

# **APPROVED DRUG PRODUCTS**

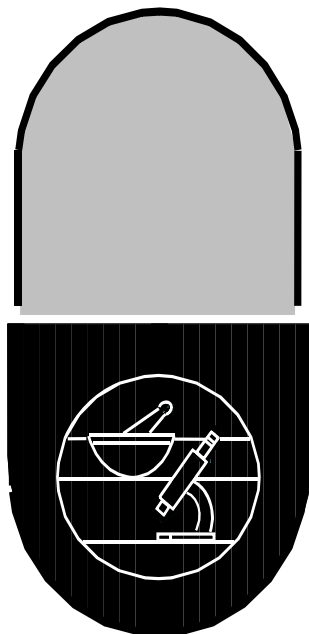
## **With Therapeutic Equivalence Evaluations**



**The "Orange Book"**

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**CUMULATIVE  
SUPPLEMENT 4**  
April 2011



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**31<sup>st</sup> EDITION**

**Department of Health and Human Services**

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

2011

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

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with  
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**31<sup>st</sup> EDITION**

**Cumulative Supplement 4**

**April 2011**

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**31<sup>st</sup> EDITION**

**CUMULATIVE SUPPLEMENT 4  
April 2011**

**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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 30th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 31st 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 (20,000 and 50,000 series) 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)

### 1.4 LEVOTHYROXINE SODIUM

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

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

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

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

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

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

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

| Trade Name           | Applicant   | Potency | TE Code | Appl No | Product No |
|----------------------|-------------|---------|---------|---------|------------|
| UNITHROID            | STEVENS J   | 0.025MG | AB1     | 21210   | 001        |
| LEVOTHYROXINE SODIUM | MYLAN       | 0.025MG | AB1     | 76187   | 001        |
| LEVOXYL              | KING PHARMS | 0.025MG | AB1     | 21301   | 001        |
| SYNTHROID            | ABBOTT      | 0.025MG | AB1     | 21402   | 001        |
| LEVO-T               | ALARA PHARM | 0.025MG | AB1     | 21342   | 001        |
| SYNTHROID            | ABBOTT      | 0.025MG | AB2     | 21402   | 001        |
| LEVOTHYROXINE SODIUM | MYLAN       | 0.025MG | AB2     | 76187   | 001        |
| LEVO-T               | ALARA PHARM | 0.025MG | AB2     | 21342   | 001        |
| UNITHROID            | STEVENS J   | 0.025MG | AB2     | 21210   | 001        |
| 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 2008) 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 2010</u> | <u>MAR 2011</u> | <u>JUN 2011</u> | <u>SEPT 2011</u> | <u>DEC 2011</u> |
|--------------------------------|-----------------|-----------------|-----------------|------------------|-----------------|
| DRUG PRODUCTS LISTED           | 13838           | 14029           |                 |                  |                 |
| SINGLE SOURCE                  | 2482            | 2477            |                 |                  |                 |
|                                | (17.9%)         | (17.7%)         |                 |                  |                 |
| MULTISOURCE                    | 11267           | 11463           |                 |                  |                 |
|                                | (81.4%)         | (81.7%)         |                 |                  |                 |
| THERAPEUTICALLY EQUIVALENT     | 11107           | 11301           |                 |                  |                 |
|                                | (80.3%)         | (80.6%)         |                 |                  |                 |
| NOT THERAPEUTICALLY EQUIVALENT | 160             | 162             |                 |                  |                 |
|                                | (1.2%)          | (1.2%)          |                 |                  |                 |
| EXCEPTIONS <sup>1</sup>        | 89              | 89              |                 |                  |                 |
|                                | (0.6%)          | (0.6%)          |                 |                  |                 |
| NEW MOLECULAR ENTITIES         |                 |                 |                 |                  |                 |
| APPROVED                       | 8               | 6               |                 |                  |                 |
| NUMBER OF APPLICANTS           | 752             | 768             |                 |                  |                 |

<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 - 31ST EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2011

1-1

>A> ABIRATERONE ACETATE

>A> TABLET; ORAL

>A> ZYTIGA

>A> + CENTOCOR ORTHO 250MG N202379 001 Apr 28, 2011 Apr NEWA

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

AA MIRROR PHARMS 325MG;50MG;40MG A040864 001 Dec 01, 2008 Mar CAHN

AA 500MG;50MG;40MG A040883 001 Dec 23, 2008 Mar CAHN

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

AA WRASER PHARMS LLC 356.4MG;30MG;16MG A040688 001 Apr 03, 2007 Jan CAHN

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA BOCA PHARMA 300MG;5MG A090415 001 Jan 24, 2011 Feb CTEC

AB 300MG;5MG A090415 001 Jan 24, 2011 Jan NEWA

AA 300MG;7.5MG A090415 002 Jan 24, 2011 Feb CTEC

AB 300MG;7.5MG A090415 002 Jan 24, 2011 Jan NEWA

AA 300MG;10MG A090415 003 Jan 24, 2011 Feb CTEC

AB 300MG;10MG A090415 003 Jan 24, 2011 Jan NEWA

AA + MIKART 300MG;5MG A040658 001 Jan 19, 2006 Mar CRLD

AA 300MG;5MG A040658 001 Jan 19, 2006 Feb CTEC

AA + 300MG;7.5MG A040556 002 Mar 24, 2006 Feb CTEC

AA + 300MG;10MG A040556 001 Jun 23, 2004 Feb CTEC

LORTAB

AA UCB INC 500MG;5MG A087722 001 Jul 09, 1982 Jan CAHN

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL

PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN

@ VINTAGE PHARMS 650MG;65MG A040507 001 Jul 30, 2003 Mar DISC

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

DARVOCET-N 100

@ XANODYNE PHARM 650MG;100MG N017122 002 Jan DISC

DARVOCET-N 50

@ XANODYNE PHARM 325MG;50MG N017122 001 Jan DISC

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

@ CORNERSTONE 325MG;100MG A076743 001 May 07, 2004 Mar DISC

@ 500MG;100MG A076750 001 Jun 28, 2004 Mar DISC

>D> AB MIRROR PHARMS 650MG;100MG A077821 001 Feb 11, 2008 Apr DISC

>A> @ 650MG;100MG A077821 001 Feb 11, 2008 Apr DISC

AB 650MG;100MG A077821 001 Feb 11, 2008 Mar CAHN

@ TEVA 650MG;100MG A074119 001 Dec 19, 1994 Mar DISC

@ VINTAGE PHARMS 325MG;50MG A074843 002 Feb 15, 2001 Mar DISC

@ 650MG;100MG A074843 001 Feb 12, 1997 Mar DISC

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

|    |       |       |             |              |     |      |
|----|-------|-------|-------------|--------------|-----|------|
| AB | MYLAN | 200MG | A074977 001 | Apr 13, 1998 | Feb | CAHN |
|----|-------|-------|-------------|--------------|-----|------|

TABLET; ORAL

ACYCLOVIR

|    |       |       |             |              |     |      |
|----|-------|-------|-------------|--------------|-----|------|
| AB | MYLAN | 400MG | A074976 001 | Apr 13, 1998 | Feb | CAHN |
|----|-------|-------|-------------|--------------|-----|------|

|    |  |       |             |              |     |      |
|----|--|-------|-------------|--------------|-----|------|
| AB |  | 800MG | A074976 002 | Apr 13, 1998 | Feb | CAHN |
|----|--|-------|-------------|--------------|-----|------|

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR SODIUM

@ HOSPIRA

EQ 50MG BASE/ML

|             |              |     |      |
|-------------|--------------|-----|------|
| A075065 001 | Feb 25, 1999 | Feb | DISC |
|-------------|--------------|-----|------|

ALCLOMETASONE DIPROPIONATE

OINTMENT; TOPICAL

ACLOVATE

|    |              |       |             |              |     |      |
|----|--------------|-------|-------------|--------------|-----|------|
| AB | + NYCOMED US | 0.05% | N018702 001 | Dec 14, 1982 | Mar | CAHN |
|----|--------------|-------|-------------|--------------|-----|------|

ALENDRONATE SODIUM

TABLET; ORAL

ALENDRONATE SODIUM

|    |       |              |             |              |     |      |
|----|-------|--------------|-------------|--------------|-----|------|
| AB | MYLAN | EQ 35MG BASE | A078638 001 | Aug 04, 2008 | Feb | CAHN |
|----|-------|--------------|-------------|--------------|-----|------|

|    |  |              |             |              |     |      |
|----|--|--------------|-------------|--------------|-----|------|
| AB |  | EQ 70MG BASE | A078638 002 | Aug 04, 2008 | Feb | CAHN |
|----|--|--------------|-------------|--------------|-----|------|

|          |             |             |              |     |      |
|----------|-------------|-------------|--------------|-----|------|
| @ SANDOZ | EQ 5MG BASE | A075871 001 | Apr 22, 2009 | Mar | DISC |
|----------|-------------|-------------|--------------|-----|------|

|   |              |             |              |     |      |
|---|--------------|-------------|--------------|-----|------|
| @ | EQ 10MG BASE | A075871 002 | Apr 22, 2009 | Mar | DISC |
|---|--------------|-------------|--------------|-----|------|

|   |              |             |              |     |      |
|---|--------------|-------------|--------------|-----|------|
| @ | EQ 35MG BASE | A075871 004 | Apr 22, 2009 | Mar | DISC |
|---|--------------|-------------|--------------|-----|------|

|   |              |             |              |     |      |
|---|--------------|-------------|--------------|-----|------|
| @ | EQ 40MG BASE | A075871 003 | Apr 22, 2009 | Mar | DISC |
|---|--------------|-------------|--------------|-----|------|

|   |              |             |              |     |      |
|---|--------------|-------------|--------------|-----|------|
| @ | EQ 70MG BASE | A075871 005 | Apr 22, 2009 | Mar | DISC |
|---|--------------|-------------|--------------|-----|------|

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL

|    |               |       |             |              |     |      |
|----|---------------|-------|-------------|--------------|-----|------|
| AB | IPCA LABS LTD | 100MG | A090637 001 | Mar 16, 2011 | Feb | NEWA |
|----|---------------|-------|-------------|--------------|-----|------|

|    |  |       |             |              |     |      |
|----|--|-------|-------------|--------------|-----|------|
| AB |  | 300MG | A090637 002 | Mar 16, 2011 | Feb | NEWA |
|----|--|-------|-------------|--------------|-----|------|

AMLODIPINE BESYLATE

TABLET; ORAL

AMLODIPINE BESYLATE

|     |    |                 |               |             |              |     |      |
|-----|----|-----------------|---------------|-------------|--------------|-----|------|
| >A> | AB | EPIC PHARMA LLC | EQ 2.5MG BASE | A078552 001 | Apr 08, 2009 | Apr | CAHN |
|-----|----|-----------------|---------------|-------------|--------------|-----|------|

|     |    |  |             |             |              |     |      |
|-----|----|--|-------------|-------------|--------------|-----|------|
| >A> | AB |  | EQ 5MG BASE | A078552 002 | Apr 08, 2009 | Apr | CAHN |
|-----|----|--|-------------|-------------|--------------|-----|------|

|     |    |  |              |             |              |     |      |
|-----|----|--|--------------|-------------|--------------|-----|------|
| >A> | AB |  | EQ 10MG BASE | A078552 003 | Apr 08, 2009 | Apr | CAHN |
|-----|----|--|--------------|-------------|--------------|-----|------|

|     |    |                   |               |             |              |     |      |
|-----|----|-------------------|---------------|-------------|--------------|-----|------|
| >D> | AB | GLENMARK GENERICS | EQ 2.5MG BASE | A078552 001 | Apr 08, 2009 | Apr | CAHN |
|-----|----|-------------------|---------------|-------------|--------------|-----|------|

|     |    |  |             |             |              |     |      |
|-----|----|--|-------------|-------------|--------------|-----|------|
| >D> | AB |  | EQ 5MG BASE | A078552 002 | Apr 08, 2009 | Apr | CAHN |
|-----|----|--|-------------|-------------|--------------|-----|------|

|     |    |  |              |             |              |     |      |
|-----|----|--|--------------|-------------|--------------|-----|------|
| >D> | AB |  | EQ 10MG BASE | A078552 003 | Apr 08, 2009 | Apr | CAHN |
|-----|----|--|--------------|-------------|--------------|-----|------|

|    |              |               |             |              |     |      |
|----|--------------|---------------|-------------|--------------|-----|------|
| AB | HIKMA PHARMS | EQ 2.5MG BASE | A077771 001 | Apr 12, 2011 | Mar | NEWA |
|----|--------------|---------------|-------------|--------------|-----|------|

|    |  |             |             |              |     |      |
|----|--|-------------|-------------|--------------|-----|------|
| AB |  | EQ 5MG BASE | A077771 002 | Apr 12, 2011 | Mar | NEWA |
|----|--|-------------|-------------|--------------|-----|------|

|    |  |              |             |              |     |      |
|----|--|--------------|-------------|--------------|-----|------|
| AB |  | EQ 10MG BASE | A077771 003 | Apr 12, 2011 | Mar | NEWA |
|----|--|--------------|-------------|--------------|-----|------|

|     |    |              |             |             |              |     |      |
|-----|----|--------------|-------------|-------------|--------------|-----|------|
| >A> | AB | SECAN PHARMS | EQ 5MG BASE | A090752 001 | Apr 15, 2011 | Apr | NEWA |
|-----|----|--------------|-------------|-------------|--------------|-----|------|

|     |    |  |              |             |              |     |      |
|-----|----|--|--------------|-------------|--------------|-----|------|
| >A> | AB |  | EQ 10MG BASE | A090752 002 | Apr 15, 2011 | Apr | NEWA |
|-----|----|--|--------------|-------------|--------------|-----|------|

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

CAPSULE; ORAL

LOTREL

|    |          |                  |             |              |     |      |
|----|----------|------------------|-------------|--------------|-----|------|
| AB | NOVARTIS | EQ 5MG BASE;40MG | N020364 007 | Apr 11, 2006 | Jan | CFTG |
|----|----------|------------------|-------------|--------------|-----|------|

## CAPSULE; ORAL

## LOTREL

|    |   |          |                   |             |              |     |      |
|----|---|----------|-------------------|-------------|--------------|-----|------|
| AB | + | NOVARTIS | EQ 10MG BASE;40MG | N020364 006 | Apr 11, 2006 | Jan | CFTG |
|----|---|----------|-------------------|-------------|--------------|-----|------|

AMOXICILLIN

## CAPSULE; ORAL

## AMOXICILLIN

|    |  |                |       |             |  |     |      |
|----|--|----------------|-------|-------------|--|-----|------|
| AB |  | AM ANTIBIOTICS | 250MG | A062058 001 |  | Feb | CDFR |
|----|--|----------------|-------|-------------|--|-----|------|

|    |  |  |       |             |  |     |      |
|----|--|--|-------|-------------|--|-----|------|
| AB |  |  | 500MG | A062058 002 |  | Feb | CDFR |
|----|--|--|-------|-------------|--|-----|------|

AMOXICILLIN; CLARITHROMYCIN; OMEPRAZOLE

## CAPSULE, TABLET, CAPSULE, DELAYED RELEASE; ORAL

## OMEPRAZOLE AND CLARITHROMYCIN AND AMOXICILLIN

|   |  |                 |                                                  |             |              |     |      |
|---|--|-----------------|--------------------------------------------------|-------------|--------------|-----|------|
| + |  | DAVA PHARMS INC | 500MG, N/A, N/A; N/A, 500MG, N/A; N/A, N/A, 20MG | N050824 001 | Feb 08, 2011 | Feb | NEWA |
|---|--|-----------------|--------------------------------------------------|-------------|--------------|-----|------|

>A> AMPICILLIN SODIUM; SULBACTAM SODIUM

## &gt;A&gt; INJECTABLE; INJECTION

## &gt;A&gt; AMPICILLIN AND SULBACTAM

|     |    |                  |                                     |             |              |     |      |
|-----|----|------------------|-------------------------------------|-------------|--------------|-----|------|
| >A> | AP | AUROBINDO PHARMA | EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL | A090349 001 | Sep 20, 2010 | Apr | CAIN |
|-----|----|------------------|-------------------------------------|-------------|--------------|-----|------|

|     |    |  |                                     |             |              |     |      |
|-----|----|--|-------------------------------------|-------------|--------------|-----|------|
| >A> | AP |  | EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL | A090340 001 | Sep 20, 2010 | Apr | CAIN |
|-----|----|--|-------------------------------------|-------------|--------------|-----|------|

|     |    |  |                                   |             |              |     |      |
|-----|----|--|-----------------------------------|-------------|--------------|-----|------|
| >A> | AP |  | EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL | A090340 002 | Sep 20, 2010 | Apr | CAIN |
|-----|----|--|-----------------------------------|-------------|--------------|-----|------|

|     |    |  |                                   |             |              |     |      |
|-----|----|--|-----------------------------------|-------------|--------------|-----|------|
| >A> | AP |  | EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL | A090349 002 | Sep 20, 2010 | Apr | CAIN |
|-----|----|--|-----------------------------------|-------------|--------------|-----|------|

|     |    |  |                                    |             |              |     |      |
|-----|----|--|------------------------------------|-------------|--------------|-----|------|
| >A> | AP |  | EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL | A090339 001 | Sep 20, 2010 | Apr | CAIN |
|-----|----|--|------------------------------------|-------------|--------------|-----|------|

>D> AMPICILLIN; SULBACTAM

## &gt;D&gt; INJECTABLE; INJECTION

## &gt;D&gt; AMPICILLIN AND SULBACTAM

|     |    |                  |                                     |             |              |     |      |
|-----|----|------------------|-------------------------------------|-------------|--------------|-----|------|
| >D> | AP | AUROBINDO PHARMA | EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL | A090349 001 | Sep 20, 2010 | Apr | CAIN |
|-----|----|------------------|-------------------------------------|-------------|--------------|-----|------|

|     |    |  |                                     |             |              |     |      |
|-----|----|--|-------------------------------------|-------------|--------------|-----|------|
| >D> | AP |  | EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL | A090340 001 | Sep 20, 2010 | Apr | CAIN |
|-----|----|--|-------------------------------------|-------------|--------------|-----|------|

|     |    |  |                                   |             |              |     |      |
|-----|----|--|-----------------------------------|-------------|--------------|-----|------|
| >D> | AP |  | EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL | A090340 002 | Sep 20, 2010 | Apr | CAIN |
|-----|----|--|-----------------------------------|-------------|--------------|-----|------|

|     |    |  |                                   |             |              |     |      |
|-----|----|--|-----------------------------------|-------------|--------------|-----|------|
| >D> | AP |  | EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL | A090349 002 | Sep 20, 2010 | Apr | CAIN |
|-----|----|--|-----------------------------------|-------------|--------------|-----|------|

|     |    |  |                                    |             |              |     |      |
|-----|----|--|------------------------------------|-------------|--------------|-----|------|
| >D> | AP |  | EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL | A090339 001 | Sep 20, 2010 | Apr | CAIN |
|-----|----|--|------------------------------------|-------------|--------------|-----|------|

ANASTROZOLE

## TABLET; ORAL

## ANASTROZOLE

|    |  |                |     |             |              |     |      |
|----|--|----------------|-----|-------------|--------------|-----|------|
| AB |  | SANTOS BIOTECH | 1MG | A078944 001 | Jun 28, 2010 | Feb | CAHN |
|----|--|----------------|-----|-------------|--------------|-----|------|

ASPIRIN; CARISOPRODOL

## TABLET; ORAL

## CARISOPRODOL AND ASPIRIN

|    |  |               |             |             |              |     |      |
|----|--|---------------|-------------|-------------|--------------|-----|------|
| AB |  | MIRROR PHARMS | 325MG;200MG | A040832 001 | Jan 07, 2010 | Mar | CAHN |
|----|--|---------------|-------------|-------------|--------------|-----|------|

|    |  |             |             |             |              |     |      |
|----|--|-------------|-------------|-------------|--------------|-----|------|
| AB |  | PROSAM LABS | 325MG;200MG | A040252 001 | Dec 10, 1997 | Feb | CAHN |
|----|--|-------------|-------------|-------------|--------------|-----|------|

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE

## TABLET; ORAL

## CARISOPRODOL, ASPIRIN AND CODEINE PHOSPHATE

|    |  |               |                  |             |              |     |      |
|----|--|---------------|------------------|-------------|--------------|-----|------|
| AB |  | MIRROR PHARMS | 325MG;200MG;16MG | A040860 001 | Jan 07, 2010 | Mar | CAHN |
|----|--|---------------|------------------|-------------|--------------|-----|------|

|    |  |             |                  |             |              |     |      |
|----|--|-------------|------------------|-------------|--------------|-----|------|
| AB |  | PROSAM LABS | 325MG;200MG;16MG | A040283 001 | Dec 29, 1998 | Feb | CAHN |
|----|--|-------------|------------------|-------------|--------------|-----|------|

ASPIRIN; OXYCODONE HYDROCHLORIDE

## TABLET; ORAL

## OXYCODONE AND ASPIRIN

|          |                |                |             |              |     |      |
|----------|----------------|----------------|-------------|--------------|-----|------|
| AA       | COASTAL PHARMS | 325MG;4.8355MG | A091670 001 | Mar 16, 2011 | Feb | NEWA |
| AA       | WATSON LABS    | 325MG;4.8355MG | A090084 001 | Mar 22, 2011 | Mar | NEWA |
| PERCODAN |                |                |             |              |     |      |
| AA       | + ENDO PHARMS  | 325MG;4.8355MG | N007337 007 | Aug 05, 2005 | Feb | CFTG |

ATENOLOL

## TABLET; ORAL

## ATENOLOL

|    |       |       |             |              |     |      |
|----|-------|-------|-------------|--------------|-----|------|
| AB | MYLAN | 25MG  | A074126 003 | Aug 26, 1998 | Feb | CAHN |
| AB |       | 50MG  | A074126 001 | Mar 23, 1994 | Feb | CAHN |
| AB |       | 100MG | A074126 002 | Mar 23, 1994 | Feb | CAHN |

ATOVAQUONE; PROGUANIL HYDROCHLORIDE

## TABLET; ORAL

## ATOVAQUONE AND PROGUANIL HYDROCHLORIDE

|          |                   |             |             |              |     |      |
|----------|-------------------|-------------|-------------|--------------|-----|------|
| AB       | GLENMARK GENERICS | 250MG;100MG | A091211 001 | Jan 12, 2011 | Jan | NEWA |
| MALARONE |                   |             |             |              |     |      |
| AB       | + GLAXOSMITHKLINE | 250MG;100MG | N021078 001 | Jul 14, 2000 | Jan | CFTG |

AZILSARTAN MEDOXOMIL

## TABLET; ORAL

## EDARBI

## TAKEDA PHARMS

+

80MG

|             |              |     |      |
|-------------|--------------|-----|------|
| N200796 001 | Feb 25, 2011 | Feb | NEWA |
| N200796 002 | Feb 25, 2011 | Feb | NEWA |

AZTREONAM

## INJECTABLE; INJECTION

## AZTREONAM

|    |         |          |             |              |     |      |
|----|---------|----------|-------------|--------------|-----|------|
| AP | BEDFORD | 1GM/VIAL | A065286 001 | Mar 23, 2011 | Mar | NEWA |
| AP |         | 2GM/VIAL | A065286 002 | Mar 23, 2011 | Mar | NEWA |

BACITRACIN

## OINTMENT; OPHTHALMIC

## BACITRACIN

+ FERA PHARMS

500 UNITS/GM

A061212 001 Feb CAHN

+ NYCOMED US

500 UNITS/GM

A061212 001 Jan CAHN

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

## OINTMENT; OPHTHALMIC

## NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC

|    |             |                                                  |             |  |     |      |
|----|-------------|--------------------------------------------------|-------------|--|-----|------|
| AT | FERA PHARMS | 400 UNITS/GM;EQ 3.5MG<br>BASE/GM;10,000 UNITS/GM | A060764 002 |  | Feb | CAHN |
| AT | NYCOMED US  | 400 UNITS/GM;EQ 3.5MG<br>BASE/GM;10,000 UNITS/GM | A060764 002 |  | Jan | CAHN |

BACITRACIN ZINC; POLYMYXIN B SULFATE

## OINTMENT; OPHTHALMIC

## BACITRACIN ZINC AND POLYMYXIN B SULFATE

|    |             |                              |             |              |     |      |
|----|-------------|------------------------------|-------------|--------------|-----|------|
| AT | FERA PHARMS | 500 UNITS/GM;10,000 UNITS/GM | A065022 001 | Feb 27, 2002 | Feb | CAHN |
| AT | NYCOMED US  | 500 UNITS/GM;10,000 UNITS/GM | A065022 001 | Feb 27, 2002 | Jan | CAHN |

BACITRACIN; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

BACITRACIN-NEOMYCIN-POLYMYXIN W/ HYDROCORTISONE ACETATE

|   |             |                                                     |             |  |     |      |
|---|-------------|-----------------------------------------------------|-------------|--|-----|------|
| + | FERA PHARMS | 400 UNITS/GM;1%;EQ 3.5MG<br>BASE/GM;10,000 UNITS/GM | A062166 002 |  | Feb | CAHN |
| + | NYCOMED US  | 400 UNITS/GM;1%;EQ 3.5MG<br>BASE/GM;10,000 UNITS/GM | A062166 002 |  | Jan | CAHN |

BACLOFEN

INJECTABLE; INTRATHECAL

GABLOFEN

|    |                 |           |             |              |     |      |
|----|-----------------|-----------|-------------|--------------|-----|------|
| AP | CNS THERAPS INC | 0.05MG/ML | N022462 001 | Nov 19, 2010 | Feb | CTEC |
| AP |                 | 0.5MG/ML  | N022462 002 | Nov 19, 2010 | Feb | CTEC |
| AP |                 | 2MG/ML    | N022462 003 | Nov 19, 2010 | Feb | CTEC |

LIORESAL

|    |   |           |           |             |              |     |      |
|----|---|-----------|-----------|-------------|--------------|-----|------|
| AP | + | MEDTRONIC | 0.05MG/ML | N020075 003 | Nov 07, 1996 | Feb | CTEC |
| AP | + |           | 0.5MG/ML  | N020075 001 | Jun 17, 1992 | Feb | CTEC |
| AP | + |           | 2MG/ML    | N020075 002 | Jun 17, 1992 | Feb | CTEC |

TABLET; ORAL

BACLOFEN

|    |             |      |             |              |     |      |
|----|-------------|------|-------------|--------------|-----|------|
| AB | PROSAM LABS | 10MG | A077089 001 | Oct 31, 2007 | Feb | CAHN |
| AB |             | 20MG | A077088 001 | Oct 31, 2007 | Feb | CAHN |

BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

BENAZEPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

|    |       |             |             |              |     |      |
|----|-------|-------------|-------------|--------------|-----|------|
| AB | MYLAN | 5MG;6.25MG  | A076612 001 | Feb 11, 2004 | Feb | CAHN |
| AB |       | 10MG;12.5MG | A076612 002 | Feb 11, 2004 | Feb | CAHN |
| AB |       | 20MG;12.5MG | A076612 003 | Feb 11, 2004 | Feb | CAHN |
| AB |       | 20MG;25MG   | A076612 004 | Feb 11, 2004 | Feb | CAHN |

BENZTROPINE MESYLATE

INJECTABLE; INJECTION

BENZTROPINE MESYLATE

|    |          |        |             |              |     |      |
|----|----------|--------|-------------|--------------|-----|------|
| AP | LUITPOLD | 1MG/ML | A091152 001 | Mar 29, 2010 | Feb | CAHN |
|----|----------|--------|-------------|--------------|-----|------|

BETAMETHASONE VALERATE

LOTION; TOPICAL

BETAMETHASONE VALERATE

|     |    |                |              |             |              |     |      |
|-----|----|----------------|--------------|-------------|--------------|-----|------|
| >D> | AB | STAT TRADE     | EQ 0.1% BASE | A070052 001 | Jul 31, 1985 | Apr | CAHN |
| >A> | AB | STI PHARMA LLC | EQ 0.1% BASE | A070052 001 | Jul 31, 1985 | Apr | CAHN |

BICALUTAMIDE

TABLET; ORAL

BICALUTAMIDE

|    |        |      |             |              |     |      |
|----|--------|------|-------------|--------------|-----|------|
| AB | ROXANE | 50MG | A078285 001 | Mar 24, 2011 | Mar | NEWA |
|----|--------|------|-------------|--------------|-----|------|

BROMFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

BROMDAY

|     |   |                  |       |             |              |     |      |
|-----|---|------------------|-------|-------------|--------------|-----|------|
|     | + | ISTA PHARMS INC  | 0.09% | N021664 002 | Oct 16, 2010 | Mar | CRLD |
| >A> |   | BROMFENAC SODIUM |       |             |              |     |      |
| >A> |   | COASTAL PHARMS   | 0.09% | A201211 001 | May 11, 2011 | Apr | NEWA |
|     |   | XIBROM           |       |             |              |     |      |
|     | @ | ISTA PHARMS INC  | 0.09% | N021664 001 | Mar 24, 2005 | Mar | DISC |



CALCIPOTRIENE

SOLUTION; TOPICAL

CALCIPOTRIENE

|    |                  |        |             |              |     |      |
|----|------------------|--------|-------------|--------------|-----|------|
| AT | G AND W LABS INC | 0.005% | A078468 001 | Mar 24, 2011 | Mar | NEWA |
|----|------------------|--------|-------------|--------------|-----|------|

CALCIUM ACETATE

&gt;A&gt; SOLUTION; ORAL

&gt;A&gt; PHOSLYRA

|     |                   |                      |             |              |     |      |
|-----|-------------------|----------------------|-------------|--------------|-----|------|
| >A> | + FRESENIUS MEDCL | EQ 169MG CALCIUM/5ML | N022581 001 | Apr 18, 2011 | Apr | NEWA |
|-----|-------------------|----------------------|-------------|--------------|-----|------|

TABLET; ORAL

CALCIUM ACETATE

|    |              |                  |             |              |     |      |
|----|--------------|------------------|-------------|--------------|-----|------|
| AB | PADDOCK LABS | EQ 169MG CALCIUM | A091561 001 | Apr 13, 2011 | Mar | NEWA |
|----|--------------|------------------|-------------|--------------|-----|------|

ELIPHOS

|    |                 |                  |             |              |     |      |
|----|-----------------|------------------|-------------|--------------|-----|------|
| AB | + CYPRESS PHARM | EQ 169MG CALCIUM | A078502 001 | Nov 25, 2008 | Mar | CTEC |
|----|-----------------|------------------|-------------|--------------|-----|------|

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL

CARBAMAZEPINE

|                    |       |             |              |     |      |
|--------------------|-------|-------------|--------------|-----|------|
| @ JUBILANT CADISTA | 100MG | A071940 001 | Feb 01, 1988 | Jan | CAHN |
|--------------------|-------|-------------|--------------|-----|------|

CARBIDOPA; LEVODOPA

TABLET; ORAL

SINEMET

|    |                   |            |             |  |     |      |
|----|-------------------|------------|-------------|--|-----|------|
| AB | MERCK SHARP DOHME | 10MG;100MG | N017555 001 |  | Jan | CAHN |
|----|-------------------|------------|-------------|--|-----|------|

|    |  |            |             |  |     |      |
|----|--|------------|-------------|--|-----|------|
| AB |  | 25MG;100MG | N017555 003 |  | Jan | CAHN |
|----|--|------------|-------------|--|-----|------|

|    |   |            |             |  |     |      |
|----|---|------------|-------------|--|-----|------|
| AB | + | 25MG;250MG | N017555 002 |  | Jan | CAHN |
|----|---|------------|-------------|--|-----|------|

TABLET, EXTENDED RELEASE; ORAL

SINEMET CR

|    |                   |            |             |              |     |      |
|----|-------------------|------------|-------------|--------------|-----|------|
| AB | MERCK SHARP DOHME | 25MG;100MG | N019856 002 | Dec 24, 1992 | Jan | CAHN |
|----|-------------------|------------|-------------|--------------|-----|------|

|    |   |            |             |              |     |      |
|----|---|------------|-------------|--------------|-----|------|
| AB | + | 50MG;200MG | N019856 001 | May 30, 1991 | Jan | CAHN |
|----|---|------------|-------------|--------------|-----|------|

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

|    |               |       |             |              |     |      |
|----|---------------|-------|-------------|--------------|-----|------|
| AA | MIRROR PHARMS | 350MG | A040823 001 | Oct 22, 2008 | Mar | CAHN |
|----|---------------|-------|-------------|--------------|-----|------|

|    |             |       |             |              |     |      |
|----|-------------|-------|-------------|--------------|-----|------|
| AA | PROSAM LABS | 350MG | A040188 001 | Mar 07, 1997 | Feb | CAHN |
|----|-------------|-------|-------------|--------------|-----|------|

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

|    |             |                    |             |              |     |      |
|----|-------------|--------------------|-------------|--------------|-----|------|
| AP | HOSPIRA INC | EQ 500MG BASE/VIAL | A065226 001 | Apr 21, 2005 | Jan | CAHN |
|----|-------------|--------------------|-------------|--------------|-----|------|

|    |  |                  |             |              |     |      |
|----|--|------------------|-------------|--------------|-----|------|
| AP |  | EQ 1GM BASE/VIAL | A065226 002 | Apr 21, 2005 | Jan | CAHN |
|----|--|------------------|-------------|--------------|-----|------|

|    |  |                  |             |              |     |      |
|----|--|------------------|-------------|--------------|-----|------|
| AP |  | EQ 1GM BASE/VIAL | A065244 001 | Aug 12, 2005 | Jan | CAHN |
|----|--|------------------|-------------|--------------|-----|------|

|    |  |                   |             |              |     |      |
|----|--|-------------------|-------------|--------------|-----|------|
| AP |  | EQ 10GM BASE/VIAL | A065247 001 | Aug 12, 2005 | Jan | CAHN |
|----|--|-------------------|-------------|--------------|-----|------|

CEFEPIME HYDROCHLORIDE

INJECTABLE; INJECTION

CEFEPIME HYDROCHLORIDE

|    |             |                    |             |              |     |      |
|----|-------------|--------------------|-------------|--------------|-----|------|
| AP | HOSPIRA INC | EQ 500MG BASE/VIAL | A065369 001 | Jun 18, 2007 | Jan | CAHN |
|----|-------------|--------------------|-------------|--------------|-----|------|

|    |  |                  |             |              |     |      |
|----|--|------------------|-------------|--------------|-----|------|
| AP |  | EQ 1GM BASE/VIAL | A065369 002 | Jun 18, 2007 | Jan | CAHN |
|----|--|------------------|-------------|--------------|-----|------|

|    |  |                  |             |              |     |      |
|----|--|------------------|-------------|--------------|-----|------|
| AP |  | EQ 2GM BASE/VIAL | A065369 003 | Jun 18, 2007 | Jan | CAHN |
|----|--|------------------|-------------|--------------|-----|------|

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CEFOTAXIME SODIUM

|    |             |                    |             |              |     |      |
|----|-------------|--------------------|-------------|--------------|-----|------|
| AP | HOSPIRA INC | EQ 500MG BASE/VIAL | A065290 001 | Aug 11, 2006 | Jan | CAHN |
| AP |             | EQ 1GM BASE/VIAL   | A065293 001 | Aug 10, 2006 | Jan | CAHN |
| AP |             | EQ 1GM BASE/VIAL   | A065290 002 | Aug 11, 2006 | Jan | CAHN |
| AP |             | EQ 2GM BASE/VIAL   | A065290 003 | Aug 11, 2006 | Jan | CAHN |
| AP |             | EQ 2GM BASE/VIAL   | A065293 002 | Aug 10, 2006 | Jan | CAHN |
| AP |             | EQ 10GM BASE/VIAL  | A065292 001 | Aug 10, 2006 | Jan | CAHN |

CEFOXITIN SODIUM

INJECTABLE; INJECTION

CEFOXITIN

|    |             |                   |             |              |     |      |
|----|-------------|-------------------|-------------|--------------|-----|------|
| AP | HOSPIRA INC | EQ 1GM BASE/VIAL  | A065313 001 | Jan 23, 2006 | Jan | CAHN |
| AP |             | EQ 2GM BASE/VIAL  | A065313 002 | Jan 23, 2006 | Jan | CAHN |
| AP |             | EQ 10GM BASE/VIAL | A065312 001 | Feb 13, 2006 | Jan | CAHN |

CEFPODOXIME PROXETIL

TABLET; ORAL

CEFPODOXIME PROXETIL

|    |                        |               |             |              |     |      |
|----|------------------------|---------------|-------------|--------------|-----|------|
| AB | + SANDOZ               | EQ 200MG BASE | A065462 002 | May 28, 2008 | Jan | CRLD |
|    | VANTIN                 |               |             |              |     |      |
|    | @ PHARMACIA AND UPJOHN | EQ 100MG BASE | N050674 001 | Aug 07, 1992 | Jan | DISC |
|    | @                      | EQ 200MG BASE | N050674 002 | Aug 07, 1992 | Jan | DISC |

CEFTRIAXONE SODIUM

INJECTABLE; IM-IV

CEFTRIAXONE

|    |                       |                    |             |              |     |      |
|----|-----------------------|--------------------|-------------|--------------|-----|------|
| AP | HOSPIRA INC           | EQ 250MG BASE/VIAL | A065230 001 | Aug 02, 2005 | Jan | CAHN |
| AP |                       | EQ 500MG BASE/VIAL | A065230 002 | Aug 02, 2005 | Jan | CAHN |
| AP |                       | EQ 1GM BASE/VIAL   | A065230 003 | Aug 02, 2005 | Jan | CAHN |
| AP |                       | EQ 2GM BASE/VIAL   | A065230 004 | Aug 02, 2005 | Jan | CAHN |
|    | INJECTABLE; INJECTION |                    |             |              |     |      |
|    | CEFTRIAXONE           |                    |             |              |     |      |
| AP | HOSPIRA INC           | EQ 1GM BASE/VIAL   | A065231 001 | Aug 02, 2005 | Jan | CAHN |
| AP |                       | EQ 2GM BASE/VIAL   | A065231 002 | Aug 02, 2005 | Jan | CAHN |
| AP |                       | EQ 10GM BASE/VIAL  | A065232 001 | Aug 02, 2005 | Jan | CAHN |
| AP | + SANDOZ              | EQ 10GM BASE/VIAL  | A065168 001 | May 17, 2005 | Jan | CRLD |

CEFUROXIME SODIUM

INJECTABLE; IM-IV

CEFUROXIME SODIUM

|    |                    |                    |             |              |     |      |
|----|--------------------|--------------------|-------------|--------------|-----|------|
| AB | HIKMA FARMACEUTICA | EQ 750MG BASE/VIAL | A065048 001 | Jan 09, 2004 | Mar | CTEC |
| AP | HOSPIRA INC        | EQ 750MG BASE/VIAL | A065483 001 | Oct 15, 2008 | Jan | CAHN |

INJECTABLE; INJECTION

CEFUROXIME SODIUM

|    |             |                    |             |              |     |      |
|----|-------------|--------------------|-------------|--------------|-----|------|
| AP | HOSPIRA INC | EQ 1.5GM BASE/VIAL | A065483 002 | Oct 15, 2008 | Jan | CAHN |
| AP |             | EQ 1.5GM BASE/VIAL | A065503 001 | Oct 15, 2008 | Jan | CAHN |
| AP |             | EQ 7.5GM BASE/VIAL | A065484 001 | Oct 15, 2008 | Jan | CAHN |

CEPHALEXIN

FOR SUSPENSION; ORAL

CEPHALEXIN

|    |              |                   |             |  |     |      |
|----|--------------|-------------------|-------------|--|-----|------|
|    | @ ACS DOBFAR | EQ 100MG BASE/ML  | A062117 001 |  | Jan | CAHN |
| AB |              | EQ 125MG BASE/5ML | A062117 002 |  | Jan | CAHN |

FOR SUSPENSION; ORAL  
CEPHALEXIN

AB + ACS DOBFAR EQ 250MG BASE/5ML A062117 003 Jan CAHN

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL  
CHLORHEXIDINE GLUCONATE

AT LYNE 0.12% A074291 001 Dec 28, 1995 Feb CAHN

CHLOROQUINE PHOSPHATE

TABLET; ORAL  
CHLOROQUINE PHOSPHATE

AA NATCO PHARMA LTD EQ 150MG BASE A091621 001 Jan 21, 2011 Jan NEWA

AA EQ 300MG BASE A090612 001 Jan 21, 2011 Jan NEWA

CHOLESTYRAMINE

POWDER; ORAL  
CHOLESTYRAMINE

>D> AB SANDOZ EQ 4GM RESIN/PACKET A074557 001 Aug 15, 1996 Apr CRLD

>A> AB + EQ 4GM RESIN/PACKET A074557 001 Aug 15, 1996 Apr CRLD

CHOLESTYRAMINE LIGHT

>D> AB SANDOZ EQ 4GM RESIN/PACKET A074558 001 Aug 15, 1996 Apr CRLD

>A> AB + EQ 4GM RESIN/PACKET A074558 001 Aug 15, 1996 Apr CRLD

QUESTRAN

>D> AB + BRISTOL MYERS EQ 4GM RESIN/PACKET N016640 001 Apr DISC

>D> AB EQ 4GM RESIN/SC00PFUL N016640 003 Apr DISC

>A> @ EQ 4GM RESIN/PACKET N016640 001 Apr DISC

>A> @ EQ 4GM RESIN/SC00PFUL N016640 003 Apr DISC

QUESTRAN LIGHT

>D> AB + BRISTOL MYERS EQ 4GM RESIN/PACKET N019669 001 Dec 05, 1988 Apr DISC

>D> AB EQ 4GM RESIN/SC00PFUL N019669 003 Dec 05, 1988 Apr DISC

>A> @ EQ 4GM RESIN/SC00PFUL N019669 003 Dec 05, 1988 Apr DISC

>A> @ EQ 4GM RESIN/PACKET N019669 001 Dec 05, 1988 Apr DISC

AB + EQ 4GM RESIN/PACKET N019669 001 Dec 05, 1988 Mar CRLD

CICLOPIROX

SHAMPOO; TOPICAL  
CICLOPIROX

AT TARO 1% A090269 001 Feb 23, 2011 Feb NEWA

CITALOPRAM HYDROBROMIDE

TABLET; ORAL  
CITALOPRAM HYDROBROMIDE

>D> AB MATRIX LABS INC EQ 10MG BASE A077042 001 Nov 05, 2004 Apr CAHN

>D> AB EQ 20MG BASE A077042 002 Nov 05, 2004 Apr CAHN

>D> AB EQ 40MG BASE A077042 003 Nov 05, 2004 Apr CAHN

>A> AB MYLAN EQ 10MG BASE A077042 001 Nov 05, 2004 Apr CAHN

>A> AB EQ 20MG BASE A077042 002 Nov 05, 2004 Apr CAHN

>A> AB EQ 40MG BASE A077042 003 Nov 05, 2004 Apr CAHN

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL  
CLINDAGEL

BT + GALDERMA LABS LP EQ 1% BASE N050782 001 Nov 27, 2000 Mar CRLD

SOLUTION; TOPICAL

## CLINDAMYCIN PHOSPHATE

|     |               |            |             |              |     |      |
|-----|---------------|------------|-------------|--------------|-----|------|
| >A> | @ COREPHARMA  | EQ 1% BASE | A064108 001 | Sep 27, 1996 | Apr | CAHN |
| >D> | @ STIEFEL GSK | EQ 1% BASE | A064108 001 | Sep 27, 1996 | Apr | CAHN |

CLOBETASOL PROPIONATE

## CREAM; TOPICAL

## CLOBETASOL PROPIONATE

|     |              |       |             |              |     |      |
|-----|--------------|-------|-------------|--------------|-----|------|
| >A> | @ COREPHARMA | 0.05% | A075338 001 | Feb 09, 2001 | Apr | CAHN |
| >D> | @ STIEFEL    | 0.05% | A075338 001 | Feb 09, 2001 | Apr | CAHN |

## CLOBETASOL PROPIONATE (EMOLLIENT)

|     |               |       |             |              |     |      |
|-----|---------------|-------|-------------|--------------|-----|------|
| >A> | @ COREPHARMA  | 0.05% | A075733 001 | Aug 22, 2001 | Apr | CAHN |
| >D> | @ STIEFEL GSK | 0.05% | A075733 001 | Aug 22, 2001 | Apr | CAHN |

## OINTMENT; TOPICAL

## CLOBETASOL PROPIONATE

|     |               |       |             |              |     |      |
|-----|---------------|-------|-------------|--------------|-----|------|
| >A> | @ COREPHARMA  | 0.05% | A075057 001 | Aug 12, 1998 | Apr | CAHN |
| >D> | @ STIEFEL GSK | 0.05% | A075057 001 | Aug 12, 1998 | Apr | CAHN |

## SOLUTION; TOPICAL

## CLOBETASOL PROPIONATE

|     |    |            |       |             |              |     |      |
|-----|----|------------|-------|-------------|--------------|-----|------|
| >D> | AT | ALTANA     | 0.05% | A075391 001 | Feb 08, 1999 | Apr | CAHN |
| >A> | AT | NYCOMED US | 0.05% | A075391 001 | Feb 08, 1999 | Apr | CAHN |

CLONIDINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## CLONIDINE HYDROCHLORIDE

|    |           |                     |             |              |     |      |
|----|-----------|---------------------|-------------|--------------|-----|------|
| AP | WEST WARD | 1MG/10ML (0.1MG/ML) | A200300 001 | Jan 26, 2011 | Jan | NEWA |
| AP |           | 5MG/10ML (0.5MG/ML) | A200300 002 | Jan 26, 2011 | Jan | NEWA |

COLCHICINE; PROBENECID

## TABLET; ORAL

## PROBENECID AND COLCHICINE

|    |               |             |             |              |     |      |
|----|---------------|-------------|-------------|--------------|-----|------|
| AB | MIRROR PHARMS | 0.5MG;500MG | A040618 001 | May 13, 2008 | Mar | CAHN |
|----|---------------|-------------|-------------|--------------|-----|------|

CYCLOBENZAPRINE HYDROCHLORIDE

## CAPSULE, EXTENDED RELEASE; ORAL

## AMRIX

|     |           |      |             |              |     |      |
|-----|-----------|------|-------------|--------------|-----|------|
| >D> | ANESTA AG | 15MG | N021777 001 | Feb 01, 2007 | Apr | CFTG |
| >A> | AB        | 15MG | N021777 001 | Feb 01, 2007 | Apr | CFTG |
| >D> | +         | 30MG | N021777 002 | Feb 01, 2007 | Apr | CFTG |
| >A> | AB        | 30MG | N021777 002 | Feb 01, 2007 | Apr | CFTG |

## CYCLOBENZAPRINE HYDROCHLORIDE

|     |    |       |      |             |              |     |      |
|-----|----|-------|------|-------------|--------------|-----|------|
| >A> | AB | MYLAN | 15MG | A090738 001 | Apr 18, 2011 | Apr | NEWA |
| >A> | AB |       | 30MG | A090738 002 | Apr 18, 2011 | Apr | NEWA |

## TABLET; ORAL

## CYCLOBENZAPRINE HYDROCHLORIDE

|    |                  |      |             |              |     |      |
|----|------------------|------|-------------|--------------|-----|------|
| AB | JUBILANT CADISTA | 5MG  | A077563 001 | Apr 19, 2006 | Jan | CAHN |
| AB |                  | 10MG | A077563 002 | Apr 19, 2006 | Jan | CAHN |
| AB | KVK TECH         | 5MG  | A078048 001 | Feb 28, 2011 | Feb | NEWA |
| AB |                  | 10MG | A078048 002 | Feb 28, 2011 | Feb | NEWA |
| AB | PROSAM LABS      | 5MG  | A077291 001 | Feb 03, 2006 | Feb | CAHN |
| AB |                  | 10MG | A077209 001 | Oct 04, 2005 | Feb | CAHN |

DESLOMATADINE

## TABLET; ORAL

## DESLOMATADINE

|    |                    |     |             |              |     |      |
|----|--------------------|-----|-------------|--------------|-----|------|
| AB | DR REDDYS LABS LTD | 5MG | A078365 001 | Mar 08, 2011 | Feb | NEWA |
|----|--------------------|-----|-------------|--------------|-----|------|

DES Loratadine; Pseudoephedrine Sulfate

TABLET, EXTENDED RELEASE; ORAL

CLARINEX D 24 HOUR

|     |    |                                                    |           |             |              |     |      |
|-----|----|----------------------------------------------------|-----------|-------------|--------------|-----|------|
| >D> | +  | SCHERING                                           | 5MG;240MG | N021605 001 | Mar 03, 2005 | Apr | CFTG |
| >A> | AB | +                                                  | 5MG;240MG | N021605 001 | Mar 03, 2005 | Apr | CFTG |
| >A> |    | DES Loratadine AND Pseudoephedrine Sulfate 24 HOUR |           |             |              |     |      |
| >A> | AB | DR REDDYS LABS LTD                                 | 5MG;240MG | A078366 001 | Apr 26, 2011 | Apr | NEWA |

Desogestrel; Ethinyl Estradiol

TABLET; ORAL-28

EMOQUETTE

|    |         |               |             |              |     |      |
|----|---------|---------------|-------------|--------------|-----|------|
| AB | VINTAGE | 0.15MG;0.03MG | A076675 001 | Feb 25, 2011 | Feb | NEWA |
|----|---------|---------------|-------------|--------------|-----|------|

Desoximetasone

GEL; TOPICAL

DES OXIMETASONE

|    |            |       |             |              |     |      |
|----|------------|-------|-------------|--------------|-----|------|
| AB | VERSAPHARM | 0.05% | A090727 001 | Mar 10, 2011 | Feb | NEWA |
|----|------------|-------|-------------|--------------|-----|------|

Dexamethasone

ELIXIR; ORAL

DEXAMETHASONE

|     |    |                |           |             |              |     |      |
|-----|----|----------------|-----------|-------------|--------------|-----|------|
| >A> | AA | VINTAGE PHARMS | 0.5MG/5ML | A091188 001 | May 11, 2011 | Apr | NEWA |
|-----|----|----------------|-----------|-------------|--------------|-----|------|

Dexamethasone; Neomycin Sulfate; Polymyxin B Sulfate

OINTMENT; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

|    |             |                                       |             |              |     |      |
|----|-------------|---------------------------------------|-------------|--------------|-----|------|
| AT | FERA PHARMS | 0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM | A062938 001 | Jul 31, 1989 | Feb | CAHN |
|----|-------------|---------------------------------------|-------------|--------------|-----|------|

|    |            |                                       |             |              |     |      |
|----|------------|---------------------------------------|-------------|--------------|-----|------|
| AT | NYCOMED US | 0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM | A062938 001 | Jul 31, 1989 | Jan | CAHN |
|----|------------|---------------------------------------|-------------|--------------|-----|------|

Dextromethorphan Hydrobromide; Promethazine Hydrochloride

SYRUP; ORAL

PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE

|    |               |                     |             |              |     |      |
|----|---------------|---------------------|-------------|--------------|-----|------|
| AA | AMNEAL PHARMS | 15MG/5ML;6.25MG/5ML | A090575 001 | Feb 08, 2011 | Jan | NEWA |
|----|---------------|---------------------|-------------|--------------|-----|------|

Diclofenac Sodium

TABLET, EXTENDED RELEASE; ORAL

DICLOFENAC SODIUM

|     |    |              |       |             |              |     |      |
|-----|----|--------------|-------|-------------|--------------|-----|------|
| >D> | AB | BIOVAIL      | 100MG | A075492 001 | Feb 11, 2000 | Apr | CAHN |
| >A> | AB | VALEANT INTL | 100MG | A075492 001 | Feb 11, 2000 | Apr | CAHN |

Diltiazem Hydrochloride

CAPSULE, EXTENDED RELEASE; ORAL

DILTIAZEM HYDROCHLORIDE

|     |     |              |       |             |              |     |      |
|-----|-----|--------------|-------|-------------|--------------|-----|------|
| >D> | AB3 | BIOVAIL      | 120MG | A075116 001 | Dec 23, 1999 | Apr | CAHN |
| >D> | AB3 |              | 180MG | A075116 002 | Dec 23, 1999 | Apr | CAHN |
| >D> | AB3 |              | 240MG | A075116 003 | Dec 23, 1999 | Apr | CAHN |
| >D> | AB3 |              | 300MG | A075116 004 | Dec 23, 1999 | Apr | CAHN |
| >A> | AB3 | VALEANT INTL | 120MG | A075116 001 | Dec 23, 1999 | Apr | CAHN |
| >A> | AB3 |              | 180MG | A075116 002 | Dec 23, 1999 | Apr | CAHN |
| >A> | AB3 |              | 240MG | A075116 003 | Dec 23, 1999 | Apr | CAHN |
| >A> | AB3 |              | 300MG | A075116 004 | Dec 23, 1999 | Apr | CAHN |

DIPYRIDAMOLE

## TABLET; ORAL

## DIPYRIDAMOLE

|    |             |      |             |              |     |      |
|----|-------------|------|-------------|--------------|-----|------|
| AB | PROSAM LABS | 25MG | A040542 001 | Apr 21, 2006 | Feb | CAHN |
| AB |             | 50MG | A040542 002 | Apr 21, 2006 | Feb | CAHN |
| AB |             | 75MG | A040542 003 | Apr 21, 2006 | Feb | CAHN |

DISULFIRAM

## TABLET; ORAL

## ANTABUSE

|    |                |       |             |              |     |      |
|----|----------------|-------|-------------|--------------|-----|------|
| AB | ODYSSEY PHARMS | 250MG | A088482 001 | Dec 08, 1983 | Mar | CTEC |
| AB | +              | 500MG | A088483 001 | Dec 08, 1983 | Mar | CTEC |

## DISULFIRAM

|    |                     |       |             |              |     |      |
|----|---------------------|-------|-------------|--------------|-----|------|
| AB | SIGMAPHARM LABS LLC | 250MG | A091619 001 | Mar 28, 2011 | Mar | NEWA |
| AB |                     | 500MG | A091619 002 | Mar 28, 2011 | Mar | NEWA |

DIVALPROEX SODIUM

## CAPSULE, DELAYED REL PELLETS; ORAL

## DIVALPROEX SODIUM

|    |       |                        |             |              |     |      |
|----|-------|------------------------|-------------|--------------|-----|------|
| AB | MYLAN | EQ 125MG VALPROIC ACID | A090407 001 | Mar 28, 2011 | Mar | NEWA |
|----|-------|------------------------|-------------|--------------|-----|------|

## TABLET, DELAYED RELEASE; ORAL

## DIVALPROEX SODIUM

|     |    |                      |                        |             |              |     |      |
|-----|----|----------------------|------------------------|-------------|--------------|-----|------|
| >A> | AB | AUROBINDO PHARMA LTD | EQ 125MG VALPROIC ACID | A090554 001 | Apr 21, 2011 | Apr | NEWA |
| >A> | AB |                      | EQ 250MG VALPROIC ACID | A090554 002 | Apr 21, 2011 | Apr | NEWA |
| >A> | AB |                      | EQ 500MG VALPROIC ACID | A090554 003 | Apr 21, 2011 | Apr | NEWA |
|     | AB | UNICHEM LABS LTD     | EQ 125MG VALPROIC ACID | A079163 001 | Apr 05, 2011 | Mar | NEWA |
|     | AB |                      | EQ 250MG VALPROIC ACID | A079163 002 | Apr 05, 2011 | Mar | NEWA |
|     | AB |                      | EQ 500MG VALPROIC ACID | A079163 003 | Apr 05, 2011 | Mar | NEWA |
|     | AB | WATSON LABS FLORIDA  | EQ 500MG VALPROIC ACID | A079080 001 | Feb 25, 2011 | Feb | NEWA |

DOCETAXEL

## INJECTABLE; INJECTION

## DOCETAXEL

|   |             |                      |             |              |     |      |
|---|-------------|----------------------|-------------|--------------|-----|------|
| + | HOSPIRA INC | 20MG/2ML (10MG/ML)   | N022234 001 | Mar 08, 2011 | Mar | NEWA |
| + |             | 80MG/8ML (10MG/ML)   | N022234 002 | Mar 08, 2011 | Mar | NEWA |
| + |             | 160MG/16ML (10MG/ML) | N022234 003 | Mar 08, 2011 | Mar | NEWA |

## TAXOTERE

|   |                   |         |             |              |     |      |
|---|-------------------|---------|-------------|--------------|-----|------|
| @ | SANOFI AVENTIS US | 40MG/ML | N020449 001 | May 14, 1996 | Mar | DISC |
|---|-------------------|---------|-------------|--------------|-----|------|

DONEPEZIL HYDROCHLORIDE

## TABLET, ORALLY DISINTEGRATING; ORAL

## DONEPEZIL HYDROCHLORIDE

|     |    |                      |      |             |              |     |      |
|-----|----|----------------------|------|-------------|--------------|-----|------|
| >A> | AB | SANDOZ               | 5MG  | A091198 001 | May 10, 2011 | Apr | NEWA |
| >A> | AB |                      | 10MG | A091198 002 | May 10, 2011 | Apr | NEWA |
| >A> | AB | ZYDUS PHARMS USA INC | 5MG  | A090175 001 | May 10, 2011 | Apr | NEWA |
| >A> | AB |                      | 10MG | A090175 002 | May 10, 2011 | Apr | NEWA |

DOXYCYCLINE

## CAPSULE; ORAL

## DOXYCYCLINE

|    |                |               |               |              |              |      |      |
|----|----------------|---------------|---------------|--------------|--------------|------|------|
| AB | IMPAX LABS INC | EQ 150MG BASE | A200065 001   | Feb 17, 2011 | Jan          | NEWA |      |
| AB | MYLAN          | 40MG          | A090855 001   | Jul 01, 2010 | Jan          | CDFR |      |
| AB | +              | PAR PHARM     | EQ 150MG BASE | A065055 003  | Jul 15, 2005 | Feb  | CTEC |
| AB | +              | EQ 150MG BASE | A065055 003   | Jul 15, 2005 | Jan          | CTEC |      |

DROSPIRENONE; ETHINYL ESTRADIOL

TABLET; ORAL

LORYNA

|    |        |            |         |     |              |     |      |
|----|--------|------------|---------|-----|--------------|-----|------|
| AB | SANDOZ | 3MG;0.02MG | A079221 | 001 | Mar 28, 2011 | Mar | NEWA |
|----|--------|------------|---------|-----|--------------|-----|------|

TABLET; ORAL-28

SYEDA

|    |        |            |         |     |              |     |      |
|----|--------|------------|---------|-----|--------------|-----|------|
| AB | SANDOZ | 3MG;0.03MG | A090114 | 001 | Mar 28, 2011 | Mar | NEWA |
|----|--------|------------|---------|-----|--------------|-----|------|

ENOXAPARIN SODIUM

INJECTABLE; INTRAVENOUS, SUBCUTANEOUS

LOVENOX

|  |                   |                      |         |     |              |     |      |
|--|-------------------|----------------------|---------|-----|--------------|-----|------|
|  | SANOFI AVENTIS US | 300MG/3ML (100MG/ML) | N020164 | 009 | Jan 23, 2003 | Feb | CDFR |
|--|-------------------|----------------------|---------|-----|--------------|-----|------|

EPINASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

ELESTAT

|    |            |       |         |     |              |     |      |
|----|------------|-------|---------|-----|--------------|-----|------|
| AT | + ALLERGAN | 0.05% | N021565 | 001 | Oct 16, 2003 | Feb | CFTG |
|----|------------|-------|---------|-----|--------------|-----|------|

EPINASTINE HYDROCHLORIDE

|    |               |       |         |     |              |     |      |
|----|---------------|-------|---------|-----|--------------|-----|------|
| AT | CYPRESS PHARM | 0.05% | A090870 | 001 | Mar 14, 2011 | Feb | NEWA |
|----|---------------|-------|---------|-----|--------------|-----|------|

EPIRUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

EPIRUBICIN HYDROCHLORIDE

|     |    |                |                    |         |     |              |     |      |
|-----|----|----------------|--------------------|---------|-----|--------------|-----|------|
| >A> | AP | MUSTAFA NEVSAT | 50MG/25ML (2MG/ML) | A090266 | 001 | Apr 15, 2011 | Apr | NEWA |
|-----|----|----------------|--------------------|---------|-----|--------------|-----|------|

|     |    |  |                      |         |     |              |     |      |
|-----|----|--|----------------------|---------|-----|--------------|-----|------|
| >A> | AP |  | 200MG/100ML (2MG/ML) | A090266 | 002 | Apr 15, 2011 | Apr | NEWA |
|-----|----|--|----------------------|---------|-----|--------------|-----|------|

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

ERYTHROMYCIN

|    |                  |       |         |     |              |     |      |
|----|------------------|-------|---------|-----|--------------|-----|------|
| AB | ARBOR PHARMS INC | 250MG | A062746 | 001 | Dec 22, 1986 | Jan | CAHN |
|----|------------------|-------|---------|-----|--------------|-----|------|

GEL; TOPICAL

E-GLADES

|     |    |            |    |         |     |              |     |      |
|-----|----|------------|----|---------|-----|--------------|-----|------|
| >A> | AT | COREPHARMA | 2% | A065009 | 001 | Mar 18, 2002 | Apr | CAHN |
|-----|----|------------|----|---------|-----|--------------|-----|------|

|     |    |                  |    |         |     |              |     |      |
|-----|----|------------------|----|---------|-----|--------------|-----|------|
| >D> | AT | STIEFEL LABS INC | 2% | A065009 | 001 | Mar 18, 2002 | Apr | CAHN |
|-----|----|------------------|----|---------|-----|--------------|-----|------|

OINTMENT; OPHTHALMIC

ERYTHROMYCIN

|    |               |      |         |     |              |     |      |
|----|---------------|------|---------|-----|--------------|-----|------|
| AT | + FERA PHARMS | 0.5% | A062447 | 001 | Sep 26, 1983 | Feb | CAHN |
|----|---------------|------|---------|-----|--------------|-----|------|

|    |              |      |         |     |              |     |      |
|----|--------------|------|---------|-----|--------------|-----|------|
| AT | + NYCOMED US | 0.5% | A062447 | 001 | Sep 26, 1983 | Jan | CAHN |
|----|--------------|------|---------|-----|--------------|-----|------|

SOLUTION; TOPICAL

ERYDERM

|  |                    |    |         |     |  |     |      |
|--|--------------------|----|---------|-----|--|-----|------|
|  | @ ARBOR PHARMS INC | 2% | A062290 | 001 |  | Jan | CAHN |
|--|--------------------|----|---------|-----|--|-----|------|

ERYTHROMYCIN

|     |              |    |         |     |              |     |      |
|-----|--------------|----|---------|-----|--------------|-----|------|
| >A> | @ COREPHARMA | 2% | A064127 | 001 | Feb 14, 1997 | Apr | CAHN |
|-----|--------------|----|---------|-----|--------------|-----|------|

|     |           |    |         |     |              |     |      |
|-----|-----------|----|---------|-----|--------------|-----|------|
| >D> | @ STIEFEL | 2% | A064127 | 001 | Feb 14, 1997 | Apr | CAHN |
|-----|-----------|----|---------|-----|--------------|-----|------|

SWAB; TOPICAL

ERYTHROMYCIN

|     |              |    |         |     |              |     |      |
|-----|--------------|----|---------|-----|--------------|-----|------|
| >A> | @ COREPHARMA | 2% | A064128 | 001 | Jul 03, 1996 | Apr | CAHN |
|-----|--------------|----|---------|-----|--------------|-----|------|

|     |           |    |         |     |              |     |      |
|-----|-----------|----|---------|-----|--------------|-----|------|
| >D> | @ STIEFEL | 2% | A064128 | 001 | Jul 03, 1996 | Apr | CAHN |
|-----|-----------|----|---------|-----|--------------|-----|------|

TABLET; ORAL

ERYTHROMYCIN

|  |                  |       |         |     |  |     |      |
|--|------------------|-------|---------|-----|--|-----|------|
|  | ARBOR PHARMS INC | 250MG | A061621 | 001 |  | Jan | CAHN |
|--|------------------|-------|---------|-----|--|-----|------|

+ 500MG

|         |     |  |     |      |
|---------|-----|--|-----|------|
| A061621 | 002 |  | Jan | CAHN |
|---------|-----|--|-----|------|

TABLET, COATED PARTICLES; ORAL

PCE

|  |                  |       |         |     |              |     |      |
|--|------------------|-------|---------|-----|--------------|-----|------|
|  | ARBOR PHARMS INC | 333MG | N050611 | 001 | Sep 09, 1986 | Jan | CAHN |
|--|------------------|-------|---------|-----|--------------|-----|------|

## TABLET, COATED PARTICLES; ORAL

PCE

|   |                  |       |             |              |     |      |
|---|------------------|-------|-------------|--------------|-----|------|
| + | ARBOR PHARMS INC | 500MG | N050611 002 | Aug 22, 1990 | Jan | CAHN |
|---|------------------|-------|-------------|--------------|-----|------|

## TABLET, DELAYED RELEASE; ORAL

E-MYCIN

|  |                    |       |             |  |     |      |
|--|--------------------|-------|-------------|--|-----|------|
|  | @ ARBOR PHARMS INC | 250MG | A060272 001 |  | Jan | CAHN |
|--|--------------------|-------|-------------|--|-----|------|

|  |   |       |             |  |     |      |
|--|---|-------|-------------|--|-----|------|
|  | @ | 333MG | A060272 002 |  | Jan | CAHN |
|--|---|-------|-------------|--|-----|------|

ERY-TAB

|   |                  |       |             |  |     |      |
|---|------------------|-------|-------------|--|-----|------|
| + | ARBOR PHARMS INC | 250MG | A062298 001 |  | Jan | CAHN |
|---|------------------|-------|-------------|--|-----|------|

|   |  |       |             |              |     |      |
|---|--|-------|-------------|--------------|-----|------|
| + |  | 333MG | A062298 003 | Mar 29, 1982 | Jan | CAHN |
|---|--|-------|-------------|--------------|-----|------|

|   |  |       |             |  |     |      |
|---|--|-------|-------------|--|-----|------|
| + |  | 500MG | A062298 002 |  | Jan | CAHN |
|---|--|-------|-------------|--|-----|------|

ERYTHROMYCIN ETHYLSUCCINATE

## GRANULE; ORAL

E.E.S.

|    |                  |                   |             |  |     |      |
|----|------------------|-------------------|-------------|--|-----|------|
| AB | ARBOR PHARMS INC | EQ 200MG BASE/5ML | N050207 001 |  | Jan | CAHN |
|----|------------------|-------------------|-------------|--|-----|------|

ERYPED

|    |                  |                   |             |              |     |      |
|----|------------------|-------------------|-------------|--------------|-----|------|
| AB | ARBOR PHARMS INC | EQ 200MG BASE/5ML | N050207 003 | Mar 30, 1987 | Jan | CAHN |
|----|------------------|-------------------|-------------|--------------|-----|------|

|   |  |                   |             |  |     |      |
|---|--|-------------------|-------------|--|-----|------|
| + |  | EQ 400MG BASE/5ML | N050207 002 |  | Jan | CAHN |
|---|--|-------------------|-------------|--|-----|------|

## SUSPENSION; ORAL

E.E.S. 200

|    |                  |                   |             |  |     |      |
|----|------------------|-------------------|-------------|--|-----|------|
| AB | ARBOR PHARMS INC | EQ 200MG BASE/5ML | A061639 001 |  | Jan | CAHN |
|----|------------------|-------------------|-------------|--|-----|------|

E.E.S. 400

|    |   |                  |                   |             |  |     |      |
|----|---|------------------|-------------------|-------------|--|-----|------|
| AB | + | ARBOR PHARMS INC | EQ 400MG BASE/5ML | A061639 002 |  | Jan | CAHN |
|----|---|------------------|-------------------|-------------|--|-----|------|

PEDIAMYCIN

|    |                  |                   |             |  |     |      |
|----|------------------|-------------------|-------------|--|-----|------|
| AB | ARBOR PHARMS INC | EQ 200MG BASE/5ML | A062304 001 |  | Jan | CAHN |
|----|------------------|-------------------|-------------|--|-----|------|

PEDIAMYCIN 400

|    |                  |                   |             |  |     |      |
|----|------------------|-------------------|-------------|--|-----|------|
| AB | ARBOR PHARMS INC | EQ 400MG BASE/5ML | A062304 002 |  | Jan | CAHN |
|----|------------------|-------------------|-------------|--|-----|------|

## TABLET; ORAL

E.E.S. 400

|  |                    |               |             |  |     |      |
|--|--------------------|---------------|-------------|--|-----|------|
|  | @ ARBOR PHARMS INC | EQ 400MG BASE | A061905 001 |  | Jan | CAHN |
|--|--------------------|---------------|-------------|--|-----|------|

|    |   |  |               |             |              |     |      |
|----|---|--|---------------|-------------|--------------|-----|------|
| BX | + |  | EQ 400MG BASE | A061905 002 | Aug 12, 1982 | Jan | CAHN |
|----|---|--|---------------|-------------|--------------|-----|------|

ERYTHROMYCIN ETHYLSUCCINATE

|    |   |                  |               |             |  |     |      |
|----|---|------------------|---------------|-------------|--|-----|------|
| BX | + | ARBOR PHARMS INC | EQ 400MG BASE | A061904 001 |  | Jan | CAHN |
|----|---|------------------|---------------|-------------|--|-----|------|

## TABLET, CHEWABLE; ORAL

E.E.S.

|  |                    |               |             |  |     |      |
|--|--------------------|---------------|-------------|--|-----|------|
|  | @ ARBOR PHARMS INC | EQ 200MG BASE | N050297 002 |  | Jan | CAHN |
|--|--------------------|---------------|-------------|--|-----|------|

ERYPED

|  |                    |               |             |              |     |      |
|--|--------------------|---------------|-------------|--------------|-----|------|
|  | @ ARBOR PHARMS INC | EQ 200MG BASE | N050297 003 | Jul 05, 1988 | Jan | CAHN |
|--|--------------------|---------------|-------------|--------------|-----|------|

ERYTHROMYCIN STEARATE

## TABLET; ORAL

ERYTHROCIN STEARATE

|  |                    |               |             |  |     |      |
|--|--------------------|---------------|-------------|--|-----|------|
|  | @ ARBOR PHARMS INC | EQ 125MG BASE | A060359 002 |  | Jan | CAHN |
|--|--------------------|---------------|-------------|--|-----|------|

|  |  |               |             |  |     |      |
|--|--|---------------|-------------|--|-----|------|
|  |  | EQ 250MG BASE | A060359 001 |  | Jan | CAHN |
|--|--|---------------|-------------|--|-----|------|

|   |  |               |             |  |     |      |
|---|--|---------------|-------------|--|-----|------|
| + |  | EQ 500MG BASE | A060359 003 |  | Jan | CAHN |
|---|--|---------------|-------------|--|-----|------|

ESTRADIOL; NORETHINDRONE ACETATE

## TABLET; ORAL

ACTIVELLA

|    |                  |             |             |              |     |      |
|----|------------------|-------------|-------------|--------------|-----|------|
| AB | NOVO NORDISK INC | 0.5MG;0.1MG | N020907 002 | Dec 28, 2006 | Mar | CTEC |
|----|------------------|-------------|-------------|--------------|-----|------|

ESTRADIOL AND NORETHINDRONE ACETATE

|    |                    |             |             |              |     |      |
|----|--------------------|-------------|-------------|--------------|-----|------|
| AB | BRECKENRIDGE PHARM | 0.5MG;0.1MG | A078324 002 | Apr 04, 2011 | Mar | NEWA |
|----|--------------------|-------------|-------------|--------------|-----|------|



ESTROPIPATE

|     |                        |          |         |     |  |     |      |
|-----|------------------------|----------|---------|-----|--|-----|------|
| >D> | CREAM; VAGINAL         |          |         |     |  |     |      |
| >D> | OGEN                   |          |         |     |  |     |      |
| >D> | + PHARMACIA AND UPJOHN | 1.5MG/GM | A084710 | 001 |  | Apr | DISC |
| >A> | @                      | 1.5MG/GM | A084710 | 001 |  | Apr | DISC |

ETHINYL ESTRADIOL; LEVONORGESTREL

|     |                    |              |         |     |              |     |      |
|-----|--------------------|--------------|---------|-----|--------------|-----|------|
|     | TABLET; ORAL-28    |              |         |     |              |     |      |
| >A> | ORSYTHIA           |              |         |     |              |     |      |
| >A> | AB1 VINTAGE PHARMS | 0.02MG;0.1MG | A077099 | 001 | May 11, 2011 | Apr | NEWA |

ETHINYL ESTRADIOL; NORETHINDRONE

|    |                                                          |               |         |     |              |     |      |
|----|----------------------------------------------------------|---------------|---------|-----|--------------|-----|------|
|    | TABLET; ORAL-28                                          |               |         |     |              |     |      |
|    | BRIELLYN                                                 |               |         |     |              |     |      |
| AB | GLENMARK GENERICS                                        | 0.035MG;0.4MG | A090538 | 001 | Mar 22, 2011 | Mar | NEWA |
|    | TABLET, CHEWABLE; ORAL                                   |               |         |     |              |     |      |
|    | NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE |               |         |     |              |     |      |
|    | + WARNER CHILCOTT                                        | 0.025MG;0.8MG | N022573 | 001 | Dec 22, 2010 | Jan | CRLD |

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

|    |                   |              |         |     |              |     |      |
|----|-------------------|--------------|---------|-----|--------------|-----|------|
|    | TABLET; ORAL-28   |              |         |     |              |     |      |
|    | GILDESS FE 1.5/30 |              |         |     |              |     |      |
| AB | VINTAGE           | 0.03MG;1.5MG | A077075 | 001 | Apr 28, 2005 | Jan | CTNA |
|    | GILDESS FE 1/20   |              |         |     |              |     |      |
| AB | VINTAGE           | 0.02MG;1MG   | A077077 | 001 | May 20, 2005 | Jan | CTNA |

ETHINYL ESTRADIOL; NORGESTIMATE

|    |                                    |                                               |         |     |              |     |      |
|----|------------------------------------|-----------------------------------------------|---------|-----|--------------|-----|------|
|    | TABLET; ORAL-28                    |                                               |         |     |              |     |      |
|    | NORGESTIMATE AND ETHINYL ESTRADIOL |                                               |         |     |              |     |      |
| AB | WATSON LABS                        | 0.025MG,0.025MG,0.025MG;0.18MG,0.215MG,0.25MG | A090479 | 001 | Mar 09, 2011 | Feb | NEWA |

ETODOLAC

|  |               |       |         |     |              |     |      |
|--|---------------|-------|---------|-----|--------------|-----|------|
|  | CAPSULE; ORAL |       |         |     |              |     |      |
|  | ETODOLAC      |       |         |     |              |     |      |
|  | @ MYLAN       | 200MG | A075071 | 001 | Sep 30, 1998 | Feb | CAHN |
|  | @             | 300MG | A075071 | 002 | Sep 30, 1998 | Feb | CAHN |
|  | TABLET; ORAL  |       |         |     |              |     |      |
|  | ETODOLAC      |       |         |     |              |     |      |
|  | @ MYLAN       | 400MG | A075012 | 001 | Sep 30, 1998 | Feb | CAHN |
|  | @             | 500MG | A075012 | 002 | Sep 30, 1998 | Feb | CAHN |

ETRAVIRINE

|  |              |       |         |     |              |     |      |
|--|--------------|-------|---------|-----|--------------|-----|------|
|  | TABLET; ORAL |       |         |     |              |     |      |
|  | INTELENCE    |       |         |     |              |     |      |
|  | TIBOTEC      | 100MG | N022187 | 001 | Jan 18, 2008 | Jan | CRLD |
|  | +            | 200MG | N022187 | 002 | Dec 22, 2010 | Jan | NEWA |

EXEMESTANE

|    |                        |      |         |     |              |     |      |
|----|------------------------|------|---------|-----|--------------|-----|------|
|    | TABLET; ORAL           |      |         |     |              |     |      |
|    | AROMASIN               |      |         |     |              |     |      |
| AB | + PHARMACIA AND UPJOHN | 25MG | N020753 | 001 | Oct 21, 1999 | Mar | CFTG |
|    | EXEMESTANE             |      |         |     |              |     |      |
| AB | ROXANE                 | 25MG | A077431 | 001 | Apr 01, 2011 | Mar | NEWA |

FAMCICLOVIR

## TABLET; ORAL

## FAMCICLOVIR

|    |                      |       |             |              |     |      |
|----|----------------------|-------|-------------|--------------|-----|------|
| AB | AUROBINDO PHARMA LTD | 125MG | A091114 001 | Mar 21, 2011 | Mar | NEWA |
| AB |                      | 250MG | A091114 002 | Mar 21, 2011 | Mar | NEWA |
| AB |                      | 500MG | A091114 003 | Mar 21, 2011 | Mar | NEWA |
| AB | MYLAN                | 125MG | A201333 001 | Mar 24, 2011 | Mar | NEWA |
| AB |                      | 250MG | A201333 002 | Mar 24, 2011 | Mar | NEWA |
| AB |                      | 500MG | A201333 003 | Mar 24, 2011 | Mar | NEWA |
| AB | ROXANE               | 125MG | A090128 001 | Mar 21, 2011 | Mar | NEWA |
| AB |                      | 250MG | A090128 002 | Mar 21, 2011 | Mar | NEWA |
| AB |                      | 500MG | A090128 003 | Mar 21, 2011 | Mar | NEWA |
| AB | WATSON LABS          | 125MG | A078278 001 | Mar 21, 2011 | Mar | NEWA |
| AB |                      | 250MG | A078278 002 | Mar 21, 2011 | Mar | NEWA |
| AB |                      | 500MG | A078278 003 | Mar 21, 2011 | Mar | NEWA |

FAMOTIDINE

## INJECTABLE; INJECTION

## PEPCID

@ MERCK 10MG/ML

N019510 001 Nov 04, 1986 Jan DISC

## PEPCID PRESERVATIVE FREE

@ MERCK 10MG/ML

N019510 004 Nov 04, 1986 Jan DISC

## PEPCID PRESERVATIVE FREE IN PLASTIC CONTAINER

@ MERCK 0.4MG/ML

N020249 001 Feb 18, 1994 Jan DISC

## TABLET; ORAL

## FAMOTIDINE

|    |       |      |             |              |     |      |
|----|-------|------|-------------|--------------|-----|------|
| AB | MYLAN | 20MG | A075457 001 | Apr 18, 2001 | Feb | CAHN |
| AB |       | 40MG | A075457 002 | Apr 18, 2001 | Feb | CAHN |

FAMOTIDINE; IBUPROFEN

&gt;A&gt; TABLET; ORAL

&gt;A&gt; DUEXIS

&gt;A&gt; + HORIZON PHARMA 26.6MG;800MG N022519 001 Apr 23, 2011 Apr NEWA

FENOFIBRATE

## TABLET; ORAL

## FENOGLIDE

SHORE THERAP 40MG

N022118 001 Aug 10, 2007 Feb CAHN

+ 120MG

N022118 002 Aug 10, 2007 Feb CAHN

FENTANYL

## FILM, EXTENDED RELEASE; TRANSDERMAL

## FENTANYL-100

AB MALLINCKRODT INC 100MCG/HR A077154 004 Feb 09, 2011 Jan NEWA

## FENTANYL-25

AB MALLINCKRODT INC 25MCG/HR A077154 001 Feb 09, 2011 Jan NEWA

## FENTANYL-50

AB MALLINCKRODT INC 50MCG/HR A077154 002 Feb 09, 2011 Jan NEWA

## FENTANYL-75

AB MALLINCKRODT INC 75MCG/HR A077154 003 Feb 09, 2011 Jan NEWA

FENTANYL CITRATE

## TABLET; SUBLINGUAL

## ABSTRAL

PROSTRAKAN INC EQ 0.1MG BASE

N022510 001 Jan 07, 2011 Jan NEWA

## TABLET; SUBLINGUAL

## ABSTRAL

|   |                |               |             |              |     |      |
|---|----------------|---------------|-------------|--------------|-----|------|
|   | PROSTRAKAN INC | EQ 0.2MG BASE | N022510 002 | Jan 07, 2011 | Jan | NEWA |
|   |                | EQ 0.3MG BASE | N022510 003 | Jan 07, 2011 | Jan | NEWA |
| + |                | EQ 0.4MG BASE | N022510 004 | Jan 07, 2011 | Jan | NEWA |
|   |                | EQ 0.6MG BASE | N022510 005 | Jan 07, 2011 | Jan | NEWA |
|   |                | EQ 0.8MG BASE | N022510 006 | Jan 07, 2011 | Jan | NEWA |

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

|  |                    |             |             |              |     |      |
|--|--------------------|-------------|-------------|--------------|-----|------|
|  | DR REDDYS LABS LTD | 180MG;240MG | A079043 001 | Mar 17, 2010 | Jan | CTEC |
|--|--------------------|-------------|-------------|--------------|-----|------|

FLUCONAZOLE

## TABLET; ORAL

## FLUCONAZOLE

|    |              |       |             |              |     |      |
|----|--------------|-------|-------------|--------------|-----|------|
| AB | AMNEAL PHARM | 50MG  | A078423 001 | Mar 07, 2011 | Feb | NEWA |
| AB |              | 100MG | A078423 002 | Mar 07, 2011 | Feb | NEWA |
| AB |              | 150MG | A078423 003 | Mar 07, 2011 | Feb | NEWA |
| AB |              | 200MG | A078423 004 | Mar 07, 2011 | Feb | NEWA |
| AB | MYLAN        | 50MG  | A076042 001 | Jul 29, 2004 | Feb | CAHN |
| AB |              | 100MG | A076042 002 | Jul 29, 2004 | Feb | CAHN |
| AB |              | 150MG | A076042 003 | Jul 29, 2004 | Feb | CAHN |
| AB |              | 200MG | A076042 004 | Jul 29, 2004 | Feb | CAHN |

FLUDARABINE PHOSPHATE

## TABLET; ORAL

## OFORTA

|     |                     |      |             |              |     |      |
|-----|---------------------|------|-------------|--------------|-----|------|
| >D> | @ SANOFI AVENTIS US | 10MG | N022273 001 | Dec 18, 2008 | Apr | CMFD |
| >A> | +                   | 10MG | N022273 001 | Dec 18, 2008 | Apr | CMFD |
|     | @                   | 10MG | N022273 001 | Dec 18, 2008 | Jan | DISC |

FLUDEOXYGLUCOSE F-18

## INJECTABLE; INTRAVENOUS

## FLUDEOXYGLUCOSE F18

|    |   |           |              |             |              |     |      |
|----|---|-----------|--------------|-------------|--------------|-----|------|
| AP | + | FEINSTEIN | 20-200mCi/ML | N021870 001 | Aug 19, 2005 | Feb | CTEC |
| AP |   | PETNET    | 20-200mCi/ML | A079086 001 | Feb 25, 2011 | Feb | NEWA |

FLUOROURACIL

## INJECTABLE; INJECTION

## FLUOROURACIL

|     |    |           |                      |             |              |     |      |
|-----|----|-----------|----------------------|-------------|--------------|-----|------|
| >A> | AP | SANDOZ    | 2.5GM/50ML (50MG/ML) | A091299 001 | May 02, 2011 | Apr | NEWA |
| >A> | AP |           | 5GM/100ML (50MG/ML)  | A091299 002 | May 02, 2011 | Apr | NEWA |
|     |    | @ VALEANT | 500MG/10ML (50MG/ML) | N012209 001 |              | Mar | DISC |

FLUOXETINE HYDROCHLORIDE

## CAPSULE; ORAL

## FLUOXETINE HYDROCHLORIDE

|     |     |                    |              |             |              |     |      |
|-----|-----|--------------------|--------------|-------------|--------------|-----|------|
| >D> | AB1 | ALEMBIC LTD        | EQ 10MG BASE | A090223 001 | Mar 19, 2009 | Apr | CAHN |
| >D> | AB1 |                    | EQ 20MG BASE | A090223 002 | Mar 19, 2009 | Apr | CAHN |
| >D> | AB  |                    | EQ 40MG BASE | A090223 003 | Mar 19, 2009 | Apr | CAHN |
| >A> | AB1 | ALEMBIC PHARMS LTD | EQ 10MG BASE | A090223 001 | Mar 19, 2009 | Apr | CAHN |
| >A> | AB1 |                    | EQ 20MG BASE | A090223 002 | Mar 19, 2009 | Apr | CAHN |
| >A> | AB  |                    | EQ 40MG BASE | A090223 003 | Mar 19, 2009 | Apr | CAHN |

FLUTAMIDE

CAPSULE; ORAL

FLUTAMIDE

|    |       |       |             |              |     |      |
|----|-------|-------|-------------|--------------|-----|------|
| AB | MYLAN | 125MG | A076224 001 | May 09, 2003 | Feb | CAHN |
|----|-------|-------|-------------|--------------|-----|------|

FLUTICASONE PROPIONATE

LOTION; TOPICAL

CUTIVATE

|     |   |            |       |             |              |     |      |
|-----|---|------------|-------|-------------|--------------|-----|------|
| >D> | + | NYCOMED US | 0.05% | N021152 001 | Mar 31, 2005 | Apr | CFTG |
|-----|---|------------|-------|-------------|--------------|-----|------|

|     |    |   |       |             |              |     |      |
|-----|----|---|-------|-------------|--------------|-----|------|
| >A> | AB | + | 0.05% | N021152 001 | Mar 31, 2005 | Apr | CFTG |
|-----|----|---|-------|-------------|--------------|-----|------|

|     |  |                        |  |  |  |  |  |
|-----|--|------------------------|--|--|--|--|--|
| >A> |  | FLUTICASONE PROPIONATE |  |  |  |  |  |
|-----|--|------------------------|--|--|--|--|--|

|     |    |                   |       |             |              |     |      |
|-----|----|-------------------|-------|-------------|--------------|-----|------|
| >A> | AB | GLENMARK GENERICS | 0.05% | A090759 001 | May 02, 2011 | Apr | NEWA |
|-----|----|-------------------|-------|-------------|--------------|-----|------|

FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATE

@ MYLAN

50MG

|             |              |     |      |
|-------------|--------------|-----|------|
| A075950 001 | Oct 15, 2001 | Feb | CAHN |
|-------------|--------------|-----|------|

@

100MG

|             |              |     |      |
|-------------|--------------|-----|------|
| A075950 002 | Oct 15, 2001 | Feb | CAHN |
|-------------|--------------|-----|------|

FOLIC ACID

TABLET; ORAL

FOLIC ACID

|     |    |   |              |     |             |              |     |      |
|-----|----|---|--------------|-----|-------------|--------------|-----|------|
| >A> | AA | + | AMNEAL PHARM | 1MG | A040625 001 | Jul 21, 2005 | Apr | CAHN |
|-----|----|---|--------------|-----|-------------|--------------|-----|------|

|  |    |  |                  |     |             |              |     |      |
|--|----|--|------------------|-----|-------------|--------------|-----|------|
|  | AA |  | JUBILANT CADISTA | 1MG | A040514 001 | Jun 14, 2005 | Jan | CAHN |
|--|----|--|------------------|-----|-------------|--------------|-----|------|

|     |    |   |         |     |             |              |     |      |
|-----|----|---|---------|-----|-------------|--------------|-----|------|
| >D> | AA | + | PHARMAX | 1MG | A040625 001 | Jul 21, 2005 | Apr | CAHN |
|-----|----|---|---------|-----|-------------|--------------|-----|------|

FOSINOPRIL SODIUM

TABLET; ORAL

FOSINOPRIL SODIUM

|    |                      |      |             |              |     |      |
|----|----------------------|------|-------------|--------------|-----|------|
| AB | AUROBINDO PHARMA LTD | 10MG | A091163 001 | Mar 30, 2011 | Mar | NEWA |
|----|----------------------|------|-------------|--------------|-----|------|

|    |  |      |             |              |     |      |
|----|--|------|-------------|--------------|-----|------|
| AB |  | 20MG | A091163 002 | Mar 30, 2011 | Mar | NEWA |
|----|--|------|-------------|--------------|-----|------|

|    |  |      |             |              |     |      |
|----|--|------|-------------|--------------|-----|------|
| AB |  | 40MG | A091163 003 | Mar 30, 2011 | Mar | NEWA |
|----|--|------|-------------|--------------|-----|------|

FOSPHENYTOIN SODIUM

INJECTABLE; INJECTION

FOSPHENYTOIN SODIUM

|     |    |  |            |                         |             |              |     |      |
|-----|----|--|------------|-------------------------|-------------|--------------|-----|------|
| >D> | AP |  | APP PHARMS | EQ 50MG PHENYTOIN NA/ML | A078052 001 | Aug 06, 2007 | Apr | CRLD |
|-----|----|--|------------|-------------------------|-------------|--------------|-----|------|

|     |    |   |  |                         |             |              |     |      |
|-----|----|---|--|-------------------------|-------------|--------------|-----|------|
| >A> | AP | + |  | EQ 50MG PHENYTOIN NA/ML | A078052 001 | Aug 06, 2007 | Apr | CRLD |
|-----|----|---|--|-------------------------|-------------|--------------|-----|------|

GABAPENTIN

CAPSULE; ORAL

GABAPENTIN

|    |                 |       |             |              |     |      |
|----|-----------------|-------|-------------|--------------|-----|------|
| AB | MATRIX LABS LTD | 100MG | A090158 001 | Feb 14, 2011 | Jan | NEWA |
|----|-----------------|-------|-------------|--------------|-----|------|

|    |  |       |             |              |     |      |
|----|--|-------|-------------|--------------|-----|------|
| AB |  | 300MG | A090158 002 | Feb 14, 2011 | Jan | NEWA |
|----|--|-------|-------------|--------------|-----|------|

|    |  |       |             |              |     |      |
|----|--|-------|-------------|--------------|-----|------|
| AB |  | 400MG | A090158 003 | Feb 14, 2011 | Jan | NEWA |
|----|--|-------|-------------|--------------|-----|------|

SOLUTION; ORAL

GABAPENTIN

|    |                |           |             |              |     |      |
|----|----------------|-----------|-------------|--------------|-----|------|
| AA | HI TECH PHARMA | 250MG/5ML | A078974 001 | Feb 18, 2011 | Feb | NEWA |
|----|----------------|-----------|-------------|--------------|-----|------|

NEURONTIN

|    |   |             |           |             |              |     |      |
|----|---|-------------|-----------|-------------|--------------|-----|------|
| AA | + | PARKE DAVIS | 250MG/5ML | N021129 001 | Mar 02, 2000 | Feb | CFTG |
|----|---|-------------|-----------|-------------|--------------|-----|------|

TABLET; ORAL

GABAPENTIN

|    |                      |       |             |              |     |      |
|----|----------------------|-------|-------------|--------------|-----|------|
| AB | ZYDUS PHARMS USA INC | 600MG | A078926 001 | Feb 11, 2011 | Jan | NEWA |
|----|----------------------|-------|-------------|--------------|-----|------|

|    |  |       |             |              |     |      |
|----|--|-------|-------------|--------------|-----|------|
| AB |  | 800MG | A078926 002 | Feb 11, 2011 | Jan | NEWA |
|----|--|-------|-------------|--------------|-----|------|

## TABLET; ORAL

## GRALISE

|    |   |              |       |             |              |     |      |
|----|---|--------------|-------|-------------|--------------|-----|------|
| BX | + | ABBOTT PRODS | 300MG | N022544 001 | Jan 28, 2011 | Jan | NEWA |
| BX | + |              | 600MG | N022544 002 | Jan 28, 2011 | Jan | NEWA |

>A> GABAPENTIN ENACARBIL

## &gt;A&gt; TABLET, EXTENDED RELEASE; ORAL

## &gt;A&gt; HORIZANT

|     |   |               |       |             |              |     |      |
|-----|---|---------------|-------|-------------|--------------|-----|------|
| >A> | + | GLAXO GRP LTD | 600MG | N022399 001 | Apr 06, 2011 | Apr | NEWA |
|-----|---|---------------|-------|-------------|--------------|-----|------|

GADOBUTROL

## SOLUTION; INTRAVENOUS

## GADAVIST

|   |                |                              |             |              |     |      |
|---|----------------|------------------------------|-------------|--------------|-----|------|
| + | BAYER HLTHCARE | 4.5354GM/7.5ML (604.72MG/ML) | N201277 001 | Mar 14, 2011 | Mar | NEWA |
| + |                | 6.0472GM/10ML (604.72MG/ML)  | N201277 002 | Mar 14, 2011 | Mar | NEWA |
| + |                | 9.0708GM/15ML (604.72MG/ML)  | N201277 003 | Mar 14, 2011 | Mar | NEWA |
| + |                | 18.1416GM/30ML (604.72MG/ML) | N201277 004 | Mar 14, 2011 | Mar | NEWA |
| + |                | 39.3068GM/65ML (604.72MG/ML) | N201277 005 | Mar 14, 2011 | Mar | NEWA |

GALANTAMINE HYDROBROMIDE

## CAPSULE, EXTENDED RELEASE; ORAL

## GALANTAMINE HYDROBROMIDE

|    |                   |              |             |              |     |      |
|----|-------------------|--------------|-------------|--------------|-----|------|
| AB | MYLAN             | EQ 8MG BASE  | A090900 001 | Jan 24, 2011 | Jan | NEWA |
| AB |                   | EQ 16MG BASE | A090900 002 | Jan 24, 2011 | Jan | NEWA |
| AB |                   | EQ 24MG BASE | A090900 003 | Jan 24, 2011 | Jan | NEWA |
| AB | SUN PHARMA GLOBAL | EQ 8MG BASE  | A090178 001 | Feb 02, 2011 | Jan | NEWA |
| AB |                   | EQ 16MG BASE | A090178 002 | Feb 02, 2011 | Jan | NEWA |
| AB |                   | EQ 24MG BASE | A090178 003 | Feb 02, 2011 | Jan | NEWA |

## TABLET; ORAL

## GALANTAMINE HYDROBROMIDE

|    |                      |              |             |              |     |      |
|----|----------------------|--------------|-------------|--------------|-----|------|
| AB | AUROBINDO PHARMA LTD | EQ 4MG BASE  | A090957 001 | Mar 29, 2011 | Mar | NEWA |
| AB |                      | EQ 8MG BASE  | A090957 002 | Mar 29, 2011 | Mar | NEWA |
| AB |                      | EQ 12MG BASE | A090957 003 | Mar 29, 2011 | Mar | NEWA |
| AB | ZYDUS PHARMS USA INC | EQ 4MG BASE  | A078898 001 | Feb 17, 2011 | Jan | NEWA |
| AB |                      | EQ 8MG BASE  | A078898 002 | Feb 17, 2011 | Jan | NEWA |
| AB |                      | EQ 12MG BASE | A078898 003 | Feb 17, 2011 | Jan | NEWA |

GEMCITABINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## GEMCITABINE

|   |             |                  |             |              |     |      |
|---|-------------|------------------|-------------|--------------|-----|------|
| + | HOSPIRA INC | EQ 2GM BASE/VIAL | A079183 001 | Nov 15, 2010 | Feb | CRLD |
|---|-------------|------------------|-------------|--------------|-----|------|

## GEMCITABINE HYDROCHLORIDE

|    |                 |                    |                    |              |              |      |      |
|----|-----------------|--------------------|--------------------|--------------|--------------|------|------|
| AP | TEVA PARENTERAL | EQ 200MG BASE/VIAL | A077983 002        | Jan 25, 2011 | Jan          | NEWA |      |
| AP |                 | EQ 1GM BASE/VIAL   | A077983 001        | Jan 25, 2011 | Jan          | NEWA |      |
|    | GEMZAR          |                    |                    |              |              |      |      |
| AP | +               | LILLY              | EQ 200MG BASE/VIAL | N020509 001  | May 15, 1996 | Jan  | CFTG |
| AP | +               |                    | EQ 1GM BASE/VIAL   | N020509 002  | May 15, 1996 | Jan  | CFTG |

GEMFIBROZIL

## TABLET; ORAL

## GEMFIBROZIL

|    |            |       |             |              |     |      |
|----|------------|-------|-------------|--------------|-----|------|
| AB | BLU CARIBE | 600MG | A078012 001 | Mar 26, 2007 | Feb | CAHN |
|----|------------|-------|-------------|--------------|-----|------|

GENTAMICIN SULFATE

## OINTMENT; OPHTHALMIC

## GENTAMICIN SULFATE

|    |             |              |             |              |     |      |
|----|-------------|--------------|-------------|--------------|-----|------|
| AT | FERA PHARMS | EQ 0.3% BASE | A065024 001 | Jul 30, 2004 | Feb | CAHN |
| AT | NYCOMED US  | EQ 0.3% BASE | A065024 001 | Jul 30, 2004 | Jan | CAHN |

## SOLUTION/DROPS; OPHTHALMIC

## GENTAMICIN SULFATE

|    |             |              |             |              |     |      |
|----|-------------|--------------|-------------|--------------|-----|------|
| AT | FERA PHARMS | EQ 0.3% BASE | A065121 001 | Jan 30, 2004 | Feb | CAHN |
|----|-------------|--------------|-------------|--------------|-----|------|

GLIMEPIRIDE

## TABLET; ORAL

## GLIMEPIRIDE

|    |       |     |             |              |     |      |
|----|-------|-----|-------------|--------------|-----|------|
| AB | MYLAN | 1MG | A077486 001 | Feb 10, 2006 | Feb | CAHN |
| AB |       | 2MG | A077486 002 | Feb 10, 2006 | Feb | CAHN |
| AB |       | 4MG | A077486 003 | Feb 10, 2006 | Feb | CAHN |

GLIPIZIDE; METFORMIN HYDROCHLORIDE

## TABLET; ORAL

## GLIPIZIDE AND METFORMIN HYDROCHLORIDE

|    |                      |             |             |              |     |      |
|----|----------------------|-------------|-------------|--------------|-----|------|
| AB | ZYDUS PHARMS USA INC | 2.5MG;250MG | A078905 001 | Jan 31, 2011 | Jan | NEWA |
| AB |                      | 2.5MG;500MG | A078905 002 | Jan 31, 2011 | Jan | NEWA |
| AB |                      | 5MG;500MG   | A078905 003 | Jan 31, 2011 | Jan | NEWA |

GLYBURIDE

## TABLET; ORAL

## GLYBURIDE

|    |                |        |             |              |     |      |
|----|----------------|--------|-------------|--------------|-----|------|
| AB | INDICUS PHARMA | 1.25MG | A090937 001 | Feb 28, 2011 | Feb | NEWA |
| AB |                | 2.5MG  | A090937 002 | Feb 28, 2011 | Feb | NEWA |
| AB |                | 5MG    | A090937 003 | Feb 28, 2011 | Feb | NEWA |

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

## TABLET; ORAL

## FULVICIN P/G

|          |       |             |  |     |      |
|----------|-------|-------------|--|-----|------|
| @ ELORAC | 125MG | A061996 001 |  | Jan | CAHN |
| @        | 250MG | A061996 002 |  | Jan | CAHN |

## FULVICIN P/G 165

|          |       |             |              |     |      |
|----------|-------|-------------|--------------|-----|------|
| @ ELORAC | 165MG | A061996 003 | Apr 06, 1982 | Jan | CAHN |
|----------|-------|-------------|--------------|-----|------|

## FULVICIN P/G 330

|          |       |             |              |     |      |
|----------|-------|-------------|--------------|-----|------|
| @ ELORAC | 330MG | A061996 004 | Apr 06, 1982 | Jan | CAHN |
|----------|-------|-------------|--------------|-----|------|

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

## TABLET; ORAL

## HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE

|     |    |                |           |             |              |     |      |
|-----|----|----------------|-----------|-------------|--------------|-----|------|
| >A> | AB | NOVEL LABS INC | 1.5MG;5MG | A091528 001 | Apr 20, 2011 | Apr | NEWA |
|     |    | TUSSIGON       |           |             |              |     |      |
| >D> | +  | KING PHARMS    | 1.5MG;5MG | A088508 001 | Jul 30, 1985 | Apr | CTEC |
| >A> | AB | +              | 1.5MG;5MG | A088508 001 | Jul 30, 1985 | Apr | CTEC |

HYDROCHLOROTHIAZIDE

## CAPSULE; ORAL

## HYDROCHLOROTHIAZIDE

|     |    |                    |        |             |              |     |      |
|-----|----|--------------------|--------|-------------|--------------|-----|------|
| >D> | AB | ALEMBIC LTD        | 12.5MG | A200645 001 | Nov 30, 2010 | Apr | CAHN |
| >A> | AB | ALEMBIC PHARMS LTD | 12.5MG | A200645 001 | Nov 30, 2010 | Apr | CAHN |
|     | AB | JUBILANT CADISTA   | 12.5MG | A078391 001 | Feb 11, 2008 | Jan | CAHN |

## TABLET; ORAL

## HYDROCHLOROTHIAZIDE

|    |                  |      |             |              |     |      |
|----|------------------|------|-------------|--------------|-----|------|
| AB | JUBILANT CADISTA | 25MG | A040809 001 | Sep 04, 2007 | Jan | CAHN |
| AB |                  | 50MG | A040809 002 | Sep 04, 2007 | Jan | CAHN |

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

## TABLET; ORAL

## LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

|    |             |              |             |              |     |      |
|----|-------------|--------------|-------------|--------------|-----|------|
| AB | WATSON LABS | 12.5MG;50MG  | A200180 001 | Jan 12, 2011 | Jan | NEWA |
| AB |             | 12.5MG;100MG | A200180 002 | Jan 12, 2011 | Jan | NEWA |
| AB |             | 25MG;100MG   | A200180 003 | Jan 12, 2011 | Jan | NEWA |

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

## TABLET; ORAL

## QUINAPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

|     |    |                |             |             |              |     |      |
|-----|----|----------------|-------------|-------------|--------------|-----|------|
| >A> | AB | INVAGEN PHARMS | 12.5MG;10MG | A201356 001 | Apr 20, 2011 | Apr | NEWA |
| >A> | AB |                | 12.5MG;20MG | A201356 002 | Apr 20, 2011 | Apr | NEWA |
| >A> | AB |                | 25MG;20MG   | A201356 003 | Apr 20, 2011 | Apr | NEWA |

HYDROCORTISONE

## TABLET; ORAL

## HYDROCORTISONE

|     |    |             |      |             |              |     |      |
|-----|----|-------------|------|-------------|--------------|-----|------|
| >A> | AB | COREPHARMA  | 5MG  | A040646 001 | Mar 30, 2007 | Apr | CAHN |
| >A> | AB |             | 10MG | A040646 002 | Mar 30, 2007 | Apr | CAHN |
| >A> | AB |             | 20MG | A040646 003 | Mar 30, 2007 | Apr | CAHN |
| >D> | AB | STIEFEL GSK | 5MG  | A040646 001 | Mar 30, 2007 | Apr | CAHN |
| >D> | AB |             | 10MG | A040646 002 | Mar 30, 2007 | Apr | CAHN |
| >D> | AB |             | 20MG | A040646 003 | Mar 30, 2007 | Apr | CAHN |

HYDROCORTISONE ACETATE

## OINTMENT; OPHTHALMIC

## HYDROCORTISONE ACETATE

|               |      |             |  |     |      |
|---------------|------|-------------|--|-----|------|
| @ FERA PHARMS | 0.5% | A080828 001 |  | Mar | CAHN |
|---------------|------|-------------|--|-----|------|

HYDROMORPHONE HYDROCHLORIDE

## TABLET; ORAL

## HYDROMORPHONE HYDROCHLORIDE

|    |            |     |             |              |     |      |
|----|------------|-----|-------------|--------------|-----|------|
| AB | ELITE LABS | 8MG | A076723 001 | Oct 18, 2005 | Feb | CAHN |
|----|------------|-----|-------------|--------------|-----|------|

HYDROXOCOBALAMIN

## INJECTABLE; INJECTION

## CYANOKIT

|     |                   |                    |             |              |     |      |
|-----|-------------------|--------------------|-------------|--------------|-----|------|
| >D> |                   |                    |             |              |     |      |
| >A> | @ MERCK SANTE SAS | 5GM/VIAL (5GM/KIT) | N022041 001 | Apr 08, 2011 | Apr | DISC |

HYDROXYAMPHETAMINE HYDROBROMIDE

## SOLUTION/DROPS; OPHTHALMIC

## PAREDRIE

|            |    |             |  |     |      |
|------------|----|-------------|--|-----|------|
| @ PHARMICS | 1% | N000004 004 |  | Jan | CAHN |
|------------|----|-------------|--|-----|------|

HYDROXYPROGESTERONE CAPROATE

## SOLUTION; INTRAMUSCULAR

## MAKENA

|   |          |                       |             |              |     |      |
|---|----------|-----------------------|-------------|--------------|-----|------|
| + | KV PHARM | 1250MG/5ML (250MG/ML) | N021945 001 | Feb 03, 2011 | Feb | NEWA |
|---|----------|-----------------------|-------------|--------------|-----|------|

IDARUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

IDARUBICIN HYDROCHLORIDE

|    |        |        |             |              |     |      |
|----|--------|--------|-------------|--------------|-----|------|
| AP | SANDOZ | 1MG/ML | A091293 001 | Mar 29, 2011 | Mar | NEWA |
|----|--------|--------|-------------|--------------|-----|------|

ILOPERIDONE

TABLET; ORAL

FANAPT

NOVARTIS

2MG

N022192 002 May 06, 2009 Jan CAHN

4MG

N022192 003 May 06, 2009 Jan CAHN

6MG

N022192 004 May 06, 2009 Jan CAHN

8MG

N022192 005 May 06, 2009 Jan CAHN

10MG

N022192 006 May 06, 2009 Jan CAHN

IMIQUIMOD

CREAM; TOPICAL

IMIQUIMOD

|     |    |      |    |             |              |     |      |
|-----|----|------|----|-------------|--------------|-----|------|
| >A> | AB | TARO | 5% | A200173 001 | Apr 15, 2011 | Apr | NEWA |
|-----|----|------|----|-------------|--------------|-----|------|

|     |    |                 |    |             |              |     |      |
|-----|----|-----------------|----|-------------|--------------|-----|------|
| >A> | AB | TEVA PHARMS USA | 5% | A200481 001 | Apr 18, 2011 | Apr | NEWA |
|-----|----|-----------------|----|-------------|--------------|-----|------|

|  |    |        |    |             |              |     |      |
|--|----|--------|----|-------------|--------------|-----|------|
|  | AB | TOLMAR | 5% | A091044 001 | Feb 28, 2011 | Feb | NEWA |
|--|----|--------|----|-------------|--------------|-----|------|

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

|    |                  |      |             |              |     |      |
|----|------------------|------|-------------|--------------|-----|------|
| AB | HETERO DRUGS LTD | 25MG | A091240 001 | Apr 12, 2011 | Mar | NEWA |
|----|------------------|------|-------------|--------------|-----|------|

|    |  |      |             |              |     |      |
|----|--|------|-------------|--------------|-----|------|
| AB |  | 50MG | A091240 002 | Apr 12, 2011 | Mar | NEWA |
|----|--|------|-------------|--------------|-----|------|

CAPSULE, EXTENDED RELEASE; ORAL

INDOMETHACIN

|    |   |        |      |             |              |     |      |
|----|---|--------|------|-------------|--------------|-----|------|
| AB | + | SANDOZ | 75MG | A074464 001 | May 28, 1998 | Jan | CTNA |
|----|---|--------|------|-------------|--------------|-----|------|

IOFLUPANE I-123

SOLUTION; INTRAVENOUS

DATSCAN

|   |                 |                      |             |              |     |      |
|---|-----------------|----------------------|-------------|--------------|-----|------|
| + | GE HLTHCARE INC | 5MCI/2.5ML (2MCI/ML) | N022454 001 | Jan 14, 2011 | Jan | NEWA |
|---|-----------------|----------------------|-------------|--------------|-----|------|

IOPAMIDOL

INJECTABLE; INJECTION

IOPAMIDOL-200

@ HOSPIRA 41%

A074898 001 Dec 30, 1997 Feb DISC

IOPAMIDOL-200 IN PLASTIC CONTAINER

@ HOSPIRA 41%

A074636 001 Dec 30, 1997 Feb DISC

IOPAMIDOL-250

@ HOSPIRA 51%

A074898 002 Dec 30, 1997 Feb DISC

IOPAMIDOL-250 IN PLASTIC CONTAINER

@ HOSPIRA 51%

A074636 002 Dec 30, 1997 Feb DISC

IOPAMIDOL-300

@ HOSPIRA 61%

A074898 003 Dec 30, 1997 Feb DISC

IOPAMIDOL-300 IN PLASTIC CONTAINER

@ HOSPIRA 61%

A074636 003 Dec 30, 1997 Feb DISC

IOPAMIDOL-370

@ HOSPIRA 76%

A074898 004 Dec 30, 1997 Feb DISC

IOPAMIDOL-370 IN PLASTIC CONTAINER

@ HOSPIRA 76%

A074636 004 Dec 30, 1997 Feb DISC



IRON SUCROSE

## INJECTABLE; INTRAVENOUS

## VENOFER

|     |            |                                      |             |              |     |      |
|-----|------------|--------------------------------------|-------------|--------------|-----|------|
| >D> | @ LUITPOLD | EQ 50MG BASE/2.5ML (EQ 20MG BASE/ML) | N021135 002 | Mar 20, 2005 | Apr | CMFD |
| >A> |            | EQ 50MG BASE/2.5ML (EQ 20MG BASE/ML) | N021135 002 | Mar 20, 2005 | Apr | CMFD |

ISRADIPINE

## CAPSULE; ORAL

## ISRADIPINE

|    |              |       |             |              |     |      |
|----|--------------|-------|-------------|--------------|-----|------|
| AB | MIKAH PHARMA | 2.5MG | A077169 001 | Apr 24, 2006 | Feb | CAHN |
| AB |              | 5MG   | A077169 002 | Apr 24, 2006 | Feb | CAHN |

LAMOTRIGINE

## TABLET; ORAL

## LAMOTRIGINE

|     |                       |       |             |              |     |      |
|-----|-----------------------|-------|-------------|--------------|-----|------|
| AB  | ACTAVIS TOTOWA        | 25MG  | A078669 001 | Apr 08, 2011 | Mar | NEWA |
| AB  |                       | 100MG | A078669 002 | Apr 08, 2011 | Mar | NEWA |
| AB  |                       | 150MG | A078669 003 | Apr 08, 2011 | Mar | NEWA |
| AB  |                       | 200MG | A078669 004 | Apr 08, 2011 | Mar | NEWA |
| >D> | AB ALEMBIC LTD        | 25MG  | A090607 001 | Jan 13, 2011 | Apr | CAHN |
|     | AB                    | 25MG  | A090607 001 | Jan 13, 2011 | Jan | NEWA |
| >D> | AB                    | 100MG | A090607 002 | Jan 13, 2011 | Apr | CAHN |
|     | AB                    | 100MG | A090607 002 | Jan 13, 2011 | Jan | NEWA |
| >D> | AB                    | 150MG | A090607 003 | Jan 13, 2011 | Apr | CAHN |
|     | AB                    | 150MG | A090607 003 | Jan 13, 2011 | Jan | NEWA |
| >D> | AB                    | 200MG | A090607 004 | Jan 13, 2011 | Apr | CAHN |
|     | AB                    | 200MG | A090607 004 | Jan 13, 2011 | Jan | NEWA |
| >A> | AB ALEMBIC PHARMS LTD | 25MG  | A090607 001 | Jan 13, 2011 | Apr | CAHN |
| >A> | AB                    | 100MG | A090607 002 | Jan 13, 2011 | Apr | CAHN |
| >A> | AB                    | 150MG | A090607 003 | Jan 13, 2011 | Apr | CAHN |
| >A> | AB                    | 200MG | A090607 004 | Jan 13, 2011 | Apr | CAHN |
| >A> | AB HIKMA PHARMS       | 25MG  | A078134 001 | Apr 19, 2011 | Apr | NEWA |
| >A> | AB                    | 100MG | A078134 002 | Apr 19, 2011 | Apr | NEWA |
| >A> | AB                    | 150MG | A078134 003 | Apr 19, 2011 | Apr | NEWA |
| >A> | AB                    | 200MG | A078134 004 | Apr 19, 2011 | Apr | NEWA |

## TABLET, CHEWABLE; ORAL

## LAMOTRIGINE

|    |               |      |             |              |     |      |
|----|---------------|------|-------------|--------------|-----|------|
| AB | JUBILANT LIFE | 5MG  | A200220 001 | Feb 28, 2011 | Feb | NEWA |
| AB |               | 25MG | A200220 002 | Feb 28, 2011 | Feb | NEWA |

LATANOPROST

## SOLUTION/DROPS; OPHTHALMIC

## LATANOPROST

|    |                 |        |             |              |     |      |
|----|-----------------|--------|-------------|--------------|-----|------|
| AT | ALCON RES       | 0.005% | A091449 001 | Mar 22, 2011 | Mar | NEWA |
| AT | APOTEX          | 0.005% | A077697 001 | Mar 22, 2011 | Mar | NEWA |
| AT | BAUSCH AND LOMB | 0.005% | A201006 001 | Mar 22, 2011 | Mar | NEWA |
| AT | MYLAN           | 0.005% | A201786 001 | Mar 22, 2011 | Mar | NEWA |
| AT | PHARMAFORCE     | 0.005% | A200925 001 | Mar 22, 2011 | Mar | NEWA |

## XALATAN

|    |                        |        |             |              |     |      |
|----|------------------------|--------|-------------|--------------|-----|------|
| AT | + PHARMACIA AND UPJOHN | 0.005% | N020597 001 | Jun 05, 1996 | Mar | CFTG |
|----|------------------------|--------|-------------|--------------|-----|------|

LEUPROLIDE ACETATE

INJECTABLE; INJECTION

LEUPROLIDE ACETATE

|     |    |         |           |             |              |     |      |
|-----|----|---------|-----------|-------------|--------------|-----|------|
| >D> | AP | GENZYME | 1MG/0.2ML | A075721 001 | Nov 29, 2001 | Apr | DISC |
| >A> |    | @       | 1MG/0.2ML | A075721 001 | Nov 29, 2001 | Apr | DISC |

LEVETIRACETAM

TABLET; ORAL

LEVETIRACETAM

|    |  |                 |       |             |              |     |      |
|----|--|-----------------|-------|-------------|--------------|-----|------|
| AB |  | ACCORD HLTHCARE | 250MG | A090843 001 | Feb 14, 2011 | Jan | NEWA |
| AB |  |                 | 500MG | A090843 002 | Feb 14, 2011 | Jan | NEWA |
| AB |  |                 | 750MG | A090843 003 | Feb 14, 2011 | Jan | NEWA |
| AB |  |                 | 1GM   | A090843 004 | Feb 14, 2011 | Jan | NEWA |

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET; ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

|    |  |                    |     |             |              |     |      |
|----|--|--------------------|-----|-------------|--------------|-----|------|
| AB |  | DR REDDYS LABS LTD | 5MG | A090392 001 | Feb 24, 2011 | Feb | NEWA |
| AB |  | GLENMARK GENERICS  | 5MG | A090385 001 | Feb 24, 2011 | Feb | NEWA |

LEVOFLOXACIN

SOLUTION/DROPS; OPHTHALMIC

LEVOFLOXACIN

|    |  |                |      |             |              |     |      |
|----|--|----------------|------|-------------|--------------|-----|------|
| AT |  | HI TECH PHARMA | 0.5% | A076826 001 | Feb 10, 2011 | Jan | NEWA |
|----|--|----------------|------|-------------|--------------|-----|------|

LEVOLEUCOVORIN CALCIUM

POWDER; IV (INFUSION)

FUSILEV

|     |   |                 |                                        |             |              |     |      |
|-----|---|-----------------|----------------------------------------|-------------|--------------|-----|------|
| >A> | + | SPECTRUM PHARMS | EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML) | N020140 002 | Apr 20, 2011 | Apr | NEWA |
| >A> | + |                 | EQ 250MG BASE/25ML (EQ 10MG BASE/ML)   | N020140 003 | Apr 20, 2011 | Apr | NEWA |

LEVONORGESTREL

TABLET; ORAL

PLAN B

@ TEVA WOMENS

|    |   |  |        |             |              |     |      |
|----|---|--|--------|-------------|--------------|-----|------|
|    |   |  | 0.75MG | N021045 001 | Jul 28, 1999 | Feb | CAHN |
| AB | + |  | 0.75MG | N021045 002 | Aug 24, 2006 | Feb | CAHN |

LEVORPHANOL TARTRATE

TABLET; ORAL

LEVO-DROMORAN

@ VALEANT PHARM INTL

LEVORPHANOL TARTRATE

ROXANE

|  |  |     |             |              |     |      |
|--|--|-----|-------------|--------------|-----|------|
|  |  | 2MG | N008720 001 | Dec 19, 1991 | Mar | DISC |
|  |  | 2MG | A074278 001 | Mar 31, 2000 | Mar | CTEC |

LEVOTHYROXINE SODIUM\*\*

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

TABLET; ORAL

LEVO-T

|                     |  |             |         |             |              |     |      |
|---------------------|--|-------------|---------|-------------|--------------|-----|------|
| AB1,<br>AB2,<br>AB3 |  | ALARA PHARM | 0.025MG | N021342 001 | Mar 01, 2002 | Feb | CTEC |
| AB1,<br>AB2,<br>AB3 |  |             | 0.05MG  | N021342 002 | Mar 01, 2002 | Feb | CTEC |

## TABLET; ORAL

## LEV0-T

|                       |             |         |             |              |     |      |
|-----------------------|-------------|---------|-------------|--------------|-----|------|
| AB1,<br>AB2,<br>AB3   | ALARA PHARM | 0.075MG | N021342 003 | Mar 01, 2002 | Feb | CTEC |
| AB1,<br>AB2,<br>AB3   |             | 0.088MG | N021342 004 | Mar 01, 2002 | Feb | CTEC |
| AB1,<br>AB2,<br>AB3   |             | 0.1MG   | N021342 005 | Mar 01, 2002 | Feb | CTEC |
| AB1,<br>AB2,<br>AB3   |             | 0.112MG | N021342 006 | Mar 01, 2002 | Feb | CTEC |
| AB1,<br>AB2,<br>AB3   |             | 0.125MG | N021342 007 | Mar 01, 2002 | Feb | CTEC |
| AB1,<br>AB2,<br>AB3   |             | 0.137MG | N021342 012 | Dec 08, 2003 | Feb | CTEC |
| AB1,<br>AB2,<br>AB3   |             | 0.15MG  | N021342 008 | Mar 01, 2002 | Feb | CTEC |
| AB1,<br>AB2,<br>AB3   |             | 0.175MG | N021342 009 | Mar 01, 2002 | Feb | CTEC |
| AB1,<br>AB2,<br>AB3   |             | 0.2MG   | N021342 010 | Mar 01, 2002 | Feb | CTEC |
| AB1, +<br>AB2,<br>AB3 |             | 0.3MG   | N021342 011 | Mar 01, 2002 | Feb | CTEC |

LIDOCAINE HYDROCHLORIDE

## JELLY; TOPICAL

## LIDOCAINE HYDROCHLORIDE

|    |                |    |             |              |     |      |
|----|----------------|----|-------------|--------------|-----|------|
| AT | HI TECH PHARMA | 2% | A040837 001 | Mar 23, 2011 | Mar | NEWA |
|----|----------------|----|-------------|--------------|-----|------|

LITHIUM CARBONATE

## TABLET, EXTENDED RELEASE; ORAL

## LITHIUM CARBONATE

|    |                   |       |             |              |     |      |
|----|-------------------|-------|-------------|--------------|-----|------|
| AB | GLENMARK GENERICS | 450MG | A091616 001 | Feb 14, 2011 | Jan | NEWA |
|----|-------------------|-------|-------------|--------------|-----|------|

LOSARTAN POTASSIUM

## TABLET; ORAL

## LOSARTAN POTASSIUM

|     |    |                    |       |             |              |     |      |
|-----|----|--------------------|-------|-------------|--------------|-----|------|
| >D> | AB | ALEMBIC LTD        | 25MG  | A090428 001 | Oct 06, 2010 | Apr | CAHN |
| >D> | AB |                    | 100MG | A090428 003 | Oct 06, 2010 | Apr | CAHN |
| >A> | AB | ALEMBIC PHARMS LTD | 25MG  | A090428 001 | Oct 06, 2010 | Apr | CAHN |
| >A> | AB |                    | 50MG  | A090428 002 | Oct 06, 2010 | Apr | NEWA |
| >A> | AB |                    | 50MG  | A090428 002 | Oct 06, 2010 | Apr | NEWA |
| >A> | AB |                    | 100MG | A090428 003 | Oct 06, 2010 | Apr | CAHN |
|     | AB | MYLAN              | 25MG  | A091590 001 | Oct 06, 2010 | Jan | NEWA |
|     | AB |                    | 50MG  | A091590 002 | Oct 06, 2010 | Jan | NEWA |
|     | AB |                    | 100MG | A091590 003 | Oct 06, 2010 | Jan | NEWA |

LOTEPREDNOL ETABONATE

>A> OINTMENT; OPHTHALMIC

>A> LOTEMAX

|     |   |                 |      |             |              |     |      |
|-----|---|-----------------|------|-------------|--------------|-----|------|
| >A> | + | BAUSCH AND LOMB | 0.5% | N200738 001 | Apr 15, 2011 | Apr | NEWA |
|-----|---|-----------------|------|-------------|--------------|-----|------|

MECLIZINE HYDROCHLORIDE

## TABLET; ORAL

## MECLIZINE HYDROCHLORIDE

|    |                  |        |             |              |     |      |
|----|------------------|--------|-------------|--------------|-----|------|
| AA | AMNEAL PHARMS    | 12.5MG | A201451 001 | Feb 23, 2011 | Feb | NEWA |
| AA |                  | 25MG   | A201451 002 | Feb 23, 2011 | Feb | NEWA |
| AA |                  | 50MG   | A201451 003 | Feb 23, 2011 | Feb | NEWA |
| AA | JUBILANT CADISTA | 12.5MG | A040659 001 | Jun 04, 2010 | Jan | CAHN |
| AA |                  | 25MG   | A040659 002 | Jun 04, 2010 | Jan | CAHN |

MELOXICAM

## TABLET; ORAL

## MELOXICAM

|    |       |       |             |              |     |      |
|----|-------|-------|-------------|--------------|-----|------|
| AB | MYLAN | 7.5MG | A077934 001 | Jul 20, 2006 | Feb | CAHN |
| AB |       | 15MG  | A077934 002 | Jul 20, 2006 | Feb | CAHN |

MEROPENEM

## INJECTABLE; INJECTION

## MEROPENEM

|    |               |            |             |              |     |      |
|----|---------------|------------|-------------|--------------|-----|------|
| AP | SANDOZ        | 500MG/VIAL | A091201 001 | Mar 29, 2011 | Mar | NEWA |
| AP |               | 1GM/VIAL   | A091201 002 | Mar 29, 2011 | Mar | NEWA |
|    | MERREM        |            |             |              |     |      |
| AP | + ASTRAZENECA | 500MG/VIAL | N050706 003 | Jun 21, 1996 | Mar | CTNA |
| AP | +             | 1GM/VIAL   | N050706 001 | Jun 21, 1996 | Mar | CTNA |

METFORMIN HYDROCHLORIDE

## TABLET; ORAL

## METFORMIN HYDROCHLORIDE

|    |       |       |             |              |     |      |
|----|-------|-------|-------------|--------------|-----|------|
| AB | MYLAN | 500MG | A075973 001 | Jan 25, 2002 | Feb | CAHN |
| AB |       | 850MG | A075973 002 | Jan 25, 2002 | Feb | CAHN |
| AB |       | 1GM   | A075973 003 | Jan 25, 2002 | Feb | CAHN |

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

## TABLET; ORAL

## ACTOPLUS MET

|    |                                                        |                    |             |              |     |      |
|----|--------------------------------------------------------|--------------------|-------------|--------------|-----|------|
| AB | TAKEDA GLOBAL                                          | 500MG;EQ 15MG BASE | N021842 001 | Aug 29, 2005 | Feb | CFTG |
| AB | +                                                      | 850MG;EQ 15MG BASE | N021842 002 | Aug 29, 2005 | Feb | CFTG |
|    | PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE |                    |             |              |     |      |
| AB | MYLAN                                                  | 500MG;EQ 15MG BASE | A090406 001 | Feb 25, 2011 | Feb | NEWA |
| AB |                                                        | 850MG;EQ 15MG BASE | A090406 002 | Feb 25, 2011 | Feb | NEWA |

METHYLERGONOVINE MALEATE

## TABLET; ORAL

## METHERGINE

|     |                          |                |       |             |              |     |      |
|-----|--------------------------|----------------|-------|-------------|--------------|-----|------|
| >D> | +                        | NOVARTIS       | 0.2MG | N006035 003 |              | Apr | CTEC |
| >A> | AB                       | +              | 0.2MG | N006035 003 |              | Apr | CTEC |
|     | METHYLERGONOVINE MALEATE |                |       |             |              |     |      |
| >A> | AB                       | NOVEL LABS INC | 0.2MG | A091577 001 | May 02, 2011 | Apr | NEWA |

METHYLPREDNISOLONE

## TABLET; ORAL

## METHYLPREDNISOLONE

|    |                  |      |             |              |     |      |
|----|------------------|------|-------------|--------------|-----|------|
| AB | JUBILANT CADISTA | 4MG  | A040189 001 | Oct 31, 1997 | Jan | CAHN |
| AB |                  | 8MG  | A040189 002 | Oct 31, 1997 | Jan | CAHN |
| AB |                  | 16MG | A040189 003 | Jul 20, 2007 | Jan | CAHN |
| AB |                  | 32MG | A040189 004 | Jul 20, 2007 | Jan | CAHN |

METHYLPREDNISOLONE SODIUM SUCCINATE

## INJECTABLE; INJECTION

## A-METHAPRED

|     |    |               |                    |             |              |     |      |
|-----|----|---------------|--------------------|-------------|--------------|-----|------|
| >A> | AP | HEMOPARM      | EQ 40MG BASE/VIAL  | A040793 001 | Nov 25, 2008 | Apr | CAHN |
| >A> | AP |               | EQ 125MG BASE/VIAL | A040827 001 | Nov 25, 2008 | Apr | CAHN |
| >D> | AP | HEMOPHARM USA | EQ 40MG BASE/VIAL  | A040793 001 | Nov 25, 2008 | Apr | CAHN |
| >D> | AP |               | EQ 125MG BASE/VIAL | A040827 001 | Nov 25, 2008 | Apr | CAHN |
|     |    | @ HOSPIRA     | EQ 500MG BASE/VIAL | A089173 001 | Aug 18, 1987 | Feb | DISC |
|     |    | @             | EQ 1GM BASE/VIAL   | A089174 001 | Aug 18, 1987 | Feb | DISC |

METRONIDAZOLE

## GEL; TOPICAL

## METRONIDAZOLE

|    |  |                  |       |             |              |     |      |
|----|--|------------------|-------|-------------|--------------|-----|------|
| AB |  | G AND W LABS INC | 0.75% | A078178 001 | Jan 19, 2011 | Jan | NEWA |
|----|--|------------------|-------|-------------|--------------|-----|------|

MICAFUNGIN SODIUM

## INJECTABLE; IV (INFUSION)

## MYCAMINE

|   |          |            |             |              |     |      |
|---|----------|------------|-------------|--------------|-----|------|
| + | ASTELLAS | 100MG/VIAL | N021506 003 | Jun 27, 2006 | Jan | CRLD |
|---|----------|------------|-------------|--------------|-----|------|

MIDAZOLAM HYDROCHLORIDE

## INJECTABLE; INJECTION

## MIDOZALAM HYDROCHLORIDE

|     |    |                |                |             |              |     |      |
|-----|----|----------------|----------------|-------------|--------------|-----|------|
| >A> | AP | SAGENT STRIDES | EQ 1MG BASE/ML | A090316 001 | May 04, 2011 | Apr | NEWA |
| >A> | AP |                | EQ 5MG BASE/ML | A090316 002 | May 04, 2011 | Apr | NEWA |

MILRINONE LACTATE

## INJECTABLE; INJECTION

## MILRINONE LACTATE

|   |         |                |             |              |     |      |
|---|---------|----------------|-------------|--------------|-----|------|
| @ | HOSPIRA | EQ 1MG BASE/ML | A075884 001 | May 28, 2002 | Feb | DISC |
|---|---------|----------------|-------------|--------------|-----|------|

MIRTAZAPINE

## TABLET, ORALLY DISINTEGRATING; ORAL

## MIRTAZAPINE

|    |  |                   |      |             |              |     |      |
|----|--|-------------------|------|-------------|--------------|-----|------|
| AB |  | ACTAVIS ELIZABETH | 15MG | A077959 001 | Feb 14, 2011 | Jan | NEWA |
| AB |  |                   | 30MG | A077959 002 | Feb 14, 2011 | Jan | NEWA |
| AB |  |                   | 45MG | A077959 003 | Feb 14, 2011 | Jan | NEWA |

MUPIROCIN CALCIUM

## CREAM; TOPICAL

## BACTROBAN

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

NABUMETONE

## TABLET; ORAL

## NABUMETONE

|    |  |           |       |             |              |     |      |
|----|--|-----------|-------|-------------|--------------|-----|------|
| AB |  | LUPIN LTD | 500MG | A090445 001 | Jan 12, 2011 | Jan | NEWA |
| AB |  |           | 750MG | A090445 002 | Jan 12, 2011 | Jan | NEWA |

NAFCILLIN SODIUM

## INJECTABLE; INJECTION

## NAFCILLIN SODIUM

|     |    |        |                   |             |              |     |      |
|-----|----|--------|-------------------|-------------|--------------|-----|------|
| >A> | AP | IBI    | EQ 10GM BASE/VIAL | A090005 001 | Apr 20, 2011 | Apr | NEWA |
| >D> | +  | SANDOZ | EQ 10GM BASE/VIAL | A062527 004 | Aug 02, 1984 | Apr | CTEC |

## INJECTABLE; INJECTION

## NAFCILLIN SODIUM

|     |    |   |        |                   |         |     |              |     |      |
|-----|----|---|--------|-------------------|---------|-----|--------------|-----|------|
| >A> | AP | + | SANDOZ | EQ 10GM BASE/VIAL | A062527 | 004 | Aug 02, 1984 | Apr | CTEC |
|-----|----|---|--------|-------------------|---------|-----|--------------|-----|------|

NALTREXONE HYDROCHLORIDE

## TABLET; ORAL

## NALTREXONE HYDROCHLORIDE

|    |  |            |      |         |     |              |     |      |
|----|--|------------|------|---------|-----|--------------|-----|------|
| AB |  | ELITE LABS | 50MG | A075274 | 001 | May 26, 1999 | Feb | CAHN |
|----|--|------------|------|---------|-----|--------------|-----|------|

NAPROXEN

## TABLET; ORAL

## NAPROXEN

|    |  |                 |       |         |     |              |     |      |
|----|--|-----------------|-------|---------|-----|--------------|-----|------|
| AB |  | MARKSANS PHARMA | 250MG | A091416 | 001 | Feb 14, 2011 | Jan | NEWA |
| AB |  |                 | 375MG | A091416 | 002 | Feb 14, 2011 | Jan | NEWA |
| AB |  |                 | 500MG | A091416 | 003 | Feb 14, 2011 | Jan | NEWA |

NARATRIPTAN

## TABLET; ORAL

## NARATRIPTAN

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

NARATRIPTAN HYDROCHLORIDE

## TABLET; ORAL

## NARATRIPTAN

|    |  |                |               |         |     |              |     |      |
|----|--|----------------|---------------|---------|-----|--------------|-----|------|
| AB |  | INDICUS PHARMA | EQ 1MG BASE   | A200502 | 001 | Feb 28, 2011 | Feb | NEWA |
| AB |  |                | EQ 2.5MG BASE | A200502 | 002 | Feb 28, 2011 | Feb | NEWA |

NATEGLINIDE

## TABLET; ORAL

## NATEGLINIDE

|    |  |             |       |         |     |              |     |      |
|----|--|-------------|-------|---------|-----|--------------|-----|------|
| AB |  | WATSON LABS | 60MG  | A077462 | 001 | Mar 30, 2011 | Mar | NEWA |
| AB |  |             | 120MG | A077462 | 002 | Mar 30, 2011 | Mar | NEWA |

NEVIRAPINE

## TABLET, EXTENDED RELEASE; ORAL

## VIRAMUNE XR

|  |   |                      |       |         |     |              |     |      |
|--|---|----------------------|-------|---------|-----|--------------|-----|------|
|  | + | BOEHRINGER INGELHEIM | 400MG | N201152 | 001 | Mar 25, 2011 | Mar | NEWA |
|--|---|----------------------|-------|---------|-----|--------------|-----|------|

NIFEDIPINE

## TABLET, EXTENDED RELEASE; ORAL

## NIFEDIPINE

|     |     |  |              |      |         |     |              |     |      |
|-----|-----|--|--------------|------|---------|-----|--------------|-----|------|
| >D> | AB1 |  | BIOVAIL      | 30MG | A075269 | 001 | Dec 04, 2000 | Apr | CAHN |
| >D> | AB2 |  |              | 30MG | A075289 | 002 | Feb 06, 2001 | Apr | CAHN |
| >D> | AB2 |  |              | 60MG | A075289 | 001 | Sep 27, 2000 | Apr | CAHN |
| >D> | AB1 |  |              | 60MG | A075269 | 002 | Dec 04, 2000 | Apr | CAHN |
| >D> | AB1 |  |              | 90MG | A076070 | 001 | Aug 16, 2002 | Apr | CAHN |
| >A> | AB1 |  | VALEANT INTL | 30MG | A075269 | 001 | Dec 04, 2000 | Apr | CAHN |
| >A> | AB2 |  |              | 30MG | A075289 | 002 | Feb 06, 2001 | Apr | CAHN |
| >A> | AB2 |  |              | 60MG | A075289 | 001 | Sep 27, 2000 | Apr | CAHN |
| >A> | AB1 |  |              | 60MG | A075269 | 002 | Dec 04, 2000 | Apr | CAHN |
| >A> | AB1 |  |              | 90MG | A076070 | 001 | Aug 16, 2002 | Apr | CAHN |

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL

NISOLDIPINE

|       |       |                 |             |              |              |          |
|-------|-------|-----------------|-------------|--------------|--------------|----------|
| AB    | MYLAN | 8.5MG           | A091001 001 | Jan 26, 2011 | Jan          | NEWA     |
| AB    |       | 17MG            | A091001 002 | Jan 26, 2011 | Jan          | NEWA     |
| AB    |       | 25.5MG          | A091001 003 | Jan 26, 2011 | Jan          | NEWA     |
| AB    |       | 34MG            | A091001 004 | Jan 26, 2011 | Jan          | NEWA     |
| SULAR |       |                 |             |              |              |          |
| AB    | +     | SHIONOGI PHARMA | 8.5MG       | N020356 008  | Jan 02, 2008 | Jan CFTG |
| AB    | +     |                 | 17MG        | N020356 007  | Jan 02, 2008 | Jan CFTG |
| AB    |       |                 | 25.5MG      | N020356 006  | Jan 02, 2008 | Jan CFTG |
| AB    | +     |                 | 34MG        | N020356 005  | Jan 02, 2008 | Jan CFTG |

NITROFURANTOIN

SUSPENSION; ORAL

FURADANTIN

|     |                |   |                 |          |             |              |     |      |
|-----|----------------|---|-----------------|----------|-------------|--------------|-----|------|
| >A> | AB             | + | SHIONOGI INC    | 25MG/5ML | N009175 001 |              | Apr | CFTG |
| >D> |                | + | SHIONOGI PHARMA | 25MG/5ML | N009175 001 |              | Apr | CFTG |
| >A> | NITROFURANTOIN |   |                 |          |             |              |     |      |
| >A> | AB             |   | AMNEAL PHARMS   | 25MG/5ML | A201679 001 | May 11, 2011 | Apr | NEWA |

NIZATIDINE

CAPSULE; ORAL

NIZATIDINE

|    |       |       |             |              |     |      |
|----|-------|-------|-------------|--------------|-----|------|
| AB | MYLAN | 150MG | A075934 001 | Jul 09, 2002 | Feb | CAHN |
| AB |       | 300MG | A075934 002 | Jul 09, 2002 | Feb | CAHN |

NYSTATIN

SUSPENSION; ORAL

NYSTATIN

|    |            |                  |             |              |     |      |
|----|------------|------------------|-------------|--------------|-----|------|
| AA | VISTAPHARM | 100,000 UNITS/ML | A065422 001 | Mar 07, 2011 | Feb | NEWA |
|----|------------|------------------|-------------|--------------|-----|------|

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

OCTREOTIDE ACETATE

|                                        |    |                     |                   |             |              |     |      |
|----------------------------------------|----|---------------------|-------------------|-------------|--------------|-----|------|
| >A>                                    | AP | WOCKHARDT USA       | EQ 0.2MG BASE/ML  | A090986 001 | May 11, 2011 | Apr | NEWA |
| >A>                                    | AP |                     | EQ 1MG BASE/ML    | A090986 002 | May 11, 2011 | Apr | NEWA |
| OCTREOTIDE ACETATE (PRESERVATIVE FREE) |    |                     |                   |             |              |     |      |
|                                        | AP | BIONICHE PHARMA USA | EQ 0.05MG BASE/ML | A079198 001 | Feb 10, 2011 | Jan | NEWA |
|                                        | AP |                     | EQ 0.1MG BASE/ML  | A079198 002 | Feb 10, 2011 | Jan | NEWA |
|                                        | AP |                     | EQ 0.5MG BASE/ML  | A079198 003 | Feb 10, 2011 | Jan | NEWA |
| >A>                                    | AP | WOCKHARDT USA       | EQ 0.05MG BASE/ML | A090985 001 | May 11, 2011 | Apr | NEWA |
| >A>                                    | AP |                     | EQ 0.1MG BASE/ML  | A090985 002 | May 11, 2011 | Apr | NEWA |
| >A>                                    | AP |                     | EQ 0.5MG BASE/ML  | A090985 003 | May 11, 2011 | Apr | NEWA |

ONDANSETRON

TABLET, ORALLY DISINTEGRATING; ORAL

ONDANSETRON

|    |         |     |             |              |     |      |
|----|---------|-----|-------------|--------------|-----|------|
| AB | RANBAXY | 4MG | A078602 001 | Feb 24, 2011 | Feb | NEWA |
| AB |         | 8MG | A078602 002 | Feb 24, 2011 | Feb | NEWA |

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

|    |      |                |             |              |     |      |
|----|------|----------------|-------------|--------------|-----|------|
| AP | TEVA | EQ 2MG BASE/ML | A076876 001 | Nov 22, 2006 | Jan | CMFD |
|----|------|----------------|-------------|--------------|-----|------|

INJECTABLE; INJECTIONONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER

|     |    |         |                   |             |              |     |      |
|-----|----|---------|-------------------|-------------|--------------|-----|------|
| >D> | AP | HOSPIRA | EQ 0.64MG BASE/ML | A077348 001 | Feb 01, 2007 | Apr | CRLD |
| >A> | AP | +       | EQ 0.64MG BASE/ML | A077348 001 | Feb 01, 2007 | Apr | CRLD |

SOLUTION; ORALONDANSETRON HYDROCHLORIDE

|    |               |                 |             |              |     |      |
|----|---------------|-----------------|-------------|--------------|-----|------|
| AA | AMNEAL PHARMS | EQ 4MG BASE/5ML | A091483 001 | Jan 31, 2011 | Jan | NEWA |
| AA | SILARX        | EQ 4MG BASE/5ML | A091342 001 | Jan 27, 2011 | Jan | NEWA |

TABLET; ORALONDANSETRON HYDROCHLORIDE

|    |      |              |             |              |     |      |
|----|------|--------------|-------------|--------------|-----|------|
| AB | TARO | EQ 4MG BASE  | A077729 001 | Mar 28, 2011 | Mar | NEWA |
| AB |      | EQ 8MG BASE  | A077729 002 | Mar 28, 2011 | Mar | NEWA |
| AB |      | EQ 24MG BASE | A077729 003 | Mar 28, 2011 | Mar | NEWA |

OXALIPLATININJECTABLE; IV (INFUSION)OXALIPLATIN

|     |        |                     |             |              |     |      |
|-----|--------|---------------------|-------------|--------------|-----|------|
| AP  | SANDOZ | 50MG/10ML (5MG/ML)  | A078817 001 | Jan 24, 2011 | Jan | NEWA |
| >A> | AP     | 50MG/VIAL           | A090849 001 | Apr 28, 2011 | Apr | NEWA |
| >A> | AP     | 100MG/VIAL          | A090849 002 | Apr 28, 2011 | Apr | NEWA |
| AP  |        | 100MG/20ML (5MG/ML) | A078817 002 | Jan 24, 2011 | Jan | NEWA |

OXAPROZINTABLET; ORALOXAPROZIN

|    |       |       |             |              |     |      |
|----|-------|-------|-------------|--------------|-----|------|
| AB | MYLAN | 600MG | A075847 001 | Feb 28, 2001 | Feb | CAHN |
|----|-------|-------|-------------|--------------|-----|------|

OXYCODONE HYDROCHLORIDETABLET; ORALOXYCODONE HYDROCHLORIDE

|    |                |      |             |              |     |      |
|----|----------------|------|-------------|--------------|-----|------|
| AB | COASTAL PHARMS | 5MG  | A091313 001 | Feb 18, 2011 | Feb | NEWA |
| AB |                | 15MG | A091313 002 | Feb 18, 2011 | Feb | NEWA |
| AB |                | 30MG | A091313 003 | Feb 18, 2011 | Feb | NEWA |
| AB | RHODES PHARMS  | 5MG  | A091490 001 | Mar 09, 2011 | Feb | NEWA |
| AB |                | 10MG | A091490 002 | Mar 09, 2011 | Feb | NEWA |
| AB |                | 15MG | A091490 003 | Mar 09, 2011 | Feb | NEWA |
| AB |                | 20MG | A091490 004 | Mar 09, 2011 | Feb | NEWA |
| AB |                | 30MG | A091490 005 | Mar 09, 2011 | Feb | NEWA |

OXYMORPHONE HYDROCHLORIDETABLET; ORALOXYMORPHONE HYDROCHLORIDE

|    |      |      |             |              |     |      |
|----|------|------|-------------|--------------|-----|------|
| AB | TEVA | 5MG  | A091443 002 | Feb 15, 2011 | Jan | NEWA |
| AB |      | 10MG | A091443 001 | Feb 15, 2011 | Jan | NEWA |

TABLET, EXTENDED RELEASE; ORALOPANA ER

|   |             |       |             |              |     |      |
|---|-------------|-------|-------------|--------------|-----|------|
| @ | ENDO PHARMS | 7.5MG | N021610 005 | Feb 29, 2008 | Feb | DISC |
| @ |             | 15MG  | N021610 006 | Feb 29, 2008 | Feb | DISC |

PANTOPRAZOLE SODIUMTABLET, DELAYED RELEASE; ORALPANTOPRAZOLE SODIUM

|    |                    |              |             |              |     |      |
|----|--------------------|--------------|-------------|--------------|-----|------|
| AB | ACTAVIS TOTOWA     | EQ 20MG BASE | A090797 001 | Feb 07, 2011 | Jan | NEWA |
| AB |                    | EQ 40MG BASE | A090797 002 | Feb 07, 2011 | Jan | NEWA |
| AB | DR REDDYS LABS LTD | EQ 20MG BASE | A077619 001 | Jan 19, 2011 | Jan | NEWA |
| AB |                    | EQ 40MG BASE | A077619 002 | Jan 19, 2011 | Jan | NEWA |



## TABLET, DELAYED RELEASE; ORAL

## PANTOPRAZOLE SODIUM

|    |                 |              |             |              |     |      |
|----|-----------------|--------------|-------------|--------------|-----|------|
| AB | KUDCO IRELAND   | EQ 20MG BASE | A078281 001 | Jan 20, 2011 | Jan | NEWA |
| AB |                 | EQ 40MG BASE | A078281 002 | Jan 20, 2011 | Jan | NEWA |
| AB | MATRIX LABS LTD | EQ 20MG BASE | A090970 001 | Jan 19, 2011 | Jan | NEWA |
| AB |                 | EQ 40MG BASE | A090970 002 | Jan 19, 2011 | Jan | NEWA |
| AB | TORRENT PHARMS  | EQ 20MG BASE | A090074 001 | Jan 19, 2011 | Jan | NEWA |
| AB |                 | EQ 40MG BASE | A090074 002 | Jan 19, 2011 | Jan | NEWA |
| AB | WOCKHARDT       | EQ 20MG BASE | A091231 001 | Jan 19, 2011 | Jan | NEWA |
| AB |                 | EQ 40MG BASE | A091231 002 | Jan 19, 2011 | Jan | NEWA |

PAROXETINE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## PAROXETINE HYDROCHLORIDE

|     |    |                 |                |             |              |     |      |
|-----|----|-----------------|----------------|-------------|--------------|-----|------|
| >A> | AB | MYLAN           | EQ 37.5MG BASE | A091427 001 | Apr 14, 2011 | Apr | NEWA |
|     |    | PAXIL CR        |                |             |              |     |      |
| >D> | +  | GLAXOSMITHKLINE | EQ 37.5MG BASE | N020936 003 | Dec 06, 2000 | Apr | CTEC |
| >A> | AB | +               | EQ 37.5MG BASE | N020936 003 | Dec 06, 2000 | Apr | CTEC |

PENTOXIFYLLINE

## TABLET, EXTENDED RELEASE; ORAL

## PENTOXIFYLLINE

|     |    |              |       |             |              |     |      |
|-----|----|--------------|-------|-------------|--------------|-----|------|
| >D> | AB | BIOVAIL      | 400MG | A075028 001 | Jul 20, 1998 | Apr | CAHN |
| >A> | AB | VALEANT INTL | 400MG | A075028 001 | Jul 20, 1998 | Apr | CAHN |

PHENTERMINE HYDROCHLORIDE

## TABLET; ORAL

## PHENTERMINE HYDROCHLORIDE

|    |                 |        |             |              |     |      |
|----|-----------------|--------|-------------|--------------|-----|------|
| AA | EPIC PHARMA LLC | 37.5MG | A200272 001 | Jan 31, 2011 | Jan | NEWA |
|----|-----------------|--------|-------------|--------------|-----|------|

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

## INJECTABLE; INJECTION

## PIPERACILLIN AND TAZOBACTAM

|    |             |                                      |             |              |     |      |
|----|-------------|--------------------------------------|-------------|--------------|-----|------|
| AP | HOSPIRA INC | EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL  | A065386 001 | Sep 15, 2009 | Jan | CAHN |
| AP |             | EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL  | A065386 002 | Sep 15, 2009 | Jan | CAHN |
| AP |             | EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL  | A065386 003 | Sep 15, 2009 | Jan | CAHN |
| AP |             | EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL | A065446 001 | Sep 15, 2009 | Jan | CAHN |

PIROXICAM

## CAPSULE; ORAL

## PIROXICAM

|   |       |      |             |              |     |      |
|---|-------|------|-------------|--------------|-----|------|
| @ | MYLAN | 10MG | A074043 001 | Sep 22, 1992 | Feb | CAHN |
| @ |       | 20MG | A074043 002 | Sep 22, 1992 | Feb | CAHN |

PREDNISONE

## TABLET; ORAL

## PREDNISONE

|    |                  |      |             |              |     |      |
|----|------------------|------|-------------|--------------|-----|------|
| AB | JUBILANT CADISTA | 1MG  | A040611 001 | Jun 06, 2005 | Jan | CAHN |
| AB |                  | 5MG  | A040362 002 | Aug 29, 2001 | Jan | CAHN |
| AB |                  | 10MG | A040362 001 | Aug 29, 2001 | Jan | CAHN |
| AB |                  | 20MG | A040362 003 | Jun 29, 2005 | Jan | CAHN |

PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCOMP

|    |                  |              |             |              |     |      |
|----|------------------|--------------|-------------|--------------|-----|------|
| AB | JUBILANT CADISTA | EQ 5MG BASE  | A040268 001 | Feb 27, 1998 | Jan | CAHN |
| AB |                  | EQ 10MG BASE | A040268 002 | Feb 27, 1998 | Jan | CAHN |

PROPANTHELINE BROMIDE

TABLET; ORAL

PROPANTHELINE BROMIDE

|   |        |      |             |  |     |      |
|---|--------|------|-------------|--|-----|------|
| + | ROXANE | 15MG | A080927 002 |  | Jan | CMFD |
|---|--------|------|-------------|--|-----|------|

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

DARVON

|   |                |      |             |  |     |      |
|---|----------------|------|-------------|--|-----|------|
| @ | XANODYNE PHARM | 65MG | N010997 003 |  | Jan | DISC |
|---|----------------|------|-------------|--|-----|------|

PROPOXYPHENE HYDROCHLORIDE

|   |      |      |             |              |     |      |
|---|------|------|-------------|--------------|-----|------|
| @ | TEVA | 65MG | A088615 001 | Oct 22, 1984 | Mar | DISC |
|---|------|------|-------------|--------------|-----|------|

|   |                |      |             |              |     |      |
|---|----------------|------|-------------|--------------|-----|------|
| @ | VINTAGE PHARMS | 65MG | A040908 001 | Jul 17, 2009 | Mar | DISC |
|---|----------------|------|-------------|--------------|-----|------|

|   |           |      |             |  |     |      |
|---|-----------|------|-------------|--|-----|------|
| @ | WEST WARD | 65MG | A083501 001 |  | Jan | DISC |
|---|-----------|------|-------------|--|-----|------|

PROPOXYPHENE NAPSYLATE

TABLET; ORAL

DARVON-N

|   |                |       |             |  |     |      |
|---|----------------|-------|-------------|--|-----|------|
| @ | XANODYNE PHARM | 100MG | N016862 002 |  | Jan | DISC |
|---|----------------|-------|-------------|--|-----|------|

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

PROPRANOLOL HYDROCHLORIDE

|    |                      |      |             |              |     |      |
|----|----------------------|------|-------------|--------------|-----|------|
| AB | ZYDUS PHARMS USA INC | 60MG | A090321 001 | Mar 25, 2011 | Mar | NEWA |
|----|----------------------|------|-------------|--------------|-----|------|

|    |  |      |             |              |     |      |
|----|--|------|-------------|--------------|-----|------|
| AB |  | 80MG | A090321 002 | Mar 25, 2011 | Mar | NEWA |
|----|--|------|-------------|--------------|-----|------|

|    |  |       |             |              |     |      |
|----|--|-------|-------------|--------------|-----|------|
| AB |  | 120MG | A090321 003 | Mar 25, 2011 | Mar | NEWA |
|----|--|-------|-------------|--------------|-----|------|

|    |  |       |             |              |     |      |
|----|--|-------|-------------|--------------|-----|------|
| AB |  | 160MG | A090321 004 | Mar 25, 2011 | Mar | NEWA |
|----|--|-------|-------------|--------------|-----|------|

TABLET; ORAL

PROPRANOLOL HYDROCHLORIDE

|    |       |      |             |              |     |      |
|----|-------|------|-------------|--------------|-----|------|
| AB | MYLAN | 60MG | A070213 005 | Apr 08, 2011 | Mar | NEWA |
|----|-------|------|-------------|--------------|-----|------|

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

QUINAPRIL HYDROCHLORIDE

|    |       |             |             |              |     |      |
|----|-------|-------------|-------------|--------------|-----|------|
| AB | MYLAN | EQ 5MG BASE | A076036 001 | Jan 28, 2005 | Feb | CAHN |
|----|-------|-------------|-------------|--------------|-----|------|

|    |  |              |             |              |     |      |
|----|--|--------------|-------------|--------------|-----|------|
| AB |  | EQ 10MG BASE | A076036 002 | Jan 28, 2005 | Feb | CAHN |
|----|--|--------------|-------------|--------------|-----|------|

|    |  |              |             |              |     |      |
|----|--|--------------|-------------|--------------|-----|------|
| AB |  | EQ 20MG BASE | A076036 003 | Jan 28, 2005 | Feb | CAHN |
|----|--|--------------|-------------|--------------|-----|------|

|    |  |              |             |              |     |      |
|----|--|--------------|-------------|--------------|-----|------|
| AB |  | EQ 40MG BASE | A076036 004 | Jan 28, 2005 | Feb | CAHN |
|----|--|--------------|-------------|--------------|-----|------|

RANITIDINE HYDROCHLORIDE

CAPSULE; ORAL

RANITIDINE HYDROCHLORIDE

|   |       |               |             |              |     |      |
|---|-------|---------------|-------------|--------------|-----|------|
| @ | MYLAN | EQ 150MG BASE | A075564 001 | Oct 27, 2000 | Feb | CAHN |
|---|-------|---------------|-------------|--------------|-----|------|

|   |  |               |             |              |     |      |
|---|--|---------------|-------------|--------------|-----|------|
| @ |  | EQ 300MG BASE | A075564 002 | Oct 27, 2000 | Feb | CAHN |
|---|--|---------------|-------------|--------------|-----|------|

SYRUP; ORAL

RANITIDINE HYDROCHLORIDE

|    |                |                 |             |              |     |      |
|----|----------------|-----------------|-------------|--------------|-----|------|
| AA | HI TECH PHARMA | EQ 15MG BASE/ML | A091078 001 | Mar 22, 2011 | Mar | NEWA |
|----|----------------|-----------------|-------------|--------------|-----|------|

TABLET; ORAL

RANITIDINE HYDROCHLORIDE

|    |       |               |             |              |     |      |
|----|-------|---------------|-------------|--------------|-----|------|
| AB | MYLAN | EQ 150MG BASE | A074023 001 | Aug 22, 1997 | Feb | CAHN |
|----|-------|---------------|-------------|--------------|-----|------|

## TABLET; ORAL

## RANITIDINE HYDROCHLORIDE

|    |       |               |             |              |     |      |
|----|-------|---------------|-------------|--------------|-----|------|
| AB | MYLAN | EQ 300MG BASE | A074023 002 | Aug 22, 1997 | Feb | CAHN |
|----|-------|---------------|-------------|--------------|-----|------|

RIFAXIMIN

## TABLET; ORAL

## XIFAXAN

|   |              |       |             |              |     |      |
|---|--------------|-------|-------------|--------------|-----|------|
| + | SALIX PHARMS | 550MG | N022554 001 | Mar 24, 2010 | Feb | CRLD |
|---|--------------|-------|-------------|--------------|-----|------|

RISPERIDONE

## SOLUTION; ORAL

## RISPERIDONE

|    |      |        |             |              |     |      |
|----|------|--------|-------------|--------------|-----|------|
| AA | TARO | 1MG/ML | A090347 001 | Feb 07, 2011 | Jan | NEWA |
|----|------|--------|-------------|--------------|-----|------|

## TABLET; ORAL

## RISPERIDONE

## @ RATIOPHARM

## @

## @

## @

## @

## @

## @

## TABLET, ORALLY DISINTEGRATING; ORAL

## RISPERIDONE

|    |       |       |             |              |     |      |
|----|-------|-------|-------------|--------------|-----|------|
| AB | MYLAN | 0.5MG | A091537 001 | Mar 30, 2011 | Mar | NEWA |
|----|-------|-------|-------------|--------------|-----|------|

|    |  |     |             |              |     |      |
|----|--|-----|-------------|--------------|-----|------|
| AB |  | 1MG | A091537 002 | Mar 30, 2011 | Mar | NEWA |
|----|--|-----|-------------|--------------|-----|------|

|    |  |     |             |              |     |      |
|----|--|-----|-------------|--------------|-----|------|
| AB |  | 2MG | A091537 003 | Mar 30, 2011 | Mar | NEWA |
|----|--|-----|-------------|--------------|-----|------|

|    |  |     |             |              |     |      |
|----|--|-----|-------------|--------------|-----|------|
| AB |  | 3MG | A091537 004 | Mar 30, 2011 | Mar | NEWA |
|----|--|-----|-------------|--------------|-----|------|

|    |  |     |             |              |     |      |
|----|--|-----|-------------|--------------|-----|------|
| AB |  | 4MG | A091537 005 | Mar 30, 2011 | Mar | NEWA |
|----|--|-----|-------------|--------------|-----|------|

|     |    |                     |       |             |              |     |      |
|-----|----|---------------------|-------|-------------|--------------|-----|------|
| >A> | AB | WATSON LABS FLORIDA | 0.5MG | A076996 001 | Apr 19, 2011 | Apr | NEWA |
|-----|----|---------------------|-------|-------------|--------------|-----|------|

|     |    |  |     |             |              |     |      |
|-----|----|--|-----|-------------|--------------|-----|------|
| >A> | AB |  | 1MG | A076996 002 | Apr 19, 2011 | Apr | NEWA |
|-----|----|--|-----|-------------|--------------|-----|------|

|     |    |  |     |             |              |     |      |
|-----|----|--|-----|-------------|--------------|-----|------|
| >A> | AB |  | 2MG | A076996 003 | Apr 19, 2011 | Apr | NEWA |
|-----|----|--|-----|-------------|--------------|-----|------|

|     |    |  |     |             |              |     |      |
|-----|----|--|-----|-------------|--------------|-----|------|
| >A> | AB |  | 3MG | A076996 004 | Apr 19, 2011 | Apr | NEWA |
|-----|----|--|-----|-------------|--------------|-----|------|

|     |    |  |     |             |              |     |      |
|-----|----|--|-----|-------------|--------------|-----|------|
| >A> | AB |  | 4MG | A076996 005 | Apr 19, 2011 | Apr | NEWA |
|-----|----|--|-----|-------------|--------------|-----|------|

ROCURONIUM BROMIDE

## INJECTABLE; INJECTION

## ROCURONIUM BROMIDE

|    |                |                    |             |              |     |      |
|----|----------------|--------------------|-------------|--------------|-----|------|
| AP | SAGENT STRIDES | 50MG/5ML (10MG/ML) | A091458 001 | Jul 28, 2010 | Jan | CAHN |
|----|----------------|--------------------|-------------|--------------|-----|------|

|    |  |                      |             |              |     |      |
|----|--|----------------------|-------------|--------------|-----|------|
| AP |  | 100MG/10ML (10MG/ML) | A091458 002 | Jul 28, 2010 | Jan | CAHN |
|----|--|----------------------|-------------|--------------|-----|------|

ROFLUMILAST

## TABLET; ORAL

## DALIRESP

|   |                     |        |             |              |     |      |
|---|---------------------|--------|-------------|--------------|-----|------|
| + | FOREST RES INST INC | 500MCG | N022522 001 | Feb 28, 2011 | Feb | NEWA |
|---|---------------------|--------|-------------|--------------|-----|------|

RUFINAMIDE

## SUSPENSION; ORAL

## BANZEL

|   |           |         |             |              |     |      |
|---|-----------|---------|-------------|--------------|-----|------|
| + | EISAI INC | 40MG/ML | N201367 001 | Mar 03, 2011 | Mar | NEWA |
|---|-----------|---------|-------------|--------------|-----|------|

SECOBARBITAL SODIUM

## CAPSULE; ORAL

## SECONAL SODIUM

|   |                 |      |             |              |     |      |
|---|-----------------|------|-------------|--------------|-----|------|
| + | MARATHON PHARMS | 50MG | A086101 001 | Oct 03, 1983 | Jan | CAHN |
|---|-----------------|------|-------------|--------------|-----|------|

|   |  |       |             |              |     |      |
|---|--|-------|-------------|--------------|-----|------|
| + |  | 100MG | A086101 002 | Oct 03, 1983 | Jan | CAHN |
|---|--|-------|-------------|--------------|-----|------|

SERTRALINE HYDROCHLORIDE

CONCENTRATE; ORAL

SERTRALINE HYDROCHLORIDE

@ ROXANE EQ 20MG BASE/ML

A076934 001 Jun 30, 2006 Mar DISC

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

&gt;D&gt; AB IVAX SUB TEVA PHARMS EQ 25MG BASE

A075719 003 Jun 30, 2006 Apr DISC

&gt;A&gt; @ EQ 25MG BASE

A075719 003 Jun 30, 2006 Apr DISC

&gt;D&gt; AB EQ 50MG BASE

A075719 001 Jun 30, 2006 Apr DISC

&gt;A&gt; @ EQ 50MG BASE

A075719 001 Jun 30, 2006 Apr DISC

&gt;D&gt; AB EQ 100MG BASE

A075719 002 Jun 30, 2006 Apr DISC

&gt;A&gt; @ EQ 100MG BASE

A075719 002 Jun 30, 2006 Apr DISC

AB MYLAN EQ 25MG BASE

A076540 001 Mar 20, 2007 Feb CAHN

AB EQ 50MG BASE

A076540 002 Mar 20, 2007 Feb CAHN

AB EQ 100MG BASE

A076540 003 Mar 20, 2007 Feb CAHN

@ ROXANE EQ 25MG BASE

A076881 001 Feb 06, 2007 Mar DISC

@ EQ 50MG BASE

A076881 002 Feb 06, 2007 Mar DISC

@ EQ 100MG BASE

A076881 003 Feb 06, 2007 Mar DISC

SODIUM FERRIC GLUCONATE COMPLEX

INJECTABLE; INJECTION

FERRLECIT

AB + SANOFI AVENTIS US 62.5MG/5ML

N020955 001 Feb 18, 1999 Mar CFTG

SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE

AB GENERAMEDIX 62.5MG/5ML

A078215 001 Mar 31, 2011 Mar NEWA

>D> SODIUM FLUORIDE F-18

&gt;D&gt; INJECTABLE; INTRAVENOUS

&gt;D&gt; SODIUM FLUORIDE F 18

&gt;D&gt; + NIH NCI DCTD 10-200mCi/ML

N022494 001 Jan 26, 2011 Apr DISC

&gt;A&gt; @ 10-200mCi/ML

N022494 001 Jan 26, 2011 Apr DISC

+ 10-200mCi/ML

N022494 001 Jan 26, 2011 Jan NEWA

SODIUM NITRITE; SODIUM THIOSULFATE

SOLUTION, SOLUTION; INTRAVENOUS, INTRAVENOUS

NITHIODOTE

+ HOPE PHARMS 300MG/10ML (30MG/ML), N/A; N/A, 12.5G M/50ML (250MG/ML)

N201444 001 Jan 14, 2011 Feb CTNA

SODIUM NITRITE

+ HOPE PHARMS 300MG/10ML (30MG/ML), N/A; N/A, 12.5G M/50ML (250MG/ML)

N201444 001 Jan 14, 2011 Jan NEWA

SPINOSAD

SUSPENSION; TOPICAL

NATROBA

+ PARAPRO PHARMS 0.9%

N022408 001 Jan 18, 2011 Jan NEWA

SUMATRIPTAN SUCCINATE

TABLET; ORAL

SUMATRIPTAN SUCCINATE

@ ROXANE EQ 25MG BASE

A078241 001 Aug 10, 2009 Mar DISC

@ EQ 50MG BASE

A078241 002 Aug 10, 2009 Mar DISC

@ EQ 100MG BASE

A078241 003 Aug 10, 2009 Mar DISC

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

TERAZOSIN HYDROCHLORIDE

|    |                  |              |             |              |     |      |
|----|------------------|--------------|-------------|--------------|-----|------|
| AB | JUBILANT CADISTA | EQ 1MG BASE  | A075317 001 | Dec 20, 2004 | Jan | CAHN |
| AB |                  | EQ 2MG BASE  | A075317 002 | Dec 20, 2004 | Jan | CAHN |
| AB |                  | EQ 5MG BASE  | A075317 003 | Dec 20, 2004 | Jan | CAHN |
| AB |                  | EQ 10MG BASE | A075317 004 | Dec 20, 2004 | Jan | CAHN |

TERBINAFINE HYDROCHLORIDE

TABLET; ORAL

TERBINAFINE HYDROCHLORIDE

|    |          |               |             |              |     |      |
|----|----------|---------------|-------------|--------------|-----|------|
| AB | MYLAN    | EQ 250MG BASE | A077136 001 | Jul 02, 2007 | Feb | CAHN |
|    | @ ROXANE | EQ 250MG BASE | A077223 001 | Jul 02, 2007 | Feb | DISC |

TERBUTALINE SULFATE

TABLET; ORAL

TERBUTALINE SULFATE

|    |              |     |             |              |     |      |
|----|--------------|-----|-------------|--------------|-----|------|
| AB | + IMPAX LABS | 5MG | A075877 002 | Jun 26, 2001 | Jan | CRLD |
|----|--------------|-----|-------------|--------------|-----|------|

TESTOSTERONE

&gt;A&gt; GEL, METERED; TRANSDERMAL

&gt;A&gt; ANDROGEL

|     |                |                                   |             |              |     |      |
|-----|----------------|-----------------------------------|-------------|--------------|-----|------|
| >A> | + ABBOTT PRODS | 1.62% (20.25MG/1.25GM ACTIVATION) | N022309 001 | Apr 29, 2011 | Apr | NEWA |
|-----|----------------|-----------------------------------|-------------|--------------|-----|------|

FORTESTA

|  |               |                       |             |              |     |      |
|--|---------------|-----------------------|-------------|--------------|-----|------|
|  | + ENDO PHARMS | 10MG/0.5GM ACTIVATION | N021463 001 | Dec 29, 2010 | Mar | CPOT |
|--|---------------|-----------------------|-------------|--------------|-----|------|

THEOPHYLLINE

SOLUTION; ORAL

THEOPHYLLINE

|  |          |           |             |              |     |      |
|--|----------|-----------|-------------|--------------|-----|------|
|  | + SILARX | 80MG/15ML | A091156 001 | Apr 13, 2011 | Mar | NEWA |
|--|----------|-----------|-------------|--------------|-----|------|

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL

TICLOPIDINE HYDROCHLORIDE

|    |       |       |             |              |     |      |
|----|-------|-------|-------------|--------------|-----|------|
| AB | MYLAN | 250MG | A075161 001 | Sep 13, 1999 | Feb | CAHN |
|----|-------|-------|-------------|--------------|-----|------|

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

TOBRAMYCIN

|    |             |      |             |              |     |      |
|----|-------------|------|-------------|--------------|-----|------|
| AT | FERA PHARMS | 0.3% | A065026 001 | Sep 11, 2001 | Mar | CAHN |
|----|-------------|------|-------------|--------------|-----|------|

TOPOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION

TOPOTECAN HYDROCHLORIDE

|    |                    |                  |             |              |     |      |
|----|--------------------|------------------|-------------|--------------|-----|------|
| AP | DR REDDYS LABS LTD | EQ 4MG BASE/VIAL | A201191 001 | Mar 09, 2011 | Feb | NEWA |
| AP | SAGENT PHARMS      | EQ 4MG BASE/VIAL | A091284 001 | Jan 26, 2011 | Jan | NEWA |

SOLUTION; INTRAVENOUS

TOPOTECAN

|    |             |                                  |             |              |     |      |
|----|-------------|----------------------------------|-------------|--------------|-----|------|
| AP | HOSPIRA INC | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N200582 001 | Feb 02, 2011 | Feb | NEWA |
|    | SANDOZ      | EQ 1MG BASE/ML (EQ 1MG BASE/ML)  | N200199 001 | Feb 25, 2011 | Feb | NEWA |
|    |             | EQ 3MG BASE/3ML (EQ 1MG BASE/ML) | N200199 002 | Feb 25, 2011 | Feb | NEWA |
| AP | +           | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N200199 003 | Feb 25, 2011 | Feb | NEWA |

TORSEMIDE

TABLET; ORAL

TORSEMIDE

|    |                |       |             |              |     |      |
|----|----------------|-------|-------------|--------------|-----|------|
| AB | VINTAGE PHARMS | 5MG   | A090613 001 | Mar 22, 2011 | Mar | NEWA |
| AB |                | 10MG  | A090613 002 | Mar 22, 2011 | Mar | NEWA |
| AB |                | 20MG  | A090613 003 | Mar 22, 2011 | Mar | NEWA |
| AB |                | 100MG | A090613 004 | Mar 22, 2011 | Mar | NEWA |

TRAMADOL HYDROCHLORIDE

TABLET; ORAL

TRAMADOL HYDROCHLORIDE

|    |                      |      |             |              |     |      |
|----|----------------------|------|-------------|--------------|-----|------|
| AB | ZYDUS PHARMS USA INC | 50MG | A090404 001 | Jan 31, 2011 | Jan | NEWA |
|----|----------------------|------|-------------|--------------|-----|------|

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

TRIMETHOBENZAMIDE HYDROCHLORIDE

|    |             |          |             |              |     |      |
|----|-------------|----------|-------------|--------------|-----|------|
| AP | PHARMAFORCE | 100MG/ML | A091330 001 | Mar 08, 2011 | Feb | NEWA |
|----|-------------|----------|-------------|--------------|-----|------|

TRIMETHOBENZAMIDE HYDROCHLORIDE PRESERVATIVE FREE

|    |             |          |             |              |     |      |
|----|-------------|----------|-------------|--------------|-----|------|
| AP | PHARMAFORCE | 100MG/ML | A091329 001 | Mar 08, 2011 | Feb | NEWA |
|----|-------------|----------|-------------|--------------|-----|------|

TRIMIPRAMINE MALEATE

CAPSULE; ORAL

TRIMIPRAMINE MALEATE

|    |              |               |             |              |     |      |
|----|--------------|---------------|-------------|--------------|-----|------|
| AB | MIKAH PHARMA | EQ 25MG BASE  | A077361 001 | Aug 02, 2006 | Feb | CAHN |
| AB |              | EQ 50MG BASE  | A077361 002 | Aug 02, 2006 | Feb | CAHN |
| AB |              | EQ 100MG BASE | A077361 003 | Aug 02, 2006 | Feb | CAHN |

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL

VALACYCLOVIR HYDROCHLORIDE

|    |                |               |             |              |     |      |
|----|----------------|---------------|-------------|--------------|-----|------|
| AB | ACTAVIS PHARMA | EQ 500MG BASE | A090370 001 | Mar 16, 2011 | Feb | NEWA |
| AB |                | EQ 1GM BASE   | A090370 002 | Mar 16, 2011 | Feb | NEWA |

>A> VANDETANIB

&gt;A&gt; TABLET; ORAL

&gt;A&gt; VANDETANIB

|     |                |       |             |              |     |      |
|-----|----------------|-------|-------------|--------------|-----|------|
| >A> | IPR PHARMS INC | 100MG | N022405 001 | Apr 06, 2011 | Apr | NEWA |
| >A> | +              | 300MG | N022405 002 | Apr 06, 2011 | Apr | NEWA |

VENLAFAXINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

VENLAFAXINE HYDROCHLORIDE

|     |    |                      |                |             |              |     |      |
|-----|----|----------------------|----------------|-------------|--------------|-----|------|
| >A> | AB | AUROBINDO PHARMA LTD | EQ 37.5MG BASE | A200834 001 | Apr 14, 2011 | Apr | NEWA |
| >A> | AB |                      | EQ 75MG BASE   | A200834 002 | Apr 14, 2011 | Apr | NEWA |
| >A> | AB |                      | EQ 150MG BASE  | A200834 003 | Apr 14, 2011 | Apr | NEWA |
| >A> | AB | BIOVAIL LABS INTL    | EQ 75MG BASE   | A090071 002 | Apr 15, 2011 | Apr | NEWA |
| >A> | AB |                      | EQ 150MG BASE  | A090071 003 | Apr 15, 2011 | Apr | NEWA |
| >A> | AB | DR REDDYS LABS LTD   | EQ 37.5MG BASE | A078421 001 | May 06, 2011 | Apr | NEWA |
| >A> | AB |                      | EQ 75MG BASE   | A078421 002 | May 06, 2011 | Apr | NEWA |
| >A> | AB |                      | EQ 150MG BASE  | A078421 003 | May 06, 2011 | Apr | NEWA |
| >A> | AB | WOCKHARDT            | EQ 37.5MG BASE | A078865 001 | Apr 14, 2011 | Apr | NEWA |
| >A> | AB |                      | EQ 75MG BASE   | A078865 002 | Apr 14, 2011 | Apr | NEWA |
| >A> | AB |                      | EQ 150MG BASE  | A078865 003 | Apr 14, 2011 | Apr | NEWA |
| >A> | AB | ZYDUS PHARMS USA INC | EQ 37.5MG BASE | A090174 001 | Apr 14, 2011 | Apr | NEWA |
| >A> | AB |                      | EQ 75MG BASE   | A090174 002 | Apr 14, 2011 | Apr | NEWA |

|                                     |    |                                 |               |         |     |              |          |
|-------------------------------------|----|---------------------------------|---------------|---------|-----|--------------|----------|
|                                     |    | CAPSULE, EXTENDED RELEASE; ORAL |               |         |     |              |          |
|                                     |    | VENLAFAXINE HYDROCHLORIDE       |               |         |     |              |          |
| >A>                                 | AB | ZYDUS PHARMS USA INC            | EQ 150MG BASE | A090174 | 003 | Apr 14, 2011 | Apr NEWA |
| <br><u>VILAZODONE HYDROCHLORIDE</u> |    |                                 |               |         |     |              |          |
|                                     |    | TABLET; ORAL                    |               |         |     |              |          |
|                                     |    | VIIBRYD                         |               |         |     |              |          |
|                                     |    | TROVIS PHARMS                   | 10MG          | N022567 | 001 | Jan 21, 2011 | Jan NEWA |
|                                     |    |                                 | 20MG          | N022567 | 002 | Jan 21, 2011 | Jan NEWA |
|                                     |    | +                               | 40MG          | N022567 | 003 | Jan 21, 2011 | Jan NEWA |
| <br><u>VINCRIStINE SULFATE</u>      |    |                                 |               |         |     |              |          |
|                                     |    | INJECTABLE; INJECTION           |               |         |     |              |          |
|                                     |    | VINCRIStINE SULFATE             |               |         |     |              |          |
|                                     |    | @ APP PHARMS                    | 1MG/ML        | A076401 | 001 | Oct 28, 2003 | Jan DISC |
| <br><u>ZIDOVUDINE</u>               |    |                                 |               |         |     |              |          |
|                                     |    | INJECTABLE; INJECTION           |               |         |     |              |          |
|                                     |    | ZIDOVUDINE                      |               |         |     |              |          |
| AP                                  |    | LUITPOLD                        | 10MG/ML       | A091457 | 001 | May 06, 2010 | Feb CAHN |
|                                     |    | TABLET; ORAL                    |               |         |     |              |          |
|                                     |    | ZIDOVUDINE                      |               |         |     |              |          |
|                                     |    | @ MATRIX LABS LTD               | 100MG         | N200732 | 001 | Feb 23, 2011 | Feb NEWA |
| <br><u>ZOLPIDEM TARTRATE</u>        |    |                                 |               |         |     |              |          |
|                                     |    | TABLET; ORAL                    |               |         |     |              |          |
|                                     |    | ZOLPIDEM TARTRATE               |               |         |     |              |          |
| AB                                  |    | MYLAN                           | 5MG           | A078016 | 001 | Apr 23, 2007 | Feb CAHN |
| AB                                  |    |                                 | 10MG          | A078016 | 002 | Apr 23, 2007 | Feb CAHN |
|                                     |    | TABLET, EXTENDED RELEASE; ORAL  |               |         |     |              |          |
|                                     |    | ZOLPIDEM TARTRATE               |               |         |     |              |          |
| >A>                                 | AB | ANCHEN PHARMS                   | 6.25MG        | A078148 | 002 | Apr 14, 2011 | Apr NEWA |
| >A>                                 | AB | SYNTHON PHARMS                  | 6.25MG        | A078483 | 001 | Apr 12, 2011 | Apr NEWA |

OTC DRUG PRODUCT LIST - 31ST EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2011

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CETIRIZINE HYDROCHLORIDE

SOLUTION; ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

|     |        |         |             |              |     |      |
|-----|--------|---------|-------------|--------------|-----|------|
| >A> | SILARX | 5MG/5ML | A091130 001 | Apr 22, 2011 | Apr | NEWA |
|-----|--------|---------|-------------|--------------|-----|------|

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

|     |        |         |             |              |     |      |
|-----|--------|---------|-------------|--------------|-----|------|
| >A> | SILARX | 5MG/5ML | A091130 002 | Apr 22, 2011 | Apr | NEWA |
|-----|--------|---------|-------------|--------------|-----|------|

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SWAB; TOPICAL

CHLORAPREP ONE-STEP SEPP

|     |                 |                 |             |              |     |      |
|-----|-----------------|-----------------|-------------|--------------|-----|------|
| >A> | + CARDINAL HLTH | 2%;70% (0.67ML) | N021555 001 | Oct 07, 2002 | Apr | CAHN |
|-----|-----------------|-----------------|-------------|--------------|-----|------|

|     |              |                 |             |              |     |      |
|-----|--------------|-----------------|-------------|--------------|-----|------|
| >D> | + CAREFUSION | 2%;70% (0.67ML) | N021555 001 | Oct 07, 2002 | Apr | CAHN |
|-----|--------------|-----------------|-------------|--------------|-----|------|

CHLORAPREP SINGLE SWABSTICK

|     |                 |                 |             |              |     |      |
|-----|-----------------|-----------------|-------------|--------------|-----|------|
| >A> | + CARDINAL HLTH | 2%;70% (1.75ML) | N021555 002 | May 10, 2005 | Apr | CAHN |
|-----|-----------------|-----------------|-------------|--------------|-----|------|

|     |              |                 |             |              |     |      |
|-----|--------------|-----------------|-------------|--------------|-----|------|
| >D> | + CAREFUSION | 2%;70% (1.75ML) | N021555 002 | May 10, 2005 | Apr | CAHN |
|-----|--------------|-----------------|-------------|--------------|-----|------|

CHLORAPREP TRIPLE SWABSTICK

|     |                 |                 |             |              |     |      |
|-----|-----------------|-----------------|-------------|--------------|-----|------|
| >A> | + CARDINAL HLTH | 2%;70% (5.25ML) | N021555 003 | Jun 10, 2009 | Apr | NEWA |
|-----|-----------------|-----------------|-------------|--------------|-----|------|

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

|       |      |             |              |     |      |
|-------|------|-------------|--------------|-----|------|
| MYLAN | 10MG | A075674 001 | Dec 21, 2001 | Feb | CAHN |
|-------|------|-------------|--------------|-----|------|

FEXOFENADINE HYDROCHLORIDE

SUSPENSION; ORAL

CHILDREN'S ALLEGRA ALLERGY

|   |                   |          |             |              |     |      |
|---|-------------------|----------|-------------|--------------|-----|------|
| + | SANOFI AVENTIS US | 30MG/5ML | N201373 001 | Jan 24, 2011 | Jan | NEWA |
|---|-------------------|----------|-------------|--------------|-----|------|

CHILDREN'S ALLEGRA HIVES

|   |                   |          |             |              |     |      |
|---|-------------------|----------|-------------|--------------|-----|------|
| + | SANOFI AVENTIS US | 30MG/5ML | N201373 002 | Jan 24, 2011 | Jan | NEWA |
|---|-------------------|----------|-------------|--------------|-----|------|

TABLET, ORALLY DISINTEGRATING; ORAL

CHILDREN'S ALLEGRA ALLERGY

|   |                   |      |             |              |     |      |
|---|-------------------|------|-------------|--------------|-----|------|
| + | SANOFI AVENTIS US | 30MG | N021909 002 | Jan 24, 2011 | Jan | NEWA |
|---|-------------------|------|-------------|--------------|-----|------|

CHILDREN'S ALLEGRA HIVES

|   |                   |      |             |              |     |      |
|---|-------------------|------|-------------|--------------|-----|------|
| + | SANOFI AVENTIS US | 30MG | N021909 003 | Jan 24, 2011 | Jan | NEWA |
|---|-------------------|------|-------------|--------------|-----|------|

TABLET; ORAL

ALLEGRA ALLERGY

|                   |      |             |              |     |      |
|-------------------|------|-------------|--------------|-----|------|
| SANOFI AVENTIS US | 60MG | N020872 007 | Jan 24, 2011 | Jan | NEWA |
|-------------------|------|-------------|--------------|-----|------|

|   |  |       |             |              |     |      |
|---|--|-------|-------------|--------------|-----|------|
| + |  | 180MG | N020872 010 | Jan 24, 2011 | Jan | NEWA |
|---|--|-------|-------------|--------------|-----|------|

ALLEGRA HIVES

|                   |      |             |              |     |      |
|-------------------|------|-------------|--------------|-----|------|
| SANOFI AVENTIS US | 60MG | N020872 008 | Jan 24, 2011 | Jan | NEWA |
|-------------------|------|-------------|--------------|-----|------|

|   |  |       |             |              |     |      |
|---|--|-------|-------------|--------------|-----|------|
| + |  | 180MG | N020872 009 | Jan 24, 2011 | Jan | NEWA |
|---|--|-------|-------------|--------------|-----|------|

CHILDREN'S ALLEGRA ALLERGY

|                   |      |             |              |     |      |
|-------------------|------|-------------|--------------|-----|------|
| SANOFI AVENTIS US | 30MG | N020872 005 | Jan 24, 2011 | Jan | NEWA |
|-------------------|------|-------------|--------------|-----|------|

CHILDREN'S ALLEGRA HIVES

|                   |      |             |              |     |      |
|-------------------|------|-------------|--------------|-----|------|
| SANOFI AVENTIS US | 30MG | N020872 006 | Jan 24, 2011 | Jan | NEWA |
|-------------------|------|-------------|--------------|-----|------|

CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY

|                    |      |             |              |     |      |
|--------------------|------|-------------|--------------|-----|------|
| DR REDDYS LABS LTD | 30MG | A076502 004 | Apr 12, 2011 | Mar | NEWA |
|--------------------|------|-------------|--------------|-----|------|

|      |      |             |              |     |      |
|------|------|-------------|--------------|-----|------|
| TEVA | 30MG | A076447 004 | Apr 13, 2011 | Mar | NEWA |
|------|------|-------------|--------------|-----|------|

CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES

|                    |      |             |              |     |      |
|--------------------|------|-------------|--------------|-----|------|
| DR REDDYS LABS LTD | 30MG | A076502 005 | Apr 12, 2011 | Mar | NEWA |
|--------------------|------|-------------|--------------|-----|------|

|      |      |             |              |     |      |
|------|------|-------------|--------------|-----|------|
| TEVA | 30MG | A076447 005 | Apr 13, 2011 | Mar | NEWA |
|------|------|-------------|--------------|-----|------|

FEXOFENADINE HYDROCHLORIDE ALLERGY

|                    |      |             |              |     |      |
|--------------------|------|-------------|--------------|-----|------|
| DR REDDYS LABS LTD | 60MG | A076502 006 | Apr 12, 2011 | Mar | NEWA |
|--------------------|------|-------------|--------------|-----|------|



## TABLET; ORAL

## FEXOFENADINE HYDROCHLORIDE ALLERGY

|                    |       |             |              |     |      |
|--------------------|-------|-------------|--------------|-----|------|
| DR REDDYS LABS LTD | 180MG | A076502 008 | Apr 12, 2011 | Mar | NEWA |
| TEVA               | 60MG  | A076447 006 | Apr 13, 2011 | Mar | NEWA |
|                    | 180MG | A076447 008 | Apr 13, 2011 | Mar | NEWA |

## FEXOFENADINE HYDROCHLORIDE HIVES

|                    |       |             |              |     |      |
|--------------------|-------|-------------|--------------|-----|------|
| DR REDDYS LABS LTD | 60MG  | A076502 007 | Apr 12, 2011 | Mar | NEWA |
|                    | 180MG | A076502 009 | Apr 12, 2011 | Mar | NEWA |
| TEVA               | 60MG  | A076447 007 | Apr 13, 2011 | Mar | NEWA |
|                    | 180MG | A076447 009 | Apr 13, 2011 | Mar | NEWA |

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## ALLEGRA-D 12 HOUR ALLERGY AND CONGESTION

|   |                   |            |             |              |     |      |
|---|-------------------|------------|-------------|--------------|-----|------|
| + | SANOFI AVENTIS US | 60MG;120MG | N020786 002 | Jan 24, 2011 | Jan | NEWA |
|---|-------------------|------------|-------------|--------------|-----|------|

## ALLEGRA-D 24 HOUR ALLERGY AND CONGESTION

|   |                   |             |             |              |     |      |
|---|-------------------|-------------|-------------|--------------|-----|------|
| + | SANOFI AVENTIS US | 180MG;240MG | N021704 002 | Jan 24, 2011 | Jan | NEWA |
|---|-------------------|-------------|-------------|--------------|-----|------|

IBUPROFEN

## TABLET; ORAL

## IBUPROFEN

|                   |       |             |              |     |      |
|-------------------|-------|-------------|--------------|-----|------|
| MARKSANS PHARMA   | 200MG | A091237 001 | Feb 08, 2011 | Jan | NEWA |
|                   | 200MG | A091239 001 | Feb 01, 2011 | Jan | NEWA |
| MERRO PHARM       | 200MG | A070985 001 | Oct 02, 1987 | Jan | CAHN |
| SVADS HOLDINGS SA | 200MG | A079129 001 | Mar 28, 2011 | Mar | NEWA |
|                   | 200MG | A091355 001 | Apr 04, 2011 | Mar | NEWA |

INSULIN SUSP ISOPHANE RECOMBINANT HUMAN

## INJECTABLE; INJECTION

## NOVOLIN N

|   |                  |              |             |              |     |      |
|---|------------------|--------------|-------------|--------------|-----|------|
| + | NOVO NORDISK INC | 100 UNITS/ML | N019959 001 | Jul 01, 1991 | Jan | CRLD |
|---|------------------|--------------|-------------|--------------|-----|------|

LEVONORGESTREL

## TABLET; ORAL

## PLAN B

|   |             |        |             |              |     |      |
|---|-------------|--------|-------------|--------------|-----|------|
| + | TEVA WOMENS | 0.75MG | N021045 002 | Aug 24, 2006 | Feb | CAHN |
|---|-------------|--------|-------------|--------------|-----|------|

MINOXIDIL

## AEROSOL, FOAM; TOPICAL

## MINOXIDIL

|     |                |    |             |              |     |      |
|-----|----------------|----|-------------|--------------|-----|------|
| >A> |                |    |             |              |     |      |
| >A> | PERRIGO ISRAEL | 5% | A091344 001 | Apr 28, 2011 | Apr | NEWA |

NAPROXEN SODIUM

## TABLET; ORAL

## NAPROXEN SODIUM

|                 |               |             |              |     |      |
|-----------------|---------------|-------------|--------------|-----|------|
| MARKSANS PHARMA | EQ 200MG BASE | A090545 001 | Mar 16, 2011 | Feb | NEWA |
|-----------------|---------------|-------------|--------------|-----|------|

POTASSIUM IODIDE

## TABLET; ORAL

## IOSAT

|     |       |      |             |              |     |      |
|-----|-------|------|-------------|--------------|-----|------|
| >A> | ANBEX | 65MG | N018664 002 | May 12, 2011 | Apr | NEWA |
|-----|-------|------|-------------|--------------|-----|------|

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE HYDROCHLORIDE

|     |                 |               |             |              |     |      |
|-----|-----------------|---------------|-------------|--------------|-----|------|
|     | MYLAN           | EQ 75MG BASE  | A075497 001 | Jan 14, 2000 | Feb | CAHN |
| >A> | PERRIGO R AND D | EQ 150MG BASE | A091429 002 | May 11, 2011 | Apr | NEWA |
| >A> |                 | EQ 150MG BASE | A091429 001 | May 11, 2011 | Apr | NEWA |

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

**CUMULATIVE SUPPLEMENT NUMBER 4 APRIL 2011**

NO APRIL 2011 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 2011 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST - 31ST EDITION

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PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2011

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>ABIRATERONE ACETATE - ZYTIGA</u>                                                                                         |             |                              |                 |                               |                        |                                   |
| N202379 001                                                                                                                 |             |                              |                 |                               | >A> NCE                | Apr 28, 2016                      |
| <u>ADAPALENE - DIFFERIN</u>                                                                                                 |             |                              |                 |                               |                        |                                   |
| N021753 001                                                                                                                 | 7868044     | Mar 12, 2023                 | U-1078          |                               |                        |                                   |
| <u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>                                                                |             |                              |                 |                               |                        |                                   |
| N022545 001                                                                                                                 |             |                              |                 |                               | NCE                    | Mar 05, 2012                      |
| <u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>                                                                |             |                              |                 |                               |                        |                                   |
| N022545 002                                                                                                                 |             |                              |                 |                               | NCE                    | Mar 05, 2012                      |
| <u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>                                                                |             |                              |                 |                               |                        |                                   |
| N022545 003                                                                                                                 |             |                              |                 |                               | NCE                    | Mar 05, 2012                      |
| <u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>                                                                |             |                              |                 |                               |                        |                                   |
| N022545 004                                                                                                                 |             |                              |                 |                               | NCE                    | Mar 05, 2012                      |
| <u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>                                         |             |                              |                 |                               |                        |                                   |
| N200045 001                                                                                                                 | 5559111     | Jul 21, 2018                 | DS DP U-3       |                               | NCE                    | Mar 05, 2012                      |
| <u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>                                         |             |                              |                 |                               |                        |                                   |
| N200045 002                                                                                                                 | 5559111     | Jul 21, 2018                 | DS DP U-3       |                               | NCE                    | Mar 05, 2012                      |
| <u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>                                         |             |                              |                 |                               |                        |                                   |
| N200045 003                                                                                                                 | 5559111     | Jul 21, 2018                 | DS DP U-3       |                               | NCE                    | Mar 05, 2012                      |
| <u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>                                         |             |                              |                 |                               |                        |                                   |
| N200045 004                                                                                                                 | 5559111     | Jul 21, 2018                 | DS DP U-3       |                               | NCE                    | Mar 05, 2012                      |
| <u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>                                         |             |                              |                 |                               |                        |                                   |
| N200045 005                                                                                                                 | 5559111     | Jul 21, 2018                 | DS DP U-3       |                               | NCE                    | Mar 05, 2012                      |
| <u>ALVIMOPAN - ENTEREG</u>                                                                                                  |             |                              |                 |                               |                        |                                   |
| N021775 001                                                                                                                 | 5250542     | Mar 29, 2016                 | DS DP U-878     |                               |                        |                                   |
| <u>AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE - AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE</u>                     |             |                              |                 |                               |                        |                                   |
| A078381 005                                                                                                                 |             |                              |                 |                               | PC                     | Jul 02, 2011                      |
| <u>AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE - AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE</u>                     |             |                              |                 |                               |                        |                                   |
| A078381 006                                                                                                                 |             |                              |                 |                               | PC                     | Jul 02, 2011                      |
| <u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 10</u> |             |                              |                 |                               |                        |                                   |
| N021303 001                                                                                                                 | RE42096     | Oct 21, 2018                 | DP              |                               |                        |                                   |
|                                                                                                                             | RE42096*PED | Apr 21, 2019                 |                 |                               |                        |                                   |
| <u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 15</u> |             |                              |                 |                               |                        |                                   |
| N021303 006                                                                                                                 | RE42096     | Oct 21, 2018                 | DP              |                               |                        |                                   |
|                                                                                                                             | RE42096*PED | Apr 21, 2019                 |                 |                               |                        |                                   |
| <u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 20</u> |             |                              |                 |                               |                        |                                   |
| N021303 002                                                                                                                 | RE42096     | Oct 21, 2018                 | DP              |                               |                        |                                   |
|                                                                                                                             | RE42096*PED | Apr 21, 2019                 |                 |                               |                        |                                   |
| <u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 25</u> |             |                              |                 |                               |                        |                                   |
| N021303 004                                                                                                                 | RE42096     | Oct 21, 2018                 | DP              |                               |                        |                                   |
|                                                                                                                             | RE42096*PED | Apr 21, 2019                 |                 |                               |                        |                                   |

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| <u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE -<br/>ADDERALL XR 30</u> |             |                              |                 |                               |                        |                                   |
| N021303 003                                                                                                                     | RE42096     | Oct 21, 2018                 | DP              |                               |                        |                                   |
|                                                                                                                                 | RE42096*PED | Apr 21, 2019                 |                 |                               |                        |                                   |
| <u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE -<br/>ADDERALL XR 5</u>  |             |                              |                 |                               |                        |                                   |
| N021303 005                                                                                                                     | RE42096     | Oct 21, 2018                 | DP              |                               |                        |                                   |
|                                                                                                                                 | RE42096*PED | Apr 21, 2019                 |                 |                               |                        |                                   |
| <u>ARIPIRAZOLE - ABILIFY</u>                                                                                                    |             |                              |                 |                               |                        |                                   |
| N021436 001                                                                                                                     |             |                              |                 |                               | I-633                  | Feb 16, 2014                      |
| <u>ARIPIRAZOLE - ABILIFY</u>                                                                                                    |             |                              |                 |                               |                        |                                   |
| N021436 002                                                                                                                     |             |                              |                 |                               | I-633                  | Feb 16, 2014                      |
| <u>ARIPIRAZOLE - ABILIFY</u>                                                                                                    |             |                              |                 |                               |                        |                                   |
| N021436 003                                                                                                                     |             |                              |                 |                               | I-633                  | Feb 16, 2014                      |
| <u>ARIPIRAZOLE - ABILIFY</u>                                                                                                    |             |                              |                 |                               |                        |                                   |
| N021436 004                                                                                                                     |             |                              |                 |                               | I-633                  | Feb 16, 2014                      |
| <u>ARIPIRAZOLE - ABILIFY</u>                                                                                                    |             |                              |                 |                               |                        |                                   |
| N021436 005                                                                                                                     |             |                              |                 |                               | I-633                  | Feb 16, 2014                      |
| <u>ARIPIRAZOLE - ABILIFY</u>                                                                                                    |             |                              |                 |                               |                        |                                   |
| N021436 006                                                                                                                     |             |                              |                 |                               | I-633                  | Feb 16, 2014                      |
| <u>ARIPIRAZOLE - ABILIFY</u>                                                                                                    |             |                              |                 |                               |                        |                                   |
| N021713 001                                                                                                                     |             |                              |                 |                               | I-633                  | Feb 16, 2014                      |
| <u>ARIPIRAZOLE - ABILIFY</u>                                                                                                    |             |                              |                 |                               |                        |                                   |
| N021729 002                                                                                                                     |             |                              |                 |                               | I-633                  | Feb 16, 2014                      |
| <u>ARIPIRAZOLE - ABILIFY</u>                                                                                                    |             |                              |                 |                               |                        |                                   |
| N021729 003                                                                                                                     |             |                              |                 |                               | I-633                  | Feb 16, 2014                      |
| <u>ARIPIRAZOLE - ABILIFY</u>                                                                                                    |             |                              |                 |                               |                        |                                   |
| N021866 001                                                                                                                     |             |                              |                 |                               | I-633                  | Feb 16, 2014                      |
| <u>ATAZANAVIR SULFATE - REYATAZ</u>                                                                                             |             |                              |                 |                               |                        |                                   |
| N021567 001                                                                                                                     |             |                              |                 |                               | D-130                  | Feb 04, 2014                      |
| <u>ATAZANAVIR SULFATE - REYATAZ</u>                                                                                             |             |                              |                 |                               |                        |                                   |
| N021567 002                                                                                                                     |             |                              |                 |                               | D-130                  | Feb 04, 2014                      |
| <u>ATAZANAVIR SULFATE - REYATAZ</u>                                                                                             |             |                              |                 |                               |                        |                                   |
| N021567 003                                                                                                                     |             |                              |                 |                               | D-130                  | Feb 04, 2014                      |
| <u>ATAZANAVIR SULFATE - REYATAZ</u>                                                                                             |             |                              |                 |                               |                        |                                   |
| N021567 004                                                                                                                     |             |                              |                 |                               | D-130                  | Feb 04, 2014                      |
| <u>AZILSARTAN MEDOXOMIL - EDARBI</u>                                                                                            |             |                              |                 |                               |                        |                                   |
| N200796 001                                                                                                                     | 5583141     | Dec 10, 2013                 | DS DP U-3       |                               | NCE                    | Feb 25, 2016                      |
|                                                                                                                                 | 5736555     | Jun 25, 2012                 | DS DP U-3       |                               |                        |                                   |
|                                                                                                                                 | 5958961     | Jun 06, 2014                 | DP U-3          |                               |                        |                                   |
|                                                                                                                                 | 7157584     | May 22, 2025                 | DS              |                               |                        |                                   |
|                                                                                                                                 | 7572920     | Jan 07, 2025                 | DP U-3          |                               |                        |                                   |

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| <u>AZILSARTAN MEDOXOMIL - EDARBI</u>                                                            |             |                              |                 |                               |                        |                                              |
| N200796 002                                                                                     | 5583141     | Dec 10, 2013                 | DS DP U-3       |                               | NCE                    | Feb 25, 2016                                 |
|                                                                                                 | 5736555     | Jun 25, 2012                 | DS DP U-3       |                               |                        |                                              |
|                                                                                                 | 5958961     | Jun 06, 2014                 | DP U-3          |                               |                        |                                              |
|                                                                                                 | 7157584     | May 22, 2025                 | DS              |                               |                        |                                              |
|                                                                                                 | 7572920     | Jan 07, 2025                 | DP U-3          |                               |                        |                                              |
| <u>AZITHROMYCIN - ZMAX</u>                                                                      |             |                              |                 |                               |                        |                                              |
| N050797 001                                                                                     | 7887844     | Feb 14, 2024                 | DP              |                               |                        |                                              |
| <u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>                                    |             |                              |                 |                               |                        |                                              |
| N021929 002                                                                                     | 7897646     | Sep 09, 2018                 | U-1118          |                               |                        |                                              |
| <u>CELECOXIB - CELEBREX</u>                                                                     |             |                              |                 |                               |                        |                                              |
| N020998 001                                                                                     | 5760068     | Jun 02, 2015                 | U-672           |                               |                        |                                              |
| <u>CELECOXIB - CELEBREX</u>                                                                     |             |                              |                 |                               |                        |                                              |
| N020998 002                                                                                     | 5760068     | Jun 02, 2015                 | U-672           |                               |                        |                                              |
| <u>CELECOXIB - CELEBREX</u>                                                                     |             |                              |                 |                               |                        |                                              |
| N020998 003                                                                                     | 5760068     | Jun 02, 2015                 | U-672           |                               |                        |                                              |
| <u>CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE - ADVIL ALLERGY SINUS</u> |             |                              |                 |                               |                        |                                              |
| N021441 001                                                                                     | >A> 7863287 | Feb 28, 2027                 | DP              |                               |                        |                                              |
| <u>CINACALCET HYDROCHLORIDE - SENSIPAR</u>                                                      |             |                              |                 |                               |                        |                                              |
| N021688 001                                                                                     |             |                              |                 |                               | I-634<br>M-101<br>ODE  | Feb 25, 2014<br>Feb 25, 2014<br>Feb 25, 2018 |
| <u>CINACALCET HYDROCHLORIDE - SENSIPAR</u>                                                      |             |                              |                 |                               |                        |                                              |
| N021688 002                                                                                     |             |                              |                 |                               | I-634<br>M-101<br>ODE  | Feb 25, 2014<br>Feb 25, 2014<br>Feb 25, 2018 |
| <u>CINACALCET HYDROCHLORIDE - SENSIPAR</u>                                                      |             |                              |                 |                               |                        |                                              |
| N021688 003                                                                                     |             |                              |                 |                               | I-634<br>M-101<br>ODE  | Feb 25, 2014<br>Feb 25, 2014<br>Feb 25, 2018 |
| <u>CLOPIDOGREL BISULFATE - PLAVIX</u>                                                           |             |                              |                 |                               |                        |                                              |
| N020839 001                                                                                     | 4847265     | Nov 17, 2011                 | DS DP           |                               |                        |                                              |
|                                                                                                 | 4847265*PED | May 17, 2012                 |                 |                               |                        |                                              |
|                                                                                                 | 5576328     | Jan 31, 2014                 | U-432           | Y                             |                        |                                              |
|                                                                                                 | 5576328*PED | Jul 31, 2014                 |                 |                               |                        |                                              |
|                                                                                                 | 6429210     | Jun 10, 2019                 | DS DP           |                               |                        |                                              |
|                                                                                                 | 6429210*PED | Dec 10, 2019                 |                 |                               |                        |                                              |
|                                                                                                 | 6504030     | Jun 10, 2019                 | DS              |                               |                        |                                              |
|                                                                                                 | 6504030*PED | Dec 10, 2019                 |                 |                               |                        |                                              |
| <u>CLOPIDOGREL BISULFATE - PLAVIX</u>                                                           |             |                              |                 |                               |                        |                                              |
| N020839 002                                                                                     | 4847265     | Nov 17, 2011                 | DS DP           |                               |                        |                                              |
|                                                                                                 | 4847265*PED | May 17, 2012                 |                 |                               |                        |                                              |
|                                                                                                 | 6429210     | Jun 10, 2019                 | DS DP           |                               |                        |                                              |
|                                                                                                 | 6429210*PED | Dec 10, 2019                 |                 |                               |                        |                                              |
|                                                                                                 | 6504030     | Jun 10, 2019                 | DS              |                               |                        |                                              |
|                                                                                                 | 6504030*PED | Dec 10, 2019                 |                 |                               |                        |                                              |



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| <u>COLCHICINE - COLCRYS</u>                                            |             |                              |                 |                               |                        |                                   |
| N022352 001                                                            | 7906519     | Feb 17, 2029                 | U-1116          |                               |                        |                                   |
|                                                                        | 7915269     | Feb 17, 2029                 | U-1007          |                               |                        |                                   |
| <u>DESIRUDIN RECOMBINANT - IPRIVASK</u>                                |             |                              |                 |                               |                        |                                   |
| N021271 001                                                            | 6103515     | Aug 15, 2017                 | DS              |                               |                        |                                   |
| <u>DICLOFENAC POTASSIUM - ZIPSOR</u>                                   |             |                              |                 |                               |                        |                                   |
| N022202 001                                                            | 7884095     | Feb 24, 2029                 | U-1111          |                               |                        |                                   |
|                                                                        | 7884095*PED | Aug 24, 2029                 |                 |                               |                        |                                   |
| <u>DICLOFENAC SODIUM - SOLARAZE</u>                                    |             |                              |                 |                               |                        |                                   |
| N021005 001                                                            | >A> 5929048 | Jun 17, 2014                 | U-402           |                               |                        |                                   |
|                                                                        | >A> 5985850 | Aug 11, 2015                 | DP              |                               |                        |                                   |
| <u>DIENOGEST; ESTRADIOL VALERATE - NATAZIA</u>                         |             |                              |                 |                               |                        |                                   |
| N022252 001                                                            | 6133251     | Oct 25, 2016                 | DP U-828        | Y                             |                        |                                   |
|                                                                        | 6133251     | Oct 25, 2016                 | DP U-112        | Y                             |                        |                                   |
|                                                                        | 6133251     | Oct 25, 2016                 | DP U-1          | Y                             |                        |                                   |
|                                                                        | 6884793     | Oct 25, 2016                 | DP              | Y                             |                        |                                   |
| <u>DORIPENEM - DORIBAX</u>                                             |             |                              |                 |                               |                        |                                   |
| N022106 001                                                            | 5317016     | Jun 05, 2015                 | DS DP U-282     |                               |                        |                                   |
| <u>DORIPENEM - DORIBAX</u>                                             |             |                              |                 |                               |                        |                                   |
| N022106 002                                                            | 5317016     | Jun 05, 2015                 | DS DP U-282     |                               |                        |                                   |
| <u>DOXEPIN HYDROCHLORIDE - SILENOR</u>                                 |             |                              |                 |                               |                        |                                   |
| N022036 001                                                            | 7915307     | Aug 24, 2027                 | U-620           |                               |                        |                                   |
| <u>DOXEPIN HYDROCHLORIDE - SILENOR</u>                                 |             |                              |                 |                               |                        |                                   |
| N022036 002                                                            | 7915307     | Aug 24, 2027                 | U-620           |                               |                        |                                   |
| <u>DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - SAFYRAL</u> |             |                              |                 |                               |                        |                                   |
| N022574 001                                                            | 5798338     | Jul 10, 2015                 | DP              |                               |                        |                                   |
|                                                                        | 6441168     | Apr 17, 2020                 | DS              |                               |                        |                                   |
|                                                                        | 6958326     | Dec 20, 2021                 | DP              |                               |                        |                                   |
|                                                                        | 7163931     | Mar 03, 2022                 | U-1             |                               |                        |                                   |
| <u>ELTROMBOPAG OLAMINE - PROMACTA</u>                                  |             |                              |                 |                               |                        |                                   |
| N022291 001                                                            | >A> 7547719 | Jul 13, 2025                 | DS DP U-930     |                               |                        |                                   |
| <u>ELTROMBOPAG OLAMINE - PROMACTA</u>                                  |             |                              |                 |                               |                        |                                   |
| N022291 002                                                            | >A> 7547719 | Jul 13, 2025                 | DS DP U-930     |                               |                        |                                   |
| <u>ELTROMBOPAG OLAMINE - PROMACTA</u>                                  |             |                              |                 |                               |                        |                                   |
| N022291 003                                                            | >A> 7547719 | Jul 13, 2025                 | DS DP U-930     |                               |                        |                                   |

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| <u>ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO</u>                                                   |             |                              |                 |                               |                        |                                   |
| N022511 001                                                                                        | 5714504     | Feb 03, 2015                 | DP U-1053       |                               |                        |                                   |
|                                                                                                    | 5714504*PED | Aug 03, 2015                 |                 |                               |                        |                                   |
|                                                                                                    | 5900424     | May 04, 2016                 | DS U-1053       |                               |                        |                                   |
|                                                                                                    | 5900424*PED | Nov 04, 2016                 |                 |                               |                        |                                   |
|                                                                                                    | 6369085     | May 25, 2018                 | DS DP U-1053    |                               |                        |                                   |
|                                                                                                    | 6369085*PED | Nov 25, 2018                 |                 |                               |                        |                                   |
|                                                                                                    | 6875872     | May 27, 2014                 | DS              |                               |                        |                                   |
|                                                                                                    | 6875872*PED | Nov 27, 2014                 |                 |                               |                        |                                   |
|                                                                                                    | 7411070     | May 25, 2018                 | DS U-1053       |                               |                        |                                   |
|                                                                                                    | 7411070*PED | Nov 25, 2018                 |                 |                               |                        |                                   |
| <u>ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO</u>                                                   |             |                              |                 |                               |                        |                                   |
| N022511 002                                                                                        | 5714504     | Feb 03, 2015                 | DP U-1053       |                               |                        |                                   |
|                                                                                                    | 5714504*PED | Aug 03, 2015                 |                 |                               |                        |                                   |
|                                                                                                    | 5900424     | May 04, 2016                 | DS U-1053       |                               |                        |                                   |
|                                                                                                    | 5900424*PED | Nov 04, 2016                 |                 |                               |                        |                                   |
|                                                                                                    | 6369085     | May 25, 2018                 | DS DP U-1053    |                               |                        |                                   |
|                                                                                                    | 6369085*PED | Nov 25, 2018                 |                 |                               |                        |                                   |
|                                                                                                    | 6875872     | May 27, 2014                 | DS              |                               |                        |                                   |
|                                                                                                    | 6875872*PED | Nov 27, 2014                 |                 |                               |                        |                                   |
|                                                                                                    | 7411070     | May 25, 2018                 | DS U-1053       |                               |                        |                                   |
|                                                                                                    | 7411070*PED | Nov 25, 2018                 |                 |                               |                        |                                   |
| <u>ETHINYL ESTRADIOL; LEVONORGESTREL - LOSEASONIQUE</u>                                            |             |                              |                 |                               |                        |                                   |
| N022262 001                                                                                        | 7855190     | Dec 05, 2028                 | U-1             |                               |                        |                                   |
|                                                                                                    | 7858605     | Jun 23, 2023                 | DP              |                               |                        |                                   |
| <u>ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE</u>                                              |             |                              |                 |                               |                        |                                   |
| N021840 001                                                                                        | 7855190     | Dec 05, 2028                 | U-1             |                               |                        |                                   |
|                                                                                                    | 7858605     | Jun 23, 2023                 | DP              |                               |                        |                                   |
| <u>ETHINYL ESTRADIOL; NORETHINDRONE - NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE</u> |             |                              |                 |                               |                        |                                   |
| N022573 001                                                                                        | 5552394     | Jul 22, 2014                 | U-828           |                               |                        |                                   |
|                                                                                                    | 6667050     | Apr 06, 2019                 | DP U-828        |                               |                        |                                   |
| <u>ETRAVIRINE - INTELENCE</u>                                                                      |             |                              |                 |                               |                        |                                   |
| N022187 001                                                                                        | 7887845     | Mar 25, 2019                 | DP              |                               |                        |                                   |
| <u>ETRAVIRINE - INTELENCE</u>                                                                      |             |                              |                 |                               |                        |                                   |
| N022187 002                                                                                        | 6878717     | Nov 05, 2019                 | U-1016          |                               | NCE                    | Jan 18, 2013                      |
|                                                                                                    | 7037917     | Nov 05, 2019                 | DS DP U-1016    |                               |                        |                                   |
|                                                                                                    | 7887845     | Mar 25, 2019                 | DP              |                               |                        |                                   |
| <u>EVEROLIMUS - AFINITOR</u>                                                                       |             |                              |                 |                               |                        |                                   |
| N022334 001                                                                                        |             |                              |                 |                               | ODE                    | Oct 29, 2017                      |
| <u>EVEROLIMUS - AFINITOR</u>                                                                       |             |                              |                 |                               |                        |                                   |
| N022334 002                                                                                        |             |                              |                 |                               | ODE                    | Oct 29, 2017                      |
| <u>EVEROLIMUS - AFINITOR</u>                                                                       |             |                              |                 |                               |                        |                                   |
| N022334 003                                                                                        |             |                              |                 |                               | NCE                    | Mar 30, 2014                      |
|                                                                                                    |             |                              |                 |                               | ODE                    | Oct 29, 2017                      |
| <u>EXENATIDE SYNTHETIC - BYETTA</u>                                                                |             |                              |                 |                               |                        |                                   |
| N021773 001                                                                                        | 5424286     | Dec 01, 2016                 | U-653           |                               |                        |                                   |
|                                                                                                    | 5424286     | Dec 01, 2016                 | U-1108          |                               |                        |                                   |

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| <u>EXENATIDE SYNTHETIC - BYETTA</u>      |           |                              |                 |                               |                        |                                   |
| N021773 002                              | 5424286   | Dec 01, 2016                 | U-653           |                               |                        |                                   |
|                                          | 5424286   | Dec 01, 2016                 | U-1108          |                               |                        |                                   |
| <u>FAMCICLOVIR - FAMVIR</u>              |           |                              |                 |                               |                        |                                   |
| N020363 001                              |           |                              |                 |                               | M-98                   | Jan 31, 2014                      |
| <u>FAMCICLOVIR - FAMVIR</u>              |           |                              |                 |                               |                        |                                   |
| N020363 002                              |           |                              |                 |                               | M-98                   | Jan 31, 2014                      |
| <u>FAMCICLOVIR - FAMVIR</u>              |           |                              |                 |                               |                        |                                   |
| N020363 003                              |           |                              |                 |                               | M-98                   | Jan 31, 2014                      |
| <u>FAMOTIDINE; IBUPROFEN - DUEXIS</u>    |           |                              |                 |                               |                        |                                   |
| N022519 001                              |           |                              |                 |                               | >A> NC                 | Apr 23, 2014                      |
| <u>FENOFIBRATE - ANTARA (MICRONIZED)</u> |           |                              |                 |                               |                        |                                   |
| N021695 001                              | 7863331   | Aug 08, 2020                 | U-1107          |                               |                        |                                   |
|                                          | 7863331   | Aug 08, 2020                 | U-1106          |                               |                        |                                   |
| <u>FENOFIBRATE - ANTARA (MICRONIZED)</u> |           |                              |                 |                               |                        |                                   |
| N021695 003                              | 7863331   | Aug 08, 2020                 | U-1107          |                               |                        |                                   |
|                                          | 7863331   | Aug 08, 2020                 | U-1106          |                               |                        |                                   |
| <u>FENOFIBRIC ACID - FIBRICOR</u>        |           |                              |                 |                               |                        |                                   |
| N022418 001                              | 7915247   | Aug 20, 2027                 | U-1061          |                               |                        |                                   |
|                                          | 7915247   | Aug 20, 2027                 | U-1059          |                               |                        |                                   |
|                                          | 7915247   | Aug 20, 2027                 | U-1000          |                               |                        |                                   |
| <u>FENOFIBRIC ACID - FIBRICOR</u>        |           |                              |                 |                               |                        |                                   |
| N022418 002                              | 7915247   | Aug 20, 2027                 | U-1061          |                               |                        |                                   |
|                                          | 7915247   | Aug 20, 2027                 | U-1059          |                               |                        |                                   |
|                                          | 7915247   | Aug 20, 2027                 | U-1000          |                               |                        |                                   |
| <u>FENTANYL CITRATE - ABSTRAL</u>        |           |                              |                 |                               |                        |                                   |
| N022510 001                              | 6759059   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                          | 6761910   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                          | 7910132   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
| <u>FENTANYL CITRATE - ABSTRAL</u>        |           |                              |                 |                               |                        |                                   |
| N022510 002                              | 6759059   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                          | 6761910   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                          | 7910132   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
| <u>FENTANYL CITRATE - ABSTRAL</u>        |           |                              |                 |                               |                        |                                   |
| N022510 003                              | 6759059   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                          | 6761910   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                          | 7910132   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
| <u>FENTANYL CITRATE - ABSTRAL</u>        |           |                              |                 |                               |                        |                                   |
| N022510 004                              | 6759059   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                          | 6761910   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                          | 7910132   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
| <u>FENTANYL CITRATE - ABSTRAL</u>        |           |                              |                 |                               |                        |                                   |
| N022510 005                              | 6759059   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                          | 6761910   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                          | 7910132   | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |

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| <u>FENTANYL CITRATE - ABSTRAL</u>                                                                                               |             |                              |                 |                               |                        |                                   |
| N022510 006                                                                                                                     | 6759059     | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                                                                                                                 | 6761910     | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
|                                                                                                                                 | 7910132     | Sep 24, 2019                 | DP U-767        |                               |                        |                                   |
| <u>FENTANYL CITRATE - FENTORA</u>                                                                                               |             |                              |                 |                               |                        |                                   |
| N021947 001                                                                                                                     | >A> 7862832 | Jun 15, 2028                 | DP              |                               |                        |                                   |
|                                                                                                                                 | >A> 7862833 | Jun 15, 2028                 | DP              |                               |                        |                                   |
| <u>FENTANYL CITRATE - FENTORA</u>                                                                                               |             |                              |                 |                               |                        |                                   |
| N021947 002                                                                                                                     | >A> 7862832 | Jun 15, 2028                 | DP              |                               |                        |                                   |
|                                                                                                                                 | >A> 7862833 | Jun 15, 2028                 | DP              |                               |                        |                                   |
| <u>FENTANYL CITRATE - FENTORA</u>                                                                                               |             |                              |                 |                               |                        |                                   |
| N021947 003                                                                                                                     | >A> 7862832 | Jun 15, 2028                 | DP              |                               |                        |                                   |
|                                                                                                                                 | >A> 7862833 | Jun 15, 2028                 | DP              |                               |                        |                                   |
| <u>FENTANYL CITRATE - FENTORA</u>                                                                                               |             |                              |                 |                               |                        |                                   |
| N021947 004                                                                                                                     | >A> 7862832 | Jun 15, 2028                 | DP              |                               |                        |                                   |
|                                                                                                                                 | >A> 7862833 | Jun 15, 2028                 | DP              |                               |                        |                                   |
| <u>FERUMOXYTOL - FERAHEME</u>                                                                                                   |             |                              |                 |                               |                        |                                   |
| N022180 001                                                                                                                     | 7871597     | Mar 08, 2020                 | DS DP           |                               |                        |                                   |
| <u>FESOTERODINE FUMARATE - TOVIAZ</u>                                                                                           |             |                              |                 |                               |                        |                                   |
| N022030 001                                                                                                                     | 7855230     | May 11, 2019                 | U-913           |                               |                        |                                   |
| <u>FESOTERODINE FUMARATE - TOVIAZ</u>                                                                                           |             |                              |                 |                               |                        |                                   |
| N022030 002                                                                                                                     | 7855230     | May 11, 2019                 | U-913           |                               |                        |                                   |
| <u>FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE</u> |             |                              |                 |                               |                        |                                   |
| A079043 001                                                                                                                     |             |                              |                 |                               | PC                     | Jul 27, 2011                      |
| <u>FLUOCINOLONE ACETONIDE; HYDROQUINONE; TRETINOIN - TRI-LUMA</u>                                                               |             |                              |                 |                               |                        |                                   |
| N021112 001                                                                                                                     | 7915243     | Mar 22, 2026                 | DP              |                               |                        |                                   |
| <u>FULVESTRANT - FASLODEX</u>                                                                                                   |             |                              |                 |                               |                        |                                   |
| N021344 001                                                                                                                     | 6774122     | Jan 09, 2021                 | U-596           |                               | D-126                  | Sep 09, 2013                      |
|                                                                                                                                 | 6774122*PED | Jul 09, 2021                 |                 |                               | PED                    | Mar 09, 2014                      |
|                                                                                                                                 | 7456160     | Jan 09, 2021                 | U-596           |                               |                        |                                   |
|                                                                                                                                 | 7456160*PED | Jul 09, 2021                 |                 |                               |                        |                                   |
| <u>GABAPENTIN - GABAPENTIN</u>                                                                                                  |             |                              |                 |                               |                        |                                   |
| A078974 001                                                                                                                     |             |                              |                 |                               | PC                     | Aug 22, 2011                      |
| <u>GABAPENTIN - GRALISE</u>                                                                                                     |             |                              |                 |                               |                        |                                   |
| N022544 001                                                                                                                     | 6340475     | Sep 19, 2016                 | DP              |                               | NP                     | Jan 28, 2014                      |
|                                                                                                                                 | 6488962     | Jun 20, 2020                 | DP              |                               |                        |                                   |
|                                                                                                                                 | 6635280     | Sep 19, 2016                 | DP              |                               |                        |                                   |
|                                                                                                                                 | 6723340     | Oct 25, 2021                 | DP              |                               |                        |                                   |
|                                                                                                                                 | 7438927     | Feb 26, 2024                 | U-1114          |                               |                        |                                   |
|                                                                                                                                 | 7731989     | Oct 25, 2022                 | DP              |                               |                        |                                   |

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| <u>GABAPENTIN - GRALISE</u>                                  |             |                              |                 |                               |                        |                                   |
| N022544 002                                                  | 6340475     | Sep 19, 2016                 | DP              |                               | NP                     | Jan 28, 2014                      |
|                                                              | 6488962     | Jun 20, 2020                 | DP              |                               |                        |                                   |
|                                                              | 6635280     | Sep 19, 2016                 | DP              |                               |                        |                                   |
|                                                              | 6723340     | Oct 25, 2021                 | DP              |                               |                        |                                   |
|                                                              | 7438927     | Feb 26, 2024                 | U-1114          |                               |                        |                                   |
|                                                              | 7731989     | Oct 25, 2022                 | DP              |                               |                        |                                   |
| <u>GABAPENTIN ENACARBIL - HORIZANT</u>                       |             |                              |                 |                               |                        |                                   |
| N022399 001                                                  | >A> 6818787 | Nov 06, 2022                 | DS DP           |                               | >A> NCE                | Apr 06, 2016                      |
| <u>GADOBUTROL - GADAVIST</u>                                 |             |                              |                 |                               |                        |                                   |
| N201277 001                                                  | 5980864     | Nov 09, 2016                 | DS DP U-1119    |                               | NCE                    | Mar 14, 2016                      |
| <u>GADOBUTROL - GADAVIST</u>                                 |             |                              |                 |                               |                        |                                   |
| N201277 002                                                  | 5980864     | Nov 09, 2016                 | DS DP U-1119    |                               | NCE                    | Mar 14, 2016                      |
| <u>GADOBUTROL - GADAVIST</u>                                 |             |                              |                 |                               |                        |                                   |
| N201277 003                                                  | 5980864     | Nov 09, 2016                 | DS DP U-1119    |                               | NCE                    | Mar 14, 2016                      |
| <u>GADOBUTROL - GADAVIST</u>                                 |             |                              |                 |                               |                        |                                   |
| N201277 004                                                  | 5980864     | Nov 09, 2016                 | DS DP U-1119    |                               | NCE                    | Mar 14, 2016                      |
| <u>GADOBUTROL - GADAVIST</u>                                 |             |                              |                 |                               |                        |                                   |
| N201277 005                                                  | 5980864     | Nov 09, 2016                 | DS DP U-1119    |                               | NCE                    | Mar 14, 2016                      |
| <u>GADOFOSVESET TRISODIUM - ABLAVAR</u>                      |             |                              |                 |                               |                        |                                   |
| N021711 001                                                  | 5362475     | Nov 08, 2011                 | DS              |                               |                        |                                   |
|                                                              | 6676929     | May 26, 2015                 | DP              |                               |                        |                                   |
|                                                              | 7011815     | Feb 01, 2015                 | U-1112          |                               |                        |                                   |
|                                                              | 7060250     | May 26, 2015                 | DS              |                               |                        |                                   |
|                                                              | 7229606     | May 26, 2015                 | U-1112          |                               |                        |                                   |
| <u>GADOFOSVESET TRISODIUM - ABLAVAR</u>                      |             |                              |                 |                               |                        |                                   |
| N021711 002                                                  | 5362475     | Nov 08, 2011                 | DS              |                               |                        |                                   |
|                                                              | 6676929     | May 26, 2015                 | DP              |                               |                        |                                   |
|                                                              | 7011815     | Feb 01, 2015                 | U-1112          |                               |                        |                                   |
|                                                              | 7060250     | May 26, 2015                 | DS              |                               |                        |                                   |
|                                                              | 7229606     | May 26, 2015                 | U-1112          |                               |                        |                                   |
| <u>GEMCITABINE HYDROCHLORIDE - GEMCITABINE</u>               |             |                              |                 |                               |                        |                                   |
| A079183 001                                                  |             |                              |                 |                               | PC                     | May 14, 2011                      |
| <u>GEMCITABINE HYDROCHLORIDE - GEMCITABINE HYDROCHLORIDE</u> |             |                              |                 |                               |                        |                                   |
| A077983 001                                                  |             |                              |                 |                               | PC                     | Jul 24, 2011                      |
| <u>GEMCITABINE HYDROCHLORIDE - GEMCITABINE HYDROCHLORIDE</u> |             |                              |                 |                               |                        |                                   |
| A077983 002                                                  |             |                              |                 |                               | PC                     | Jul 24, 2011                      |
| <u>GRANISETRON HYDROCHLORIDE - KYTRIL</u>                    |             |                              |                 |                               |                        |                                   |
| N020239 001                                                  |             |                              |                 |                               | >A> M-102              | Apr 29, 2014                      |
| <u>GRANISETRON HYDROCHLORIDE - KYTRIL</u>                    |             |                              |                 |                               |                        |                                   |
| N020239 002                                                  |             |                              |                 |                               | >A> M-102              | Apr 29, 2014                      |
| <u>GRANISETRON HYDROCHLORIDE - KYTRIL</u>                    |             |                              |                 |                               |                        |                                   |
| N020239 003                                                  |             |                              |                 |                               | >A> M-102              | Apr 29, 2014                      |
| <u>GRANISETRON HYDROCHLORIDE - KYTRIL</u>                    |             |                              |                 |                               |                        |                                   |
| N020239 004                                                  |             |                              |                 |                               | >A> M-102              | Apr 29, 2014                      |

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| <u>GUANFACINE HYDROCHLORIDE - INTUNIV</u>              |                 |                              |                 |                               |                        |                                   |
| N022037 001                                            |                 |                              |                 |                               | I-635                  | Feb 25, 2014                      |
| <u>GUANFACINE HYDROCHLORIDE - INTUNIV</u>              |                 |                              |                 |                               |                        |                                   |
| N022037 002                                            |                 |                              |                 |                               | I-635                  | Feb 25, 2014                      |
| <u>GUANFACINE HYDROCHLORIDE - INTUNIV</u>              |                 |                              |                 |                               |                        |                                   |
| N022037 003                                            |                 |                              |                 |                               | I-635                  | Feb 25, 2014                      |
| <u>GUANFACINE HYDROCHLORIDE - INTUNIV</u>              |                 |                              |                 |                               |                        |                                   |
| N022037 004                                            |                 |                              |                 |                               | I-635                  | Feb 25, 2014                      |
| <u>HYDROXOCOBALAMIN - CYANOKIT</u>                     |                 |                              |                 |                               |                        |                                   |
| N022041 001                                            | >A> 5834448     | Nov 14, 2016                 | DP              |                               | >A> ODE                | Dec 15, 2013                      |
| <u>HYDROXYPROGESTERONE CAPROATE - MAKENA</u>           |                 |                              |                 |                               |                        |                                   |
| N021945 001                                            |                 |                              |                 |                               | ODE                    | Feb 03, 2018                      |
| <u>IMIQUIMOD - ZYCLARA</u>                             |                 |                              |                 |                               |                        |                                   |
| N022483 001                                            |                 |                              |                 |                               | I-636                  | Mar 24, 2014                      |
| <u>INSULIN GLARGINE RECOMBINANT - LANTUS</u>           |                 |                              |                 |                               |                        |                                   |
| N021081 001                                            | >A> 7918833     | Sep 23, 2027                 | DP              |                               |                        |                                   |
|                                                        | >A> 7918833*PED | Mar 23, 2028                 |                 |                               |                        |                                   |
| <u>INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR</u> |                 |                              |                 |                               |                        |                                   |
| N021629 003                                            | >A> 7918833     | Sep 23, 2027                 | DP              |                               |                        |                                   |
| <u>INSULIN RECOMBINANT HUMAN - HUMULIN R</u>           |                 |                              |                 |                               |                        |                                   |
| N018780 001                                            |                 |                              |                 |                               | NR                     | Mar 25, 2014                      |
| <u>INSULIN RECOMBINANT HUMAN - HUMULIN R PEN</u>       |                 |                              |                 |                               |                        |                                   |
| N018780 005                                            |                 |                              |                 |                               | NR                     | Mar 25, 2014                      |
| <u>IOFLUPANE I-123 - DATSCAN</u>                       |                 |                              |                 |                               |                        |                                   |
| N022454 001                                            |                 |                              |                 |                               | NCE                    | Jan 14, 2016                      |
| <u>IXABEPILONE - IXEMPRA KIT</u>                       |                 |                              |                 |                               |                        |                                   |
| N022065 001                                            | 6670384         | Jan 23, 2022                 | DP U-960        |                               | NCE                    | Oct 16, 2012                      |
|                                                        | 6670384         | Jan 23, 2022                 | DP U-959        |                               | PED                    | Apr 16, 2013                      |
|                                                        | 6670384*PED     | Jul 23, 2022                 |                 |                               |                        |                                   |
|                                                        | 7022330         | Jan 23, 2022                 | DP U-958        |                               |                        |                                   |
|                                                        | 7022330*PED     | Jul 23, 2022                 |                 |                               |                        |                                   |
|                                                        | 7125899         | May 26, 2018                 | DS DP U-957     |                               |                        |                                   |
|                                                        | 7125899*PED     | Nov 26, 2018                 |                 |                               |                        |                                   |
|                                                        | 7312237         | Aug 21, 2024                 | U-965           |                               |                        |                                   |
|                                                        | 7312237*PED     | Feb 21, 2025                 |                 |                               |                        |                                   |
|                                                        | RE41393         | Feb 08, 2022                 | U-961           |                               |                        |                                   |
|                                                        | RE41393*PED     | Aug 08, 2022                 |                 |                               |                        |                                   |
|                                                        | RE41911         | May 26, 2018                 | DS DP U-961     |                               |                        |                                   |
|                                                        | RE41911*PED     | Nov 26, 2018                 |                 |                               |                        |                                   |

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| <u>IXABEPILONE - IXEMPRA KIT</u>             |             |                              |                 |                               |                        |                                   |
| N022065 002                                  | 6670384     | Jan 23, 2022                 | DP U-960        |                               | NCE                    | Oct 16, 2012                      |
|                                              | 6670384     | Jan 23, 2022                 | DP U-959        |                               | PED                    | Apr 16, 2013                      |
|                                              | 6670384*PED | Jul 23, 2022                 |                 |                               |                        |                                   |
|                                              | 7022330     | Jan 23, 2022                 | DP U-958        |                               |                        |                                   |
|                                              | 7022330*PED | Jul 23, 2022                 |                 |                               |                        |                                   |
|                                              | 7125899     | May 26, 2018                 | DS DP U-957     |                               |                        |                                   |
|                                              | 7125899*PED | Nov 26, 2018                 |                 |                               |                        |                                   |
|                                              | 7312237     | Aug 21, 2024                 | U-965           |                               |                        |                                   |
|                                              | 7312237*PED | Feb 21, 2025                 |                 |                               |                        |                                   |
|                                              | RE41393     | Feb 08, 2022                 | U-961           |                               |                        |                                   |
|                                              | RE41393*PED | Aug 08, 2022                 |                 |                               |                        |                                   |
|                                              | RE41911     | May 26, 2018                 | DS DP U-961     |                               |                        |                                   |
|                                              | RE41911*PED | Nov 26, 2018                 |                 |                               |                        |                                   |
| <u>LAMOTRIGINE - LAMICTAL ODT</u>            |             |                              |                 |                               |                        |                                   |
| N022251 001                                  | >A> 7919115 | Jan 04, 2029                 | DS DP           |                               |                        |                                   |
| <u>LAMOTRIGINE - LAMICTAL ODT</u>            |             |                              |                 |                               |                        |                                   |
| N022251 002                                  | >A> 7919115 | Jan 04, 2029                 | DS DP           |                               |                        |                                   |
| <u>LAMOTRIGINE - LAMICTAL ODT</u>            |             |                              |                 |                               |                        |                                   |
| N022251 003                                  | >A> 7919115 | Jan 04, 2029                 | DS DP           |                               |                        |                                   |
| <u>LAMOTRIGINE - LAMICTAL ODT</u>            |             |                              |                 |                               |                        |                                   |
| N022251 004                                  | >A> 7919115 | Jan 04, 2029                 | DS DP           |                               |                        |                                   |
| <u>LANREOTIDE ACETATE - SOMATULINE DEPOT</u> |             |                              |                 |                               |                        |                                   |
| N022074 001                                  | 5595760     | Mar 08, 2020                 | DP U-831        |                               | D-131                  | Mar 04, 2014                      |
| <u>LANREOTIDE ACETATE - SOMATULINE DEPOT</u> |             |                              |                 |                               |                        |                                   |
| N022074 002                                  | 5595760     | Mar 08, 2020                 | DP U-831        |                               | D-131                  | Mar 04, 2014                      |
| <u>LANREOTIDE ACETATE - SOMATULINE DEPOT</u> |             |                              |                 |                               |                        |                                   |
| N022074 003                                  | 5595760     | Mar 08, 2020                 | DP U-831        |                               | D-131                  | Mar 04, 2014                      |
| <u>LANSOPRAZOLE - PREVACID</u>               |             |                              |                 |                               |                        |                                   |
| N021428 001                                  | 7875292     | May 17, 2019                 | DP              |                               |                        |                                   |
|                                              | 7875292*PED | Nov 17, 2019                 |                 |                               |                        |                                   |
| <u>LANSOPRAZOLE - PREVACID</u>               |             |                              |                 |                               |                        |                                   |
| N021428 002                                  | 7875292     | May 17, 2019                 | DP              |                               |                        |                                   |
|                                              | 7875292*PED | Nov 17, 2019                 |                 |                               |                        |                                   |
| <u>LENALIDOMIDE - REVLIMID</u>               |             |                              |                 |                               |                        |                                   |
| N021880 001                                  | 7855217     | Nov 24, 2024                 | DS DP           |                               |                        |                                   |
| <u>LENALIDOMIDE - REVLIMID</u>               |             |                              |                 |                               |                        |                                   |
| N021880 002                                  | 7855217     | Nov 24, 2024                 | DS DP           |                               |                        |                                   |
| <u>LENALIDOMIDE - REVLIMID</u>               |             |                              |                 |                               |                        |                                   |
| N021880 004                                  | 7855217     | Nov 24, 2024                 | DS DP           |                               |                        |                                   |
| <u>LEVOLEUCOVORIN CALCIUM - FUSILEV</u>      |             |                              |                 |                               |                        |                                   |
| N020140 002                                  | >A> 6500829 | Dec 31, 2019                 | DS DP           |                               | >A> ODE                | Mar 07, 2015                      |
| <u>LEVOLEUCOVORIN CALCIUM - FUSILEV</u>      |             |                              |                 |                               |                        |                                   |
| N020140 003                                  | >A> 6500829 | Dec 31, 2019                 | DS DP           |                               | >A> ODE                | Mar 07, 2015                      |

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| <u>LOTEPREDNOL ETABONATE - LOTEMAX</u>                                       |             |                              |                 |                               |                        |                                   |
| N200738 001                                                                  |             |                              |                 |                               | >A> NDF<br>>A> PED     | Apr 15, 2014<br>Oct 15, 2014      |
| <u>METFORMIN HYDROCHLORIDE - FORTAMET</u>                                    |             |                              |                 |                               |                        |                                   |
| N021574 001                                                                  | 7919116     | Mar 20, 2018                 | DP              |                               |                        |                                   |
| <u>METFORMIN HYDROCHLORIDE - FORTAMET</u>                                    |             |                              |                 |                               |                        |                                   |
| N021574 002                                                                  | 7919116     | Mar 20, 2018                 | DP              |                               |                        |                                   |
| <u>METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE - ACTOPLUS MET XR</u> |             |                              |                 |                               |                        |                                   |
| N022024 001                                                                  | >A> 7919116 | Mar 20, 2018                 | U-973           |                               |                        |                                   |
|                                                                              | >A> 7919116 | Mar 20, 2018                 | U-1120          |                               |                        |                                   |
| <u>METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE - ACTOPLUS MET XR</u> |             |                              |                 |                               |                        |                                   |
| N022024 002                                                                  | >A> 7919116 | Mar 20, 2018                 | U-973           |                               |                        |                                   |
|                                                                              | >A> 7919116 | Mar 20, 2018                 | U-1120          |                               |                        |                                   |
| <u>METRONIDAZOLE - VANDAZOLE</u>                                             |             |                              |                 |                               |                        |                                   |
| N021806 001                                                                  | 7456207     | Sep 22, 2024                 | DP              |                               |                        |                                   |
| <u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>                                   |             |                              |                 |                               |                        |                                   |
| N022256 001                                                                  | 7888342     | Nov 05, 2021                 | U-882           |                               |                        |                                   |
| <u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>                                   |             |                              |                 |                               |                        |                                   |
| N022256 002                                                                  | 7888342     | Nov 05, 2021                 | U-882           |                               |                        |                                   |
| <u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>                                   |             |                              |                 |                               |                        |                                   |
| N022256 003                                                                  | 7888342     | Nov 05, 2021                 | U-882           |                               |                        |                                   |
| <u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>                                   |             |                              |                 |                               |                        |                                   |
| N022256 004                                                                  | 7888342     | Nov 05, 2021                 | U-882           |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - SOLODYN</u>                                   |             |                              |                 |                               |                        |                                   |
| N050808 001                                                                  | 7919483     | Feb 28, 2027                 | U-1078          |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - SOLODYN</u>                                   |             |                              |                 |                               |                        |                                   |
| N050808 002                                                                  | 7919483     | Feb 28, 2027                 | U-1078          |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - SOLODYN</u>                                   |             |                              |                 |                               |                        |                                   |
| N050808 003                                                                  | 7919483     | Feb 28, 2027                 | U-1078          |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - SOLODYN</u>                                   |             |                              |                 |                               |                        |                                   |
| N050808 004                                                                  | 7919483     | Feb 28, 2027                 | U-1078          |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - SOLODYN</u>                                   |             |                              |                 |                               |                        |                                   |
| N050808 005                                                                  | 7919483     | Feb 28, 2027                 | U-1078          |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - SOLODYN</u>                                   |             |                              |                 |                               |                        |                                   |
| N050808 006                                                                  | 7919483     | Feb 28, 2027                 | U-1078          |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - SOLODYN</u>                                   |             |                              |                 |                               |                        |                                   |
| N050808 007                                                                  | 7919483     | Feb 28, 2027                 | U-1078          |                               |                        |                                   |
| <u>MINOCYCLINE HYDROCHLORIDE - SOLODYN</u>                                   |             |                              |                 |                               |                        |                                   |
| N050808 008                                                                  | 7919483     | Feb 28, 2027                 | U-1078          |                               |                        |                                   |
| <u>MOMETASONE FUROATE MONOHYDRATE - NASONEX</u>                              |             |                              |                 |                               |                        |                                   |
| N020762 001                                                                  |             |                              |                 |                               | M-99                   | Jan 19, 2014                      |



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| 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>MOXIFLOXACIN HYDROCHLORIDE - MOXEZA</u>                 |                 |                              |                 |                               |                        |                                   |
| N022428 001                                                | >A> 7671070*PED | Mar 29, 2020                 |                 |                               |                        |                                   |
| <u>MUIPIROCIN CALCIUM - BACTROBAN</u>                      |                 |                              |                 |                               |                        |                                   |
| N050746 001                                                | >A> 6025389     | Oct 20, 2014                 | DP U-1122       |                               |                        |                                   |
| <u>NEVIRAPINE - VIRAMUNE XR</u>                            |                 |                              |                 |                               |                        |                                   |
| N201152 001                                                | 5366972         | Nov 22, 2011                 | DS DP U-167     |                               | NDF                    | Mar 25, 2014                      |
|                                                            | 5366972*PED     | May 22, 2012                 |                 |                               |                        |                                   |
| <u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>                     |                 |                              |                 |                               |                        |                                   |
| N021087 001                                                | 5952375         | Feb 27, 2015                 | DS DP           |                               |                        |                                   |
|                                                            | 5952375*PED     | Aug 27, 2015                 |                 |                               |                        |                                   |
| <u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>                     |                 |                              |                 |                               |                        |                                   |
| N021087 002                                                | 5952375         | Feb 27, 2015                 | DS DP           |                               |                        |                                   |
|                                                            | 5952375*PED     | Aug 27, 2015                 |                 |                               |                        |                                   |
| <u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>                     |                 |                              |                 |                               |                        |                                   |
| N021087 003                                                | 5952375         | Feb 27, 2015                 | DS DP           |                               |                        |                                   |
|                                                            | 5952375*PED     | Aug 27, 2015                 |                 |                               |                        |                                   |
| <u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>                     |                 |                              |                 |                               |                        |                                   |
| N021246 001                                                | 5763483         | Dec 27, 2016                 | DS U-376        |                               |                        |                                   |
|                                                            | 5763483         | Dec 27, 2016                 | DS U-1113       |                               |                        |                                   |
|                                                            | 5952375         | Feb 27, 2015                 | DS DP           |                               |                        |                                   |
|                                                            | 5952375*PED     | Aug 27, 2015                 |                 |                               |                        |                                   |
| <u>PACLITAXEL - ABRAXANE</u>                               |                 |                              |                 |                               |                        |                                   |
| N021660 001                                                | >A> 7923536     | Dec 09, 2023                 | U-1117          |                               |                        |                                   |
|                                                            | RE41884         | Aug 14, 2016                 | U-1117          |                               |                        |                                   |
| <u>PALIPERIDONE - INVEGA</u>                               |                 |                              |                 |                               |                        |                                   |
| N021999 001                                                |                 |                              |                 |                               | >A> NPP                | Apr 06, 2014                      |
|                                                            |                 |                              |                 |                               | >A> PED                | Oct 06, 2014                      |
| <u>PALIPERIDONE - INVEGA</u>                               |                 |                              |                 |                               |                        |                                   |
| N021999 002                                                |                 |                              |                 |                               | >A> NPP                | Apr 06, 2014                      |
|                                                            |                 |                              |                 |                               | >A> PED                | Oct 06, 2014                      |
| <u>PALIPERIDONE - INVEGA</u>                               |                 |                              |                 |                               |                        |                                   |
| N021999 003                                                |                 |                              |                 |                               | >A> NPP                | Apr 06, 2014                      |
|                                                            |                 |                              |                 |                               | >A> PED                | Oct 06, 2014                      |
| <u>PALIPERIDONE - INVEGA</u>                               |                 |                              |                 |                               |                        |                                   |
| N021999 004                                                |                 |                              |                 |                               | >A> NPP                | Apr 06, 2014                      |
|                                                            |                 |                              |                 |                               | >A> PED                | Oct 06, 2014                      |
| <u>PALIPERIDONE - INVEGA</u>                               |                 |                              |                 |                               |                        |                                   |
| N021999 006                                                |                 |                              |                 |                               | >A> NPP                | Apr 06, 2014                      |
|                                                            |                 |                              |                 |                               | >A> PED                | Oct 06, 2014                      |
| <u>PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE</u> |                 |                              |                 |                               |                        |                                   |
| A091427 001                                                |                 |                              |                 |                               | >A> PC                 | Nov 01, 2011                      |
| <u>PEMETREXED DISODIUM - ALIMTA</u>                        |                 |                              |                 |                               |                        |                                   |
| N021462 001                                                |                 |                              |                 |                               | M-61<br>PED            | Mar 17, 2014<br>Sep 17, 2014      |
| <u>PEMETREXED DISODIUM - ALIMTA</u>                        |                 |                              |                 |                               |                        |                                   |
| N021462 002                                                |                 |                              |                 |                               | M-61<br>PED            | Mar 17, 2014<br>Sep 17, 2014      |

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| 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>PERFLUTREN - DEFINITY</u>                                               |             |                              |                 |                               |                        |                                   |
| N021064 001                                                                | 5527521     | Feb 22, 2015                 | DP U-665        |                               |                        |                                   |
|                                                                            | 5585112     | Dec 17, 2013                 | DP              |                               |                        |                                   |
| <u>PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN</u>                      |             |                              |                 |                               |                        |                                   |
| N050684 001                                                                | >A> 7915229 | Apr 14, 2023                 | DP              |                               |                        |                                   |
| <u>PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN</u>                      |             |                              |                 |                               |                        |                                   |
| N050684 002                                                                | >A> 7915229 | Apr 14, 2023                 | DP              |                               |                        |                                   |
| <u>PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN</u>                      |             |                              |                 |                               |                        |                                   |
| N050684 003                                                                | >A> 7915229 | Apr 14, 2023                 | DP              |                               |                        |                                   |
| <u>PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN</u>                      |             |                              |                 |                               |                        |                                   |
| N050684 004                                                                | >A> 7915229 | Apr 14, 2023                 | DP              |                               |                        |                                   |
| <u>PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN IN PLASTIC CONTAINER</u> |             |                              |                 |                               |                        |                                   |
| N050750 001                                                                | >A> 7915229 | Apr 14, 2023                 | DP              |                               |                        |                                   |
| <u>PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN IN PLASTIC CONTAINER</u> |             |                              |                 |                               |                        |                                   |
| N050750 002                                                                | >A> 7915229 | Apr 14, 2023                 | DP              |                               |                        |                                   |
| <u>PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN IN PLASTIC CONTAINER</u> |             |                              |                 |                               |                        |                                   |
| N050750 003                                                                | >A> 7915229 | Apr 14, 2023                 | DP              |                               |                        |                                   |
| <u>PLERIXAFOR - MOZOBIL</u>                                                |             |                              |                 |                               |                        |                                   |
| N022311 001                                                                | 7897590     | Jul 22, 2023                 | U-936           |                               |                        |                                   |
|                                                                            | RE42152     | Dec 10, 2013                 | DP              |                               |                        |                                   |
| <u>RALTEGRAVIR POTASSIUM - ISENTRESS</u>                                   |             |                              |                 |                               |                        |                                   |
| N022145 001                                                                | 7169780     | Oct 03, 2023                 | DS DP           |                               |                        |                                   |
| <u>RANOLAZINE - RANEXA</u>                                                 |             |                              |                 |                               |                        |                                   |
| N021526 001                                                                | 6369062     | May 27, 2019                 | DP              | Y                             |                        |                                   |
| <u>RETAPAMULIN - ALTABAX</u>                                               |             |                              |                 |                               |                        |                                   |
| N022055 001                                                                | 7875630     | Feb 14, 2027                 | DS              |                               |                        |                                   |
|                                                                            | RE39128     | Apr 12, 2021                 | DS DP U-805     |                               |                        |                                   |
| <u>RIFAXIMIN - XIFAXAN</u>                                                 |             |                              |                 |                               |                        |                                   |
| N021361 001                                                                | 7902206     | Jun 19, 2024                 | DS DP           |                               |                        |                                   |
|                                                                            | 7906542     | Jun 01, 2025                 | DS DP           |                               |                        |                                   |
|                                                                            | >A> 7928115 | Jul 24, 2029                 | U-1121          |                               |                        |                                   |
| <u>RIFAXIMIN - XIFAXAN</u>                                                 |             |                              |                 |                               |                        |                                   |
| N022554 001                                                                | 7612199     | Jun 19, 2024                 | DS DP           |                               |                        |                                   |
|                                                                            | 7902206     | Jun 19, 2024                 | DS DP           |                               |                        |                                   |
|                                                                            | 7906542     | Jun 01, 2025                 | DS DP           |                               |                        |                                   |
| <u>RIZATRIPTAN BENZOATE - MAXALT</u>                                       |             |                              |                 |                               |                        |                                   |
| N020864 001                                                                | 5602162     | Feb 11, 2014                 |                 | Y                             |                        |                                   |
| <u>RIZATRIPTAN BENZOATE - MAXALT</u>                                       |             |                              |                 |                               |                        |                                   |
| N020864 002                                                                | 5602162     | Feb 11, 2014                 |                 | Y                             |                        |                                   |
| <u>RIZATRIPTAN BENZOATE - MAXALT-MLT</u>                                   |             |                              |                 |                               |                        |                                   |
| N020865 001                                                                | 5602162     | Feb 11, 2014                 | U-240           | Y                             |                        |                                   |

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| 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>RIZATRIPTAN BENZOATE - MAXALT-MLT</u>               |             |                              |                 |                               |                        |                                   |
| N020865 002                                            | 5602162     | Feb 11, 2014                 | U-240           | Y                             |                        |                                   |
| <u>ROFLUMILAST - DALIRES</u>                           |             |                              |                 |                               |                        |                                   |
| N022522 001                                            | 5712298     | Jan 27, 2015                 | DS DP U-1115    |                               | NCE                    | Feb 28, 2016                      |
| <u>ROTIGOTINE - NEUPRO</u>                             |             |                              |                 |                               |                        |                                   |
| N021829 001                                            | >A> 6699498 | Nov 27, 2020                 | DP              |                               |                        |                                   |
| <u>ROTIGOTINE - NEUPRO</u>                             |             |                              |                 |                               |                        |                                   |
| N021829 002                                            | >A> 6699498 | Nov 27, 2020                 | DP              |                               |                        |                                   |
| <u>ROTIGOTINE - NEUPRO</u>                             |             |                              |                 |                               |                        |                                   |
| N021829 003                                            | >A> 6699498 | Nov 27, 2020                 | DP              |                               |                        |                                   |
| <u>RUFINAMIDE - BANZEL</u>                             |             |                              |                 |                               |                        |                                   |
| N201367 001                                            | 6740669     | Aug 17, 2020                 | DS DP           |                               | NCE<br>ODE             | Nov 14, 2013<br>Nov 14, 2015      |
| <u>SODIUM NITRITE; SODIUM THIOSULFATE - NITHIODOTE</u> |             |                              |                 |                               |                        |                                   |
| N201444 001                                            |             |                              |                 |                               | ODE                    | Jan 14, 2018                      |
| <u>SODIUM OXYBATE - XYREM</u>                          |             |                              |                 |                               |                        |                                   |
| N021196 001                                            | 7668730     | Jun 16, 2024                 | U-1110          |                               |                        |                                   |
|                                                        | 7895059     | Dec 17, 2022                 | U-1110          |                               |                        |                                   |
| <u>SORAFENIB TOSYLATE - NEXAVAR</u>                    |             |                              |                 |                               |                        |                                   |
| N021923 001                                            | 7897623     | Jan 12, 2020                 | DP              |                               |                        |                                   |
| <u>SPINOSAD - NATROBA</u>                              |             |                              |                 |                               |                        |                                   |
| N022408 001                                            | 5496931     | Mar 05, 2013                 | DS U-1105       |                               | NCE                    | Jan 18, 2016                      |
|                                                        | 6063771     | Jun 22, 2019                 | DP U-1105       |                               |                        |                                   |
|                                                        | 6342482     | Jun 22, 2019                 | DP U-1105       |                               |                        |                                   |
|                                                        | 7030095     | Jul 02, 2021                 | DP U-1105       |                               |                        |                                   |
| <u>SUMATRIPTAN SUCCINATE - SUMAVEL DOSEPRO</u>         |             |                              |                 |                               |                        |                                   |
| N022239 001                                            | 7776007     | Apr 09, 2025                 | DP              |                               |                        |                                   |
|                                                        | 7901385     | Jul 31, 2026                 | DP              |                               |                        |                                   |
| <u>TELIVUDINE - TYZEKA</u>                             |             |                              |                 |                               |                        |                                   |
| N022011 001                                            | 7858594     | Sep 11, 2023                 | DS DP U-999     |                               |                        |                                   |
| <u>TESTOSTERONE - ANDROGEL</u>                         |             |                              |                 |                               |                        |                                   |
| N022309 001                                            |             |                              |                 |                               | >A> NP                 | Apr 29, 2014                      |
| <u>TESTOSTERONE - FORTESTA</u>                         |             |                              |                 |                               |                        |                                   |
| N021463 001                                            | >A> 6319913 | Nov 09, 2018                 | U-490           |                               |                        |                                   |
|                                                        | >A> 6579865 | Nov 09, 2018                 | DP              |                               |                        |                                   |
| <u>THALIDOMIDE - THALOMID</u>                          |             |                              |                 |                               |                        |                                   |
| N020785 001                                            | 7874984     | Aug 28, 2018                 | U-733           |                               |                        |                                   |
|                                                        | 7874984     | Aug 28, 2018                 | U-732           |                               |                        |                                   |
|                                                        | 7874984     | Aug 28, 2018                 | U-442           |                               |                        |                                   |
|                                                        | 7874984     | Aug 28, 2018                 | U-371           |                               |                        |                                   |
|                                                        | 7874984     | Aug 28, 2018                 | U-1109          |                               |                        |                                   |

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|----------------------------------------------|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>THALIDOMIDE - THALOMID</u>                |             |                              |                 |                               |                        |                                   |
| N020785 002                                  | 7874984     | Aug 28, 2018                 | U-733           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-732           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-442           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-371           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-1109          |                               |                        |                                   |
| <u>THALIDOMIDE - THALOMID</u>                |             |                              |                 |                               |                        |                                   |
| N020785 003                                  | 7874984     | Aug 28, 2018                 | U-733           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-732           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-442           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-371           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-1109          |                               |                        |                                   |
| <u>THALIDOMIDE - THALOMID</u>                |             |                              |                 |                               |                        |                                   |
| N020785 004                                  | 7874984     | Aug 28, 2018                 | U-733           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-732           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-442           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-371           |                               |                        |                                   |
|                                              | 7874984     | Aug 28, 2018                 | U-1109          |                               |                        |                                   |
| <u>TIGECYCLINE - TYGACIL</u>                 |             |                              |                 |                               |                        |                                   |
| N021821 001                                  | 7879828     | Feb 05, 2029                 | DP              |                               |                        |                                   |
| <u>VANDETANIB - VANDETANIB</u>               |             |                              |                 |                               |                        |                                   |
| N022405 001                                  | >A> 6414148 | Sep 23, 2017                 | DS              |                               | >A> NCE                | Apr 06, 2016                      |
|                                              | >A> 7173038 | Aug 14, 2021                 | DS DP           |                               | >A> ODE                | Apr 06, 2018                      |
| <u>VANDETANIB - VANDETANIB</u>               |             |                              |                 |                               |                        |                                   |
| N022405 002                                  | >A> 6414148 | Sep 23, 2017                 | DS              |                               | >A> NCE                | Apr 06, 2016                      |
|                                              | >A> 7173038 | Aug 14, 2021                 | DS DP           |                               | >A> ODE                | Apr 06, 2018                      |
| <u>VILAZODONE HYDROCHLORIDE - VIIBRYD</u>    |             |                              |                 |                               |                        |                                   |
| N022567 001                                  | 5532241     | Sep 29, 2014                 | DS DP           |                               | NCE                    | Jan 21, 2016                      |
|                                              | 7834020     | Jun 05, 2022                 | DS DP U-839     |                               |                        |                                   |
| <u>VILAZODONE HYDROCHLORIDE - VIIBRYD</u>    |             |                              |                 |                               |                        |                                   |
| N022567 002                                  | 5532241     | Sep 29, 2014                 | DS DP           |                               | NCE                    | Jan 21, 2016                      |
|                                              | 7834020     | Jun 05, 2022                 | DS DP U-839     |                               |                        |                                   |
| <u>VILAZODONE HYDROCHLORIDE - VIIBRYD</u>    |             |                              |                 |                               |                        |                                   |
| N022567 003                                  | 5532241     | Sep 29, 2014                 | DS DP           |                               | NCE                    | Jan 21, 2016                      |
|                                              | 7834020     | Jun 05, 2022                 | DS DP U-839     |                               |                        |                                   |
| <u>ZOLPIDEM TARTRATE - ZOLPIDEM TARTRATE</u> |             |                              |                 |                               |                        |                                   |
| A078148 001                                  |             |                              |                 |                               | PC                     | Jun 04, 2011                      |

## 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.
3. \*\*\*\* The expiration date for U.S. Patent No. 5,608,075 is March 4, 2009.

## 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, 31<sup>st</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>

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<http://www.accessdata.fda.gov/scripts/cder/ob/docs/excltermsall.cfm>