015315     | Mar 21, 2023                 | DS              |                               |                        |                                   |
|                                                      | 7101993     | Sep 05, 2023                 | DS              |                               |                        |                                   |
|                                                      | 7407943     | Aug 01, 2021                 | U-1353          |                               |                        |                                   |
|                                                      | 7511131     | Dec 13, 2025                 | DS              |                               |                        |                                   |
| <u>MOMETASONE FUROATE - ELOCON</u>                   |             |                              |                 |                               |                        |                                   |
| N019625 002                                          |             |                              |                 | >A> NP                        |                        | Apr 19, 2016                      |
| <u>MUPIROCIN CALCIUM - BACTROBAN</u>                 |             |                              |                 |                               |                        |                                   |
| N050703 001                                          | 5569672     | Oct 29, 2013                 | U-1358          |                               |                        |                                   |
| <u>MUPIROCIN CALCIUM - BACTROBAN</u>                 |             |                              |                 |                               |                        |                                   |
| N050746 001                                          | 5569672     | Oct 29, 2013                 | U-1358          |                               |                        |                                   |
| <u>NEPAFENAC - NEPAFENAC</u>                         |             |                              |                 |                               |                        |                                   |
| N203491 001                                          | 5475034     | Jun 06, 2014                 | U-100           |                               |                        |                                   |
|                                                      | 6403609     | Jul 17, 2018                 | DP              |                               |                        |                                   |
|                                                      | 7947295     | Jun 08, 2024                 | DP              |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                      | PATENT NO       | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|------------------------------------------------------|-----------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>NILOTINIB HYDROCHLORIDE MONOHYDRATE - TASIGNA</u> |                 |                              |                 |                               |                        |                                   |
| N022068 001                                          | 8389537         | Jul 18, 2026                 | DS DP U-1374    |                               |                        |                                   |
| <u>NILOTINIB HYDROCHLORIDE MONOHYDRATE - TASIGNA</u> |                 |                              |                 |                               |                        |                                   |
| N022068 002                                          | 8389537         | Jul 18, 2026                 | DS DP U-1374    |                               |                        |                                   |
| <u>NITRIC OXIDE - INOMAX</u>                         |                 |                              |                 |                               |                        |                                   |
| N020845 002                                          | >A> 8431163     | Jun 30, 2029                 | U-1286          |                               |                        |                                   |
|                                                      | >A> 8431163*PED | Dec 30, 2029                 |                 |                               |                        |                                   |
| <u>NITRIC OXIDE - INOMAX</u>                         |                 |                              |                 |                               |                        |                                   |
| N020845 003                                          | >A> 8431163     | Jun 30, 2029                 | U-1286          |                               |                        |                                   |
|                                                      | >A> 8431163*PED | Dec 30, 2029                 |                 |                               |                        |                                   |
| <u>OLOPATADINE HYDROCHLORIDE - PATANASE</u>          |                 |                              |                 |                               |                        |                                   |
| N021861 001                                          | 8399508         | Sep 17, 2022                 | U-726           |                               |                        |                                   |
|                                                      | 8399508*PED     | Mar 17, 2023                 |                 |                               |                        |                                   |
| <u>OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID OTC</u>  |                 |                              |                 |                               |                        |                                   |
| N022281 001                                          | >A> 6489346     | Jul 15, 2016                 | DP U-1025       | Y                             |                        |                                   |
|                                                      | >A> 6645988     | Jul 15, 2016                 | DP              | Y                             |                        |                                   |
|                                                      | >A> 6699885     | Jul 15, 2016                 | DP              | Y                             |                        |                                   |
| <u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>               |                 |                              |                 |                               |                        |                                   |
| N021087 001                                          |                 |                              |                 |                               | NPP                    | Dec 21, 2015                      |
| <u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>               |                 |                              |                 |                               |                        |                                   |
| N021087 002                                          |                 |                              |                 |                               | NPP                    | Dec 21, 2015                      |
| <u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>               |                 |                              |                 |                               |                        |                                   |
| N021087 003                                          |                 |                              |                 |                               | NPP                    | Dec 21, 2015                      |
| <u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>               |                 |                              |                 |                               |                        |                                   |
| N021246 001                                          |                 |                              |                 |                               | NPP                    | Dec 21, 2015                      |
| <u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>               |                 |                              |                 |                               |                        |                                   |
| N021246 002                                          |                 |                              |                 |                               | NPP                    | Dec 21, 2015                      |
| <u>OSPEMIFENE - OSPHENA</u>                          |                 |                              |                 |                               |                        |                                   |
| N203505 001                                          | 6245819         | Jul 21, 2020                 | U-1369          |                               | NCE                    | Feb 26, 2018                      |
|                                                      | >A> 8236861     | Aug 11, 2026                 | U-1370          |                               |                        |                                   |
|                                                      | >A> 8236861     | Aug 11, 2026                 | U-1369          |                               |                        |                                   |
| <u>OXYBUTYNIN - OXYTROL FOR WOMEN</u>                |                 |                              |                 |                               |                        |                                   |
| N202211 001                                          | 5601839         | Apr 26, 2015                 | DP U-1329       |                               | NP                     | Jan 25, 2016                      |
|                                                      | 5834010         | Apr 26, 2015                 | DP U-1329       |                               |                        |                                   |
|                                                      | 6743441         | Apr 26, 2020                 | DP U-1329       |                               |                        |                                   |
|                                                      | 7081249         | Apr 26, 2020                 | DP U-1329       |                               |                        |                                   |
|                                                      | 7081250         | Apr 26, 2020                 | DP U-1329       |                               |                        |                                   |
|                                                      | 7081251         | Apr 26, 2020                 | DP U-1329       |                               |                        |                                   |
|                                                      | 7081252         | Apr 26, 2020                 | DP U-1329       |                               |                        |                                   |
|                                                      | 7179483         | Apr 26, 2020                 | U-1329          |                               |                        |                                   |
| <u>OXYCODONE HYDROCHLORIDE - OXECTA</u>              |                 |                              |                 |                               |                        |                                   |
| N202080 001                                          | >A> 8409616     | Nov 26, 2023                 | DP              |                               |                        |                                   |
| <u>OXYCODONE HYDROCHLORIDE - OXECTA</u>              |                 |                              |                 |                               |                        |                                   |
| N202080 002                                          | >A> 8409616     | Nov 26, 2023                 | DP              |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                              | PATENT NO | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|--------------------------------------------------------------|-----------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>OXYMORPHONE HYDROCHLORIDE - OXYMORPHONE HYDROCHLORIDE</u> |           |                              |                 |                               |                        |                                   |
| A079087                                                      | 006       |                              |                 |                               | >A> PC                 | Jul 07, 2013                      |
| <u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - CREON</u>        |           |                              |                 |                               |                        |                                   |
| N020725                                                      | 005       |                              |                 |                               | M-93<br>NCE            | Jul 29, 2019<br>Apr 30, 2014      |
| <u>PLERIXAFOR - MOZOBIL</u>                                  |           |                              |                 |                               |                        |                                   |
| N022311                                                      | 001       | RE42152                      | Dec 10, 2018    | DP                            |                        |                                   |
| <u>POMALIDOMIDE - POMALYST</u>                               |           |                              |                 |                               |                        |                                   |
| N204026                                                      | 001       | 5635517                      | Jul 24, 2016    | U-1359                        | NCE                    | Feb 08, 2018                      |
|                                                              |           | 6045501                      | Aug 28, 2018    | U-1361                        | ODE                    | Feb 08, 2020                      |
|                                                              |           | 6315720                      | Oct 23, 2020    | U-1361                        |                        |                                   |
|                                                              |           | 6316471                      | Aug 10, 2016    | DP U-1360                     |                        |                                   |
|                                                              |           | 6476052                      | Jul 24, 2016    | DP U-1360                     |                        |                                   |
|                                                              |           | 6561976                      | Aug 28, 2018    | U-1361                        |                        |                                   |
|                                                              |           | 6561977                      | Oct 23, 2020    | U-1361                        |                        |                                   |
|                                                              |           | 6755784                      | Oct 23, 2020    | U-1361                        |                        |                                   |
|                                                              |           | 6908432                      | Aug 28, 2018    | U-1361                        |                        |                                   |
|                                                              |           | 8158653                      | Aug 10, 2016    | DP                            |                        |                                   |
|                                                              |           | 8198262                      | Oct 19, 2024    | U-1360                        |                        |                                   |
|                                                              |           | 8204763                      | Aug 28, 2018    | U-1361                        |                        |                                   |
|                                                              |           | 8315886                      | Oct 23, 2020    | U-1361                        |                        |                                   |
| <u>POMALIDOMIDE - POMALYST</u>                               |           |                              |                 |                               |                        |                                   |
| N204026                                                      | 002       | 5635517                      | Jul 24, 2016    | U-1359                        | NCE                    | Feb 08, 2018                      |
|                                                              |           | 6045501                      | Aug 28, 2018    | U-1361                        | ODE                    | Feb 08, 2020                      |
|                                                              |           | 6315720                      | Oct 23, 2020    | U-1361                        |                        |                                   |
|                                                              |           | 6316471                      | Aug 10, 2016    | DP U-1360                     |                        |                                   |
|                                                              |           | 6476052                      | Jul 24, 2016    | DP U-1360                     |                        |                                   |
|                                                              |           | 6561976                      | Aug 28, 2018    | U-1361                        |                        |                                   |
|                                                              |           | 6561977                      | Oct 23, 2020    | U-1361                        |                        |                                   |
|                                                              |           | 6755784                      | Oct 23, 2020    | U-1361                        |                        |                                   |
|                                                              |           | 6908432                      | Aug 28, 2018    | U-1361                        |                        |                                   |
|                                                              |           | 8158653                      | Aug 10, 2016    | DP                            |                        |                                   |
|                                                              |           | 8198262                      | Oct 19, 2024    | U-1360                        |                        |                                   |
|                                                              |           | 8204763                      | Aug 28, 2018    | U-1361                        |                        |                                   |
|                                                              |           | 8315886                      | Oct 23, 2020    | U-1361                        |                        |                                   |
| <u>POMALIDOMIDE - POMALYST</u>                               |           |                              |                 |                               |                        |                                   |
| N204026                                                      | 003       | 5635517                      | Jul 24, 2016    | U-1359                        | NCE                    | Feb 08, 2018                      |
|                                                              |           | 6045501                      | Aug 28, 2018    | U-1361                        | ODE                    | Feb 08, 2020                      |
|                                                              |           | 6315720                      | Oct 23, 2020    | U-1361                        |                        |                                   |
|                                                              |           | 6316471                      | Aug 10, 2016    | DP U-1360                     |                        |                                   |
|                                                              |           | 6476052                      | Jul 24, 2016    | DP U-1360                     |                        |                                   |
|                                                              |           | 6561976                      | Aug 28, 2018    | U-1361                        |                        |                                   |
|                                                              |           | 6561977                      | Oct 23, 2020    | U-1361                        |                        |                                   |
|                                                              |           | 6755784                      | Oct 23, 2020    | U-1361                        |                        |                                   |
|                                                              |           | 6908432                      | Aug 28, 2018    | U-1361                        |                        |                                   |
|                                                              |           | 8158653                      | Aug 10, 2016    | DP                            |                        |                                   |
|                                                              |           | 8198262                      | Oct 19, 2024    | U-1360                        |                        |                                   |
|                                                              |           | 8204763                      | Aug 28, 2018    | U-1361                        |                        |                                   |
|                                                              |           | 8315886                      | Oct 23, 2020    | U-1361                        |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                              | PATENT NO       | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|----------------------------------------------|-----------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>POMALIDOMIDE - POMALYST</u>               |                 |                              |                 |                               |                        |                                   |
| N204026 004                                  | 5635517         | Jul 24, 2016                 | U-1359          |                               | NCE                    | Feb 08, 2018                      |
|                                              | 6045501         | Aug 28, 2018                 | U-1361          |                               | ODE                    | Feb 08, 2020                      |
|                                              | 6315720         | Oct 23, 2020                 | U-1361          |                               |                        |                                   |
|                                              | 6316471         | Aug 10, 2016                 | DP U-1360       |                               |                        |                                   |
|                                              | 6476052         | Jul 24, 2016                 | DP U-1360       |                               |                        |                                   |
|                                              | 6561976         | Aug 28, 2018                 | U-1361          |                               |                        |                                   |
|                                              | 6561977         | Oct 23, 2020                 | U-1361          |                               |                        |                                   |
|                                              | 6755784         | Oct 23, 2020                 | U-1361          |                               |                        |                                   |
|                                              | 6908432         | Aug 28, 2018                 | U-1361          |                               |                        |                                   |
|                                              | 8158653         | Aug 10, 2016                 | DP              |                               |                        |                                   |
|                                              | 8198262         | Oct 19, 2024                 | U-1360          |                               |                        |                                   |
|                                              | 8204763         | Aug 28, 2018                 | U-1361          |                               |                        |                                   |
|                                              | 8315886         | Oct 23, 2020                 | U-1361          |                               |                        |                                   |
| <u>PONATINIB HYDROCHLORIDE - ICLUSIG</u>     |                 |                              |                 |                               |                        |                                   |
| N203469 001                                  |                 |                              |                 |                               | ODE                    | Dec 14, 2019                      |
| <u>PONATINIB HYDROCHLORIDE - ICLUSIG</u>     |                 |                              |                 |                               |                        |                                   |
| N203469 002                                  |                 |                              |                 |                               | ODE                    | Dec 14, 2019                      |
| <u>PRALATREXATE - FOLOTYN</u>                |                 |                              |                 |                               |                        |                                   |
| N022468 001                                  | 6028071         | Jul 16, 2022                 | DS DP U-1004    |                               |                        |                                   |
| <u>PRALATREXATE - FOLOTYN</u>                |                 |                              |                 |                               |                        |                                   |
| N022468 002                                  | 6028071         | Jul 16, 2022                 | DS DP U-1004    |                               |                        |                                   |
| <u>PRASUGREL HYDROCHLORIDE - EFFIENT</u>     |                 |                              |                 |                               |                        |                                   |
| N022307 001                                  | >A> 8404703     | Mar 02, 2022                 | U-1381          |                               |                        |                                   |
| <u>PRASUGREL HYDROCHLORIDE - EFFIENT</u>     |                 |                              |                 |                               |                        |                                   |
| N022307 002                                  | >A> 8404703     | Mar 02, 2022                 | U-1381          |                               |                        |                                   |
| <u>PREDNISONE - RAYOS</u>                    |                 |                              |                 |                               |                        |                                   |
| N202020 001                                  | 8394407         | Apr 23, 2024                 | DP U-1362       |                               | >A> M-128              | Jul 26, 2015                      |
| <u>PREDNISONE - RAYOS</u>                    |                 |                              |                 |                               |                        |                                   |
| N202020 002                                  | 8394407         | Apr 23, 2024                 | DP U-1362       |                               | >A> M-128              | Jul 26, 2015                      |
| <u>PREDNISONE - RAYOS</u>                    |                 |                              |                 |                               |                        |                                   |
| N202020 003                                  | 8394407         | Apr 23, 2024                 | DP U-1362       |                               | >A> M-128              | Jul 26, 2015                      |
| <u>PREGABALIN - LYRICA</u>                   |                 |                              |                 |                               |                        |                                   |
| N022488 001                                  |                 |                              |                 |                               | I-651                  | Jun 20, 2015                      |
| <u>RABEPRAZOLE SODIUM - ACIPHEX SPRINKLE</u> |                 |                              |                 |                               |                        |                                   |
| N204736 001                                  | >A> 5045552     | May 08, 2013                 | DS DP U-385     |                               | NDF                    | Mar 26, 2016                      |
|                                              | >A> 5045552*PED | Nov 08, 2013                 |                 |                               | PED                    | Sep 26, 2016                      |
| <u>RABEPRAZOLE SODIUM - ACIPHEX SPRINKLE</u> |                 |                              |                 |                               |                        |                                   |
| N204736 002                                  | >A> 5045552     | May 08, 2013                 | DS DP U-385     |                               | NDF                    | Mar 26, 2016                      |
|                                              | >A> 5045552*PED | Nov 08, 2013                 |                 |                               | PED                    | Sep 26, 2016                      |
| <u>REGORAFENIB - STIVARGA</u>                |                 |                              |                 |                               |                        |                                   |
| N203085 001                                  |                 |                              |                 |                               | I-667<br>ODE           | Feb 25, 2016<br>Feb 25, 2020      |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                    | PATENT NO       | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|----------------------------------------------------|-----------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>RITONAVIR - NORVIR</u>                          |                 |                              |                 |                               |                        |                                   |
| N022417 001                                        | >A> 8399015     | Aug 25, 2024                 | DP              |                               |                        |                                   |
|                                                    | >A> 8399015*PED | Feb 25, 2025                 |                 |                               |                        |                                   |
| <u>RIZATRIPTAN BENZOATE - RIZATRIPTAN BENZOATE</u> |                 |                              |                 |                               |                        |                                   |
| A078173 001                                        |                 |                              |                 |                               | PC                     | Jun 29, 2013                      |
| <u>RIZATRIPTAN BENZOATE - RIZATRIPTAN BENZOATE</u> |                 |                              |                 |                               |                        |                                   |
| A078173 002                                        |                 |                              |                 |                               | PC                     | Jun 29, 2013                      |
| <u>ROPIVACAINE HYDROCHLORIDE - NAROPIN</u>         |                 |                              |                 |                               |                        |                                   |
| N020533 001                                        | 5670524         | Sep 23, 2014                 | DS DP U-833     |                               |                        |                                   |
| <u>ROPIVACAINE HYDROCHLORIDE - NAROPIN</u>         |                 |                              |                 |                               |                        |                                   |
| N020533 003                                        | 5670524         | Sep 23, 2014                 | DS DP U-833     |                               |                        |                                   |
| <u>ROPIVACAINE HYDROCHLORIDE - NAROPIN</u>         |                 |                              |                 |                               |                        |                                   |
| N020533 004                                        | 5670524         | Sep 23, 2014                 | DS DP U-833     |                               |                        |                                   |
| <u>ROPIVACAINE HYDROCHLORIDE - NAROPIN</u>         |                 |                              |                 |                               |                        |                                   |
| N020533 005                                        | 5670524         | Sep 23, 2014                 | DS DP U-833     |                               |                        |                                   |
| <u>RUXOLITINIB PHOSPHATE - JAKAFI</u>              |                 |                              |                 |                               |                        |                                   |
| N202192 001                                        | >A> 8415362     | Dec 24, 2027                 | DS DP           |                               |                        |                                   |
| <u>RUXOLITINIB PHOSPHATE - JAKAFI</u>              |                 |                              |                 |                               |                        |                                   |
| N202192 002                                        | >A> 8415362     | Dec 24, 2027                 | DS DP           |                               |                        |                                   |
| <u>RUXOLITINIB PHOSPHATE - JAKAFI</u>              |                 |                              |                 |                               |                        |                                   |
| N202192 003                                        | >A> 8415362     | Dec 24, 2027                 | DS DP           |                               |                        |                                   |
| <u>RUXOLITINIB PHOSPHATE - JAKAFI</u>              |                 |                              |                 |                               |                        |                                   |
| N202192 004                                        | >A> 8415362     | Dec 24, 2027                 | DS DP           |                               |                        |                                   |
| <u>RUXOLITINIB PHOSPHATE - JAKAFI</u>              |                 |                              |                 |                               |                        |                                   |
| N202192 005                                        | >A> 8415362     | Dec 24, 2027                 | DS DP           |                               |                        |                                   |
| <u>SAPROPTERIN DIHYDROCHLORIDE - KUVAN</u>         |                 |                              |                 |                               |                        |                                   |
| N022181 001                                        | 8318745         | Nov 17, 2024                 | DP              |                               |                        |                                   |
| <u>SAQUINAVIR MESYLATE - INVIRASE</u>              |                 |                              |                 |                               |                        |                                   |
| N020628 001                                        |                 |                              |                 |                               | M-61<br>PED            | Nov 30, 2015<br>May 30, 2016      |
| <u>SAQUINAVIR MESYLATE - INVIRASE</u>              |                 |                              |                 |                               |                        |                                   |
| N021785 001                                        |                 |                              |                 |                               | M-61<br>PED            | Nov 30, 2015<br>May 30, 2016      |
| <u>SUMATRIPTAN SUCCINATE - SUMAVEL DOSEPRO</u>     |                 |                              |                 |                               |                        |                                   |
| N022239 001                                        | 8343130         | Oct 18, 2022                 | DP              |                               |                        |                                   |
| <u>SUMATRIPTAN SUCCINATE - ZECUITY</u>             |                 |                              |                 |                               |                        |                                   |
| N202278 001                                        | 6745071         | Feb 21, 2023                 | DP              |                               | NDF                    | Jan 17, 2016                      |
|                                                    | 7973058         | Apr 12, 2027                 | U-1328          |                               |                        |                                   |
|                                                    | 8155737         | Apr 12, 2027                 | U-1328          |                               |                        |                                   |
|                                                    | 8366600         | Apr 21, 2029                 | U-1327          |                               |                        |                                   |
| <u>TAPENTADOL HYDROCHLORIDE - NUCYN TA ER</u>      |                 |                              |                 |                               |                        |                                   |
| N200533 001                                        | 8114383         | Oct 10, 2024                 | DP              |                               | Y                      |                                   |
|                                                    | >A> 8420056     | Nov 20, 2023                 | DP              |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                                       | PATENT NO   | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|-------------------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>TAPENTADOL HYDROCHLORIDE - NUCYNТА ER</u>          |             |                              |                 |                               |                        |                                   |
| N200533 002                                           | 8114383     | Oct 10, 2024                 | DP              | Y                             |                        |                                   |
|                                                       | >A> 8420056 | Nov 20, 2023                 | DP              |                               |                        |                                   |
| <u>TAPENTADOL HYDROCHLORIDE - NUCYNТА ER</u>          |             |                              |                 |                               |                        |                                   |
| N200533 003                                           | 8114383     | Oct 10, 2024                 | DP              | Y                             |                        |                                   |
|                                                       | >A> 8420056 | Nov 20, 2023                 | DP              |                               |                        |                                   |
| <u>TAPENTADOL HYDROCHLORIDE - NUCYNТА ER</u>          |             |                              |                 |                               |                        |                                   |
| N200533 004                                           | 8114383     | Oct 10, 2024                 | DP              | Y                             |                        |                                   |
|                                                       | >A> 8420056 | Nov 20, 2023                 | DP              |                               |                        |                                   |
| <u>TAPENTADOL HYDROCHLORIDE - NUCYNТА ER</u>          |             |                              |                 |                               |                        |                                   |
| N200533 005                                           | 8114383     | Oct 10, 2024                 | DP              | Y                             |                        |                                   |
|                                                       | >A> 8420056 | Nov 20, 2023                 | DP              |                               |                        |                                   |
| <u>TECHNETIUM TC-99M TILMANOCEPT - LYMPHOSEEK KIT</u> |             |                              |                 |                               |                        |                                   |
| N202207 001                                           |             |                              |                 |                               | NCE                    | Mar 13, 2018                      |
| <u>TEDUGLUTIDE - GATTEX KIT</u>                       |             |                              |                 |                               |                        |                                   |
| N203441 001                                           | 5789379     | Apr 14, 2015                 | DS DP U-1320    |                               | ODE                    | Dec 21, 2019                      |
|                                                       | 7056886     | Sep 18, 2022                 | DP U-1320       |                               |                        |                                   |
|                                                       | 7847061     | Nov 01, 2025                 | U-1320          |                               |                        |                                   |
| <u>TELAVANCIN HYDROCHLORIDE - VIBATIV</u>             |             |                              |                 |                               |                        |                                   |
| N022110 001                                           | >A> 6635618 | Sep 11, 2023                 | DS DP U-728     |                               |                        |                                   |
| <u>TELAVANCIN HYDROCHLORIDE - VIBATIV</u>             |             |                              |                 |                               |                        |                                   |
| N022110 002                                           | >A> 6635618 | Sep 11, 2023                 | DS DP U-728     |                               |                        |                                   |
| <u>TELIVUDINE - TYZEKA</u>                            |             |                              |                 |                               |                        |                                   |
| N022011 001                                           |             |                              |                 |                               | M-124                  | Jan 28, 2016                      |
| <u>TELIVUDINE - TYZEKA</u>                            |             |                              |                 |                               |                        |                                   |
| N022154 001                                           |             |                              |                 |                               | M-124                  | Jan 28, 2016                      |
| <u>TESTOSTERONE - AXIRON</u>                          |             |                              |                 |                               |                        |                                   |
| N022504 001                                           | >A> 8419307 | Feb 26, 2027                 | U-1386          |                               |                        |                                   |
|                                                       | >A> 8435944 | Jul 05, 2027                 | U-1390          |                               |                        |                                   |
| <u>TESTOSTERONE - TESTOSTERONE</u>                    |             |                              |                 |                               |                        |                                   |
| N203098 001                                           |             |                              |                 |                               | NP                     | Jan 31, 2016                      |
| <u>TESTOSTERONE - TESTOSTERONE</u>                    |             |                              |                 |                               |                        |                                   |
| N203098 002                                           |             |                              |                 |                               | NP                     | Jan 31, 2016                      |
| <u>TESTOSTERONE - TESTOSTERONE</u>                    |             |                              |                 |                               |                        |                                   |
| N203098 003                                           |             |                              |                 |                               | NP                     | Jan 31, 2016                      |
| <u>TIGECYCLINE - TYGACIL</u>                          |             |                              |                 |                               |                        |                                   |
| N021821 001                                           | 8372995     | Oct 08, 2030                 | DP              |                               |                        |                                   |
| <u>TOBRAMYCIN - BETHKIS</u>                           |             |                              |                 |                               |                        |                                   |
| N201820 001                                           | 6987094     | Sep 22, 2022                 | DP              |                               |                        |                                   |
|                                                       | 7696178     | Mar 17, 2023                 | DP              |                               |                        |                                   |
|                                                       | 7939502     | Jun 14, 2022                 | U-1324          |                               |                        |                                   |

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2013

See List footnote for information regarding List content

| APPL/PROD<br>NO                              | PATENT NO       | PATENT<br>EXPIRATION<br>DATE | PATENT<br>CODES | PATENT<br>DELIST<br>REQUESTED | EXCLUSIVITY<br>CODE(S) | EXCLUSIVITY<br>EXPIRATION<br>DATE |
|----------------------------------------------|-----------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>TOBRAMYCIN - TOBI PODHALER</u>            |                 |                              |                 |                               |                        |                                   |
| N201688 001                                  | >A> 7097827     | Jun 27, 2021                 | DP              |                               | NP                     | Mar 22, 2016                      |
|                                              | >A> 7368102     | Dec 19, 2022                 | DP U-909        |                               |                        |                                   |
|                                              | >A> 7442388     | May 10, 2020                 | DP              |                               |                        |                                   |
|                                              | >A> 7516741     | Jan 11, 2024                 | DP              |                               |                        |                                   |
|                                              | >A> 7559325     | Oct 27, 2025                 | DP              |                               |                        |                                   |
|                                              | >A> 8069851     | Sep 24, 2024                 | DP              |                               |                        |                                   |
|                                              | >A> 8349294     | May 10, 2020                 | DP              |                               |                        |                                   |
| <u>TOLTERODINE TARTRATE - DETROL LA</u>      |                 |                              |                 |                               |                        |                                   |
| N021228 001                                  | >A> 6911217     | Nov 11, 2019                 | DP U-544        |                               |                        |                                   |
|                                              | >A> 6911217*PED | May 11, 2020                 | DP U-544        |                               |                        |                                   |
| <u>TRANEXAMIC ACID - TRANEXAMIC ACID</u>     |                 |                              |                 |                               |                        |                                   |
| A202093 001                                  |                 |                              |                 |                               | PC                     | Jul 02, 2013                      |
| <u>TRAVOPROST - TRAVATAN Z</u>               |                 |                              |                 |                               |                        |                                   |
| N021994 001                                  | 8388941         | Sep 20, 2027                 | DP              |                               |                        |                                   |
| <u>TROSPIUM CHLORIDE - TROSPIUM CHLORIDE</u> |                 |                              |                 |                               |                        |                                   |
| A091289 001                                  |                 |                              |                 |                               | PC                     | Apr 10, 2013                      |
| <u>ULIPRISTAL ACETATE - ELLA</u>             |                 |                              |                 |                               |                        |                                   |
| N022474 001                                  | >A> 8426392     | Jun 12, 2030                 | U-1389          |                               |                        |                                   |
| <u>UNOPROSTONE ISOPROPYL - RESCULA</u>       |                 |                              |                 |                               |                        |                                   |
| N021214 001                                  | 6770675         | Nov 24, 2018                 | DP U-1322       |                               |                        |                                   |
| <u>ZOLEDRONIC ACID - RECLAST</u>             |                 |                              |                 |                               |                        |                                   |
| N021817 001                                  | 8052987         | Oct 27, 2023                 | U-1199          |                               |                        |                                   |

## 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, 33<sup>rd</sup> 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 patent terms is available at  
<http://www.accessdata.fda.gov/scripts/cder/ob/docs/excltermsall.cfm>