

# **APPROVED DRUG PRODUCTS**

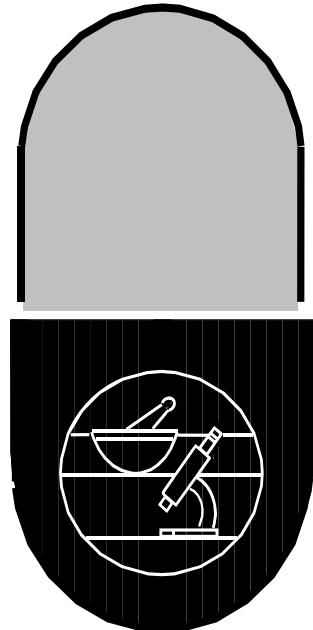
## **With Therapeutic Equivalence Evaluations**



### **The "Orange Book"**

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**CUMULATIVE  
SUPPLEMENT 2  
FEBRUARY 2013**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**33rd EDITION**

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

**2013**

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

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

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

**Cumulative Supplement 2**

**February 2013**

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**APPROVED DRUG PRODUCTS  
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**33<sup>rd</sup> EDITION**

**CUMULATIVE SUPPLEMENT 2  
February 2013**

**1.0 INTRODUCTION**

**1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT**

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

## 1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

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

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

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

### **1.3 APPLICANT NAME CHANGES**

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

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

FORMER APPLICANT NAME  
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME  
(NEW ABBREVIATED NAME)

### **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
LEVOHYROXINE 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
LEVOHYROXINE SODIUM	MYLAN	0.025MG	AB2	76187	001
LEVO-T	ALARA PHARM	0.025MG	AB2	21342	001
UNITHROID	STEVENS J	0.025MG	AB2	21210	001
LEVOHYROXINE 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
LEVOHYROXINE SODIUM	MYLAN	0.025MG	AB3	76187	001
LEVOHYROXINE SODIUM	MERCK KGAA	0.025MG	AB3	76752	001
LEVOTHROID	LLOYD	0.025MG	AB4	21116	001
LEVOHYROXINE SODIUM	MYLAN	0.025MG	AB4	76187	001

## 1.5 AVAILABILITY OF THE EDITION

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

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Publications. The PDF annual and cumulative supplements duplicate previous paper

versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The downloaded Annual Edition and Cumulative Supplements are also available in a paper version (Approved Drug Products with Therapeutic Equivalence Evaluations, ADP) from the U.S. Government Printing Office: <http://bookstore.gpo.gov>; toll free 866-512-1800.

There are historical lists of Orange Book cumulative supplement product monthly changes at

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

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

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

## **1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST**

### **DESCRIPTION OF REPORT**

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

The baseline column (Dec 2011) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

### **DEFINITIONS**

#### **Drug Product**

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

#### **New Molecular Entity**

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST  
COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 2012	MAR 2013	JUN 2013	SEPT 2013	DEC 2013
DRUG PRODUCTS LISTED	15343				
SINGLE SOURCE	2400				
	(15.9%)				
MULTISOURCE	12825				
	(83.6%)				
THERAPEUTICALLY EQUIVALENT	12683				
	(82.7%)				
NOT THERAPEUTICALLY EQUIVALENT	142				
	(0.9%)				
EXCEPTIONS <sup>1</sup>	78				
	(0.5%)				
NEW MOLECULAR ENTITIES					
APPROVED	17				
NUMBER OF APPLICANTS	835				

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

The change code and description:

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

CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.

## PRESCRIPTION DRUG PRODUCT LIST - 33RD EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2013

1-1

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

## TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

>D> AA MIRROR PHARMS 500MG;50MG;40MG  
 >A> @ MIRROR PHARMS LLC 500MG;50MG;40MG

A040883 001 Dec 23, 2008 Feb DISC  
 A040883 001 Dec 23, 2008 Feb DISC

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

## CAPSULE; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

>D> AA + MIKART 356.4MG;30MG;16MG  
 >A> @ 356.4MG;30MG;16MG

A040109 001 Aug 26, 1997 Feb DISC  
 A040109 001 Aug 26, 1997 Feb DISC

## TABLET; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

>D> AA + MIKART 712.8MG;60MG;32MG  
 >A> @ 712.8MG;60MG;32MG

A040316 001 Apr 28, 1999 Feb DISC  
 A040316 001 Apr 28, 1999 Feb DISC

ACETAMINOPHEN; CODEINE PHOSPHATE

## TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>D> + MIKART 650MG;30MG  
 >A> @ 650MG;30MG  
 >D> + 650MG;60MG  
 >A> @ 650MG;60MG

A089231 001 Mar 03, 1986 Feb DISC  
 A089231 001 Mar 03, 1986 Feb DISC  
 A089363 001 Sep 09, 1991 Feb DISC  
 A089363 001 Sep 09, 1991 Feb DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

## CAPSULE; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D> AA MIKART 500MG;5MG  
 >A> @ 500MG;5MG

A081067 001 Nov 30, 1989 Feb DISC  
 A081067 001 Nov 30, 1989 Feb DISC

## TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D> AA + MIKART 500MG;2.5MG  
 >A> @ 500MG;2.5MG  
 >D> + 650MG;5MG  
 >A> @ 650MG;5MG

A089698 001 Aug 25, 1989 Feb DISC  
 A089698 001 Aug 25, 1989 Feb DISC  
 A040849 001 Jun 09, 2010 Feb DISC  
 A040849 001 Jun 09, 2010 Feb DISC

ACETAZOLAMIDE

## TABLET; ORAL

ACETAZOLAMIDE

@ WATSON LABS 250MG

A088882 001 Oct 22, 1985 Jan DISC

ACETAZOLAMIDE SODIUM

## INJECTABLE; INJECTION

ACETAZOLAMIDE SODIUM

AP SAGENT AGILA EQ 500MG BASE/VIAL

A200880 001 May 09, 2012 Jan CAHN

ALBENDAZOLE

## TABLET; ORAL

ALBENZA

>A> + AMEDRA PHARMS 200MG  
 >D> + COREPHARMA 200MG

N020666 001 Jun 11, 1996 Feb CAHN  
 N020666 001 Jun 11, 1996 Feb CAHN

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

AN + MYLAN SPECLT EQ 0.083% BASE A072652 001 Feb 21, 1992 Jan CAHN

ALENDRONATE SODIUM

SOLUTION; ORAL

ALENDRONATE SODIUM

&gt;A&gt; AA ROXANE EQ 70MG BASE/75ML A090520 001 Feb 25, 2013 Feb NEWA

FOSAMAX

&gt;D&gt; + MERCK EQ 70MG BASE/75ML N021575 001 Sep 17, 2003 Feb CFTG

&gt;A&gt; AA + EQ 70MG BASE/75ML N021575 001 Sep 17, 2003 Feb CFTG

ALOGLIPTIN BENZOATE

TABLET; ORAL

NESINA

TAKEDA PHARMS USA

EQ 6.25MG BASE

N022271 001 Jan 25, 2013 Jan NEWA

EQ 12.5MG BASE

N022271 002 Jan 25, 2013 Jan NEWA

+

EQ 25MG BASE

N022271 003 Jan 25, 2013 Jan NEWA

ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

KAZANO

TAKEDA PHARMS USA

EQ 12.5MG BASE;500MG

N203414 001 Jan 25, 2013 Jan NEWA

+

EQ 12.5MG BASE;1GM

N203414 002 Jan 25, 2013 Jan NEWA

ALOGLIPTIN BENZOATE; PIOGLITAZONE

TABLET; ORAL

OSENI

&gt;D&gt; TAKEDA PHARMS USA EQ 12.5MG BASE;EQ 15MG BASE N022426 004 Jan 25, 2013 Feb CAIN

EQ 12.5MG BASE;EQ 15MG BASE

N022426 004 Jan 25, 2013 Jan NEWA

&gt;D&gt; EQ 12.5MG BASE;EQ 30MG BASE N022426 005 Jan 25, 2013 Feb CAIN

EQ 12.5MG BASE;EQ 30MG BASE

N022426 005 Jan 25, 2013 Jan NEWA

&gt;D&gt; EQ 12.5MG BASE;EQ 45MG BASE N022426 006 Jan 25, 2013 Feb CAIN

EQ 12.5MG BASE;EQ 45MG BASE

N022426 006 Jan 25, 2013 Jan NEWA

&gt;D&gt; EQ 25MG BASE;EQ 15MG BASE N022426 001 Jan 25, 2013 Feb CAIN

EQ 25MG BASE;EQ 15MG BASE

N022426 001 Jan 25, 2013 Jan NEWA

&gt;D&gt; EQ 25MG BASE;EQ 30MG BASE N022426 002 Jan 25, 2013 Feb CAIN

EQ 25MG BASE;EQ 30MG BASE

N022426 002 Jan 25, 2013 Jan NEWA

&gt;D&gt; + EQ 25MG BASE;EQ 45MG BASE N022426 003 Jan 25, 2013 Feb CAIN

+

EQ 25MG BASE;EQ 45MG BASE

N022426 003 Jan 25, 2013 Jan NEWA

ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL

OSENI

&gt;A&gt; TAKEDA PHARMS USA EQ 12.5MG BASE;EQ 15MG BASE N022426 004 Jan 25, 2013 Feb CAIN

EQ 12.5MG BASE;EQ 30MG BASE

N022426 005 Jan 25, 2013 Feb CAIN

&gt;A&gt; EQ 12.5MG BASE;EQ 45MG BASE N022426 006 Jan 25, 2013 Feb CAIN

EQ 25MG BASE;EQ 15MG BASE

N022426 001 Jan 25, 2013 Feb CAIN

&gt;A&gt; EQ 25MG BASE;EQ 30MG BASE N022426 002 Jan 25, 2013 Feb CAIN

EQ 25MG BASE;EQ 45MG BASE

N022426 003 Jan 25, 2013 Feb CAIN

&gt;A&gt; + EQ 25MG BASE;EQ 45MG BASE N022426 003 Jan 25, 2013 Feb CAIN

AMMONIA N-13

INJECTABLE; INTRAVENOUS

>A>	AMMONIA N 13							
>A>	AP	CARDINAL HEALTH 414	30MCI-300MCI/8ML (3.75-37.5MCI/ML)	A203700	001	Feb 25, 2013	Feb NEWA	
>A>	AP	+	FEINSTEIN	30MCI-300MCI/8ML (3.75-37.5MCI/ML)	N022119	001	Aug 23, 2007	Feb CFTG
>A>	AP	MCPRF	30MCI-300MCI/8ML (3.75-37.5MCI/ML)	A203321	001	Feb 25, 2013	Feb NEWA	

AMMONIA, N-13

INJECTABLE; INTRAVENOUS

AMMONIA N 13

>D>	+	FEINSTEIN	30MCI-300MCI/8ML (3.75-37.5MCI/ML)	N022119	001	Aug 23, 2007	Feb CFTG
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AMOXICILLIN

FOR SUSPENSION; ORAL

AMOXICILLIN

>D>	AB	RANBAXY	200MG/5ML	A065113	001	Nov 29, 2002	Feb DISC
>A>		@	200MG/5ML	A065113	001	Nov 29, 2002	Feb DISC
>D>	AB		400MG/5ML	A065113	002	Nov 29, 2002	Feb DISC
>A>		@	400MG/5ML	A065113	002	Nov 29, 2002	Feb DISC

TABLET, CHEWABLE; ORAL

AMOXICILLIN

>D>		RANBAXY	200MG	A065060	001	Nov 29, 2000	Feb DISC
>A>		@	200MG	A065060	001	Nov 29, 2000	Feb DISC
>D>			400MG	A065060	002	Nov 29, 2000	Feb DISC
>A>		@	400MG	A065060	002	Nov 29, 2000	Feb DISC

AMOXIL

>D>	AB	DR REDDYS LABS INC	200MG	N050761	001	Apr 15, 1999	Feb DISC
>A>		@	200MG	N050761	001	Apr 15, 1999	Feb DISC
>D>	AB		400MG	N050761	002	Apr 15, 1999	Feb DISC
>A>		@	400MG	N050761	002	Apr 15, 1999	Feb DISC

TABLET, FOR SUSPENSION; ORAL

AMOXICILLIN

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

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

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

TABLET; ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

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

ANASTROZOLE

TABLET; ORAL

ANASTROZOLE

>D>	AB	KUDCO IRELAND	1MG	A091331 001 Jan 05, 2011 Feb DISC
>A>		@	1MG	A091331 001 Jan 05, 2011 Feb DISC

ARIPIPRAZOLE

FOR SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR

ABILITY MAINTENA KIT

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

BENZPHETAMINE HYDROCHLORIDE

TABLET; ORAL

BENZPHETAMINE HYDROCHLORIDE

>D>	AA	COREPHARMA	50MG	A040714 001 Oct 29, 2007 Feb DISC
>A>		@	50MG	A040714 001 Oct 29, 2007 Feb DISC

BENZTROPINE MESYLATE

INJECTABLE; INJECTION

BENZTROPINE MESYLATE

AP	NAVINTA LLC	1MG/ML	A091525 001 Feb 05, 2013 Jan NEWA
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BEXAROTENE

GEL; TOPICAL

TARGRETIN

>D>	+	EISAI INC	1%	N021056 001 Jun 28, 2000 Feb CAHN
>A>	+	VALEANT PHARMS INC	1%	N021056 001 Jun 28, 2000 Feb CAHN

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

BLEOMYCIN SULFATE

>D>	AP	PHARMACHEMIE BV	EQ 15 UNITS BASE/VIAL	A065201 001 Dec 13, 2007 Feb DISC
>A>		@	EQ 15 UNITS BASE/VIAL	A065201 001 Dec 13, 2007 Feb DISC

BROMFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

BROMFENAC SODIUM

>A>	AT	LUITPOLD	0.09%	A202030 001 Jan 09, 2013 Feb CAHN
>D>	AT	PHARMAFORCE	0.09%	A202030 001 Jan 09, 2013 Feb CAHN

BUDESONIDE

TABLET, EXTENDED RELEASE; ORAL

UCERIS

+ SANTARUS 9MG

N203634 001 Jan 14, 2013 Jan NEWA

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE

TABLET; SUBLINGUAL

BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE DIHYDRATE

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

TABLET; SUBLINGUALSUBOXONE

>A>	AB	RECKITT BENCKISER	EQ 2MG BASE;EQ 0.5MG BASE	N020733 001 Oct 08, 2002 Feb CFTG
>D>	+		EQ 8MG BASE;EQ 2MG BASE	N020733 002 Oct 08, 2002 Feb CFTG
>A>	AB	+	EQ 8MG BASE;EQ 2MG BASE	N020733 002 Oct 08, 2002 Feb CFTG

BUPROPION HYDROCHLORIDE

>D>		TABLET; ORAL		
>D>		BUPROPION HYDROCHLORIDE		
>D>	AB	TEVA	75MG	A075310 001 Nov 29, 1999 Feb CDFR
>A>		@	75MG	A075310 001 Nov 29, 1999 Feb CDFR
>D>	AB		100MG	A075310 002 Nov 29, 1999 Feb DISC
>A>		@	100MG	A075310 002 Nov 29, 1999 Feb DISC

CABERGOLINE

		TABLET; ORAL		
		CABERGOLINE		
>A>	AB	APOTEX CORP	0.5MG	A201503 001 Mar 08, 2013 Feb NEWA

CAFFEINE; ERGOTAMINE TARTRATE

		TABLET; ORAL		
		ERGOTAMINE TARTRATE AND CAFFEINE		
		@ MIKART	100MG;1MG	A040590 001 Sep 16, 2005 Jan DISC

CALCIUM ACETATE

		CAPSULE; ORAL		
		CALCIUM ACETATE		
AB		INVAGEN PHARMS	EQ 169MG CALCIUM	A203135 001 Feb 07, 2013 Jan NEWA
		TABLET; ORAL		
		CALCIUM ACETATE		
AB		INVAGEN PHARMS	EQ 169MG CALCIUM	A202420 001 Feb 05, 2013 Jan NEWA

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

		SOLUTION; INTRAPERITONEAL		
>D>		INPERSOL-LC/LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER		
>D>	AT	FRESENIUS	18.4MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374 001 Jun 13, 1994 Feb DISC
>A>		@	18.4MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374 001 Jun 13, 1994 Feb DISC
>D>		INPERSOL-LC/LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER		
>D>	AT	FRESENIUS	18.4MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374 002 Jun 13, 1994 Feb DISC
>A>		@	18.4MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374 002 Jun 13, 1994 Feb DISC
>D>		INPERSOL-LC/LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER		
>D>		FRESENIUS	18.4MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374 003 Jun 13, 1994 Feb DISC
>A>		@	18.4MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374 003 Jun 13, 1994 Feb DISC
>D>		INPERSOL-LC/LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER		
>D>	AT	FRESENIUS	18.4MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374 004 Jun 13, 1994 Feb DISC
>A>		@	18.4MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374 004 Jun 13, 1994 Feb DISC

CARBIDOPA; LEVODOPA

		TABLET, EXTENDED RELEASE; ORAL		
		CARBIDOPA AND LEVODOPA		
AB		ACCORD HLTHCARE	25MG;100MG	A202323 001 Feb 08, 2013 Jan NEWA

TABLET, EXTENDED RELEASE; ORAL  
CARBIDOPA AND LEVODOPA

AB ACCORD HLTHCARE 50MG;200MG A202323 002 Feb 08, 2013 Jan NEWA

CARBOPLATIN

INJECTABLE; INJECTION  
CARBOPLATIN

>D>	AP	PLIVA	50MG/VIAL	A076602 001 Nov 16, 2004 Feb DISC
>A>		@	50MG/VIAL	A076602 001 Nov 16, 2004 Feb DISC
>D>	AP		150MG/VIAL	A076602 002 Nov 16, 2004 Feb DISC
>A>		@	150MG/VIAL	A076602 002 Nov 16, 2004 Feb DISC
>D>	AP		450MG/VIAL	A076602 003 Nov 16, 2004 Feb DISC
>A>		@	450MG/VIAL	A076602 003 Nov 16, 2004 Feb DISC

CARISOPRODOL

TABLET; ORAL  
CARISOPRODOL

>D>	AA	COREPHARMA	350MG	A040397 001 Sep 21, 2000 Feb DISC
>A>		@	350MG	A040397 001 Sep 21, 2000 Feb DISC

CARMUSTINE

INJECTABLE; INJECTION  
BICNU  
+ EMCURE PHARMS LTD 100MG/VIAL

N017422 001 Jan CAHN

CARVEDILOL

TABLET; ORAL  
CARVEDILOL

>D>	AB	WOCKHARDT	3.125MG	A078786 001 Dec 22, 2009 Feb DISC
>D>	AB		6.25MG	A078786 002 Dec 22, 2009 Feb DISC
>D>	AB		12.5MG	A078786 003 Dec 22, 2009 Feb DISC
>D>	AB		25MG	A078786 004 Dec 22, 2009 Feb DISC
>A>		@ WOCKHARDT LTD	3.125MG	A078786 001 Dec 22, 2009 Feb DISC
>A>		@	6.25MG	A078786 002 Dec 22, 2009 Feb DISC
>A>		@	12.5MG	A078786 003 Dec 22, 2009 Feb DISC
>A>		@	25MG	A078786 004 Dec 22, 2009 Feb DISC

CEFAZOLIN SODIUM

INJECTABLE; INJECTION  
CEFAZOLIN SODIUM

>D>	AP	HOSPIRA INC	EQ 500MG BASE/VIAL	A065226 001 Apr 21, 2005 Feb CRLD
>A>	AP	+	EQ 500MG BASE/VIAL	A065226 001 Apr 21, 2005 Feb CRLD
>D>	AP		EQ 1GM BASE/VIAL	A065226 002 Apr 21, 2005 Feb CRLD
>D>	AP		EQ 1GM BASE/VIAL	A065244 001 Aug 12, 2005 Feb CRLD
>A>	AP	+	EQ 1GM BASE/VIAL	A065244 001 Aug 12, 2005 Feb CRLD
>A>	AP	+	EQ 1GM BASE/VIAL	A065226 002 Apr 21, 2005 Feb CRLD
>D>	AP		EQ 10GM BASE/VIAL	A065247 001 Aug 12, 2005 Feb CRLD
>A>	AP	+	EQ 10GM BASE/VIAL	A065247 001 Aug 12, 2005 Feb CRLD

CEFIXIME

>A>		FOR SUSPENSION; ORAL		
>A>		SUPRAX		
>A>	+	LUPIN LTD	500MG/5ML	N202091 001 Feb 20, 2013 Feb CDFR
>A>		LUPIN PHARMS	100MG/5ML	A065129 001 Feb 23, 2004 Feb CDFR
>A>			200MG/5ML	A065355 001 Apr 10, 2007 Feb CDFR

>D> SUSPENSION; ORAL  
 >D> SUPRAX  
 >D> LUPIN PHARMS 100MG/5ML A065129 001 Feb 23, 2004 Feb CDFR  
 >D> + 200MG/5ML A065355 001 Apr 10, 2007 Feb CDFR

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL  
 CETIRIZINE HYDROCHLORIDE  
 >D> AA AUROBINDO PHARMA 5MG/5ML A090751 001 Dec 16, 2009 Feb DISC  
 >A> @ AUROBINDO PHARMA LTD 5MG/5ML A090751 001 Dec 16, 2009 Feb DISC

CHLOROTHIAZIDE

TABLET; ORAL  
 DIURIL  
 @ OAK PHARMS AKORN 250MG N011145 004 Jan CAHN  
 @ 500MG N011145 002 Jan CAHN

CHLOROTHIAZIDE SODIUM

INJECTABLE; INJECTION  
 DIURIL  
 AP + OAK PHARMS AKORN EQ 500MG BASE/VIAL N011145 005 Jan CAHN

>A> CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE

SOLUTION; ORAL  
 VITUZ  
 >A> + CYPRESS PHARM 4MG/5ML;5MG/5ML N204307 001 Feb 20, 2013 Feb NEWA

CHLORPROPAMIDE

TABLET; ORAL  
 CHLORPROPAMIDE  
 @ WATSON LABS INC 100MG A088852 001 Sep 26, 1984 Jan DISC  
 @ 250MG A088826 001 Sep 26, 1984 Jan DISC

CICLOPIROX

SOLUTION; TOPICAL  
 CICLOPIROX  
 @ TEVA PHARMS 8% A078079 001 Sep 18, 2007 Jan DISC  
 PENLAC  
 >D> AT + SANOFI AVENTIS US 8% N021022 001 Dec 17, 1999 Feb CAHN  
 >A> AT + VALEANT INTL 8% N021022 001 Dec 17, 1999 Feb CAHN

CISPLATIN

INJECTABLE; INJECTION  
 PLATINOL  
 @ HQ SPCLT PHARMA 10MG/VIAL N018057 001 Jan CAHN  
 @ 50MG/VIAL N018057 002 Jan CAHN  
 PLATINOL-AQ  
 @ HQ SPCLT PHARMA 0.5MG/ML N018057 003 Jul 18, 1984 Jan CAHN  
 @ 1MG/ML N018057 004 Nov 08, 1988 Jan CAHN

CITALOPRAM HYDROBROMIDE

TABLET; ORAL  
 CITALOPRAM HYDROBROMIDE  
 >D> AB COREPHARMA EQ 10MG BASE A077036 001 Oct 28, 2004 Feb DISC  
 >A> @ EQ 10MG BASE A077036 001 Oct 28, 2004 Feb DISC  
 >D> AB EQ 20MG BASE A077036 002 Oct 28, 2004 Feb DISC

## TABLET; ORAL

## CITALOPRAM HYDROBROMIDE

>A>	@ COREPHARMA	EQ 20MG BASE	A077036 002 Oct 28, 2004 Feb DISC
>D> AB		EQ 40MG BASE	A077036 003 Oct 28, 2004 Feb DISC
>A>	@	EQ 40MG BASE	A077036 003 Oct 28, 2004 Feb DISC

CLEVIDIPINE

>A>	EMULSION; INTRAVENOUS		
>A>	CLEVIPREX		
>A>	+	MEDICINES CO	25MG/50ML (0.5MG/ML)
>A>	+		50MG/100ML (0.5MG/ML)

N022156 001 Aug 01, 2008 Feb CAIN
N022156 002 Aug 01, 2008 Feb CAIN

CLEVIDIPINE BUTYRATE

>D>	EMULSION; INTRAVENOUS		
>D>	CLEVIPREX		
>D>	+	MEDICINES CO	25MG/50ML (0.5MG/ML)
>D>	+		50MG/100ML (0.5MG/ML)

N022156 001 Aug 01, 2008 Feb CAIN
N022156 002 Aug 01, 2008 Feb CAIN

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL			
CLINDAMYCIN PHOSPHATE			
>D> AT	PERRIGO NEW YORK	EQ 1% BASE	A064050 001 Nov 30, 1995 Feb DISC
>A>	@	EQ 1% BASE	A064050 001 Nov 30, 1995 Feb DISC

CLONAZEPAM

TABLET; ORAL			
CLONAZEPAM			
>D> AB	APOTEX	0.5MG	A075468 001 Oct 06, 2000 Feb DISC
>D> AB		1MG	A075468 002 Oct 06, 2000 Feb DISC
>D> AB		2MG	A075468 003 Oct 06, 2000 Feb DISC
>A>	@ APOTEX INC	0.5MG	A075468 001 Oct 06, 2000 Feb DISC
>A>	@	1MG	A075468 002 Oct 06, 2000 Feb DISC
>A>	@	2MG	A075468 003 Oct 06, 2000 Feb DISC

CLOZAPINE

>A>	SUSPENSION; ORAL		
>A>	VERSACLOZ		
>A>	+	DOUGLAS PHARMS	50MG/ML

N203479 001 Feb 06, 2013 Feb NEWA
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COSYNTROPIN

INJECTABLE; INJECTION			
COSYNTROPIN			
>D> AP	BIONICHE PHARMA	0.25MG/VIAL	A090574 001 Dec 17, 2009 Feb CAHN
>A> AP	MYLAN LLC	0.25MG/VIAL	A090574 001 Dec 17, 2009 Feb CAHN

CYCLOBENZAPRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL			
AMRIX			
AB	IVAX INTL	15MG	N021777 001 Feb 01, 2007 Jan CAHN
AB	+	30MG	N021777 002 Feb 01, 2007 Jan CAHN
CYCLOBENZAPRINE HYDROCHLORIDE			
AB	TWI PHARMS INC	15MG	A091281 001 Jan 31, 2013 Jan NEWA
AB		30MG	A091281 002 Jan 31, 2013 Jan NEWA

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION  
 CYTOXAN (LYOPHILIZED)  
 @ BAXTER HLTHCARE 500MG/VIAL N012142 008 Jan 04, 1984 Jan CTNA  
 @ 1GM/VIAL N012142 010 Sep 24, 1985 Jan CTNA  
 @ 2GM/VIAL N012142 009 Dec 10, 1985 Jan CTNA

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION  
 DESMOPRESSIN ACETATE  
 AP SUN PHARM INDs LTD 0.004MG/ML A091280 001 Jan 25, 2013 Jan NEWA

DESOGESTREL; ETHINYLMESTRADIOL

TABLET; ORAL-28  
 >A> ENSKYCE  
 >A> AB LUPIN LTD 0.15MG;0.03MG A201887 001 Mar 07, 2013 Feb NEWA

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC  
 NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE  
 @ ALCON PHARMS LTD 0.1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML A062721 001 Nov 17, 1986 Jan DISC

DEXTROSE; POTASSIUM CHLORIDE

INJECTABLE; INJECTION  
 POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% IN PLASTIC CONTAINER  
 @ B BRAUN 5GM/100ML;220MG/100ML N018744 003 Nov 09, 1982 Jan DISC

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL  
 DILTIAZEM HYDROCHLORIDE  
 >D> AB4 ACTAVIS ELIZABETH 120MG A091022 001 Sep 28, 2012 Feb CAHN  
 >D> AB4 180MG A091022 002 Sep 28, 2012 Feb CAHN  
 >D> AB4 240MG A091022 003 Sep 28, 2012 Feb CAHN  
 >D> AB4 300MG A091022 004 Sep 28, 2012 Feb CAHN  
 >D> AB4 360MG A091022 005 Sep 28, 2012 Feb CAHN  
 >D> AB4 420MG A091022 006 Sep 28, 2012 Feb CAHN  
 AB3 PAR PHARM 120MG A074984 001 Dec 20, 1999 Jan CAHN  
 AB3 180MG A074984 002 Dec 20, 1999 Jan CAHN  
 AB3 240MG A074984 003 Dec 20, 1999 Jan CAHN  
 AB3 300MG A074984 004 Dec 20, 1999 Jan CAHN  
 >A> AB4 SANDOZ 120MG A091022 001 Sep 28, 2012 Feb CAHN  
 >A> AB4 180MG A091022 002 Sep 28, 2012 Feb CAHN  
 >A> AB4 240MG A091022 003 Sep 28, 2012 Feb CAHN  
 >A> AB4 300MG A091022 004 Sep 28, 2012 Feb CAHN  
 >A> AB4 360MG A091022 005 Sep 28, 2012 Feb CAHN  
 >A> AB4 420MG A091022 006 Sep 28, 2012 Feb CAHN

## TABLET; ORAL

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



FENOFIBRIC ACID

TABLET; ORAL						
FIBRICOR						
>D>	AR HOLDING CO INC	35MG	N022418	001	Aug 14, 2009	Feb CAHN
>D>	+	105MG	N022418	002	Aug 14, 2009	Feb CAHN
>A>	MUTUAL PHARM CO INC	35MG	N022418	001	Aug 14, 2009	Feb CAHN
>A>	+	105MG	N022418	002	Aug 14, 2009	Feb CAHN

FENTANYL CITRATE

TABLET; Buccal						
FENTORA						
>D>	AB CEPHALON	EQ 0.1MG BASE	N021947	001	Sep 25, 2006	Feb CDFR
>D>	AB	EQ 0.2MG BASE	N021947	002	Sep 25, 2006	Feb CDFR
>D>	@	EQ 0.3MG BASE	N021947	006	Mar 02, 2007	Feb CDFR
>D>	AB +	EQ 0.4MG BASE	N021947	003	Sep 25, 2006	Feb CDFR
>D>	AB	EQ 0.6MG BASE	N021947	004	Sep 25, 2006	Feb CDFR
>D>	AB	EQ 0.8MG BASE	N021947	005	Sep 25, 2006	Feb CDFR
>A>	TABLET; Buccal, Sublingual					
FENTORA						
>A>	AB CEPHALON	EQ 0.1MG BASE	N021947	001	Sep 25, 2006	Feb CDFR
>A>	AB	EQ 0.2MG BASE	N021947	002	Sep 25, 2006	Feb CDFR
>A>	@	EQ 0.3MG BASE	N021947	006	Mar 02, 2007	Feb CDFR
>A>	AB +	EQ 0.4MG BASE	N021947	003	Sep 25, 2006	Feb CDFR
>A>	AB	EQ 0.6MG BASE	N021947	004	Sep 25, 2006	Feb CDFR
>A>	AB	EQ 0.8MG BASE	N021947	005	Sep 25, 2006	Feb CDFR

FERUMOXSIL

SUSPENSION; ORAL						
GASTROMARK						
>D>	+ AMAG PHARMS INC	EQ 0.175MG IRON/ML	N020410	001	Dec 06, 1996	Feb DISC
>A>	@	EQ 0.175MG IRON/ML	N020410	001	Dec 06, 1996	Feb DISC

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION						
FLUDARABINE PHOSPHATE						
AP + FRESENIUS KABI USA	50MG/2ML (25MG/ML)	A078393	001	Oct 15, 2007	Jan CRLD	
AP TEVA PARENTERAL	50MG/2ML (25MG/ML)	A076661	001	Apr 28, 2004	Jan CRLD	

FLUDEOXYGLUCOSE F-18

INJECTABLE; INTRAVENOUS						
FLUDEOXYGLUCOSE F18						
+ FEINSTEIN	20-300mCi/ML	N021870	002	Nov 21, 2008	Jan CFTG	
HOUSTON CYCLOTRON	20-500mCi/ML	A203665	001	Feb 14, 2013	Jan NEWA	

FLUOCINONIDE

CREAM; TOPICAL						
LIDEX						
@ CNTY LINE PHARMS	0.05%	N016908	002		Jan	CAHN
LIDEX-E						
@ CNTY LINE PHARMS	0.05%	N016908	003		Jan	CAHN
GEL; TOPICAL						
FLUOCINONIDE						
AB + TARO	0.05%	A074935	001	Jul 29, 1997	Jan	CRLD
LIDEX						
@ CNTY LINE PHARMS	0.05%	N017373	001		Jan	CAHN

OINTMENT; TOPICAL

FLUOCINONIDE

AB	+	TARO	0.05%	A075008 001	Jun 30, 1999	Jan	CRLD
		LIDEX		N016909 002		Jan	CAHN
	@	CNTY LINE PHARMS	0.05%				
SOLUTION; TOPICAL							
FLUOCINONIDE							
AT	+	TARO	0.05%	A074799 001	Dec 31, 1996	Jan	CRLD
		LIDEX		N018849 001	Apr 06, 1984	Jan	DISC
	@	MEDICIS	0.05%				

FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

>D>	AP	+	BIONICHE PHARMA	500MG/10ML (50MG/ML)	A040743 002	Apr 26, 2007	Feb	CAHN
>D>	AP	+		1GM/20ML (50MG/ML)	A040743 001	Apr 26, 2007	Feb	CAHN
>A>	AP	+	MYLAN LLC	500MG/10ML (50MG/ML)	A040743 002	Apr 26, 2007	Feb	CAHN
>A>	AP	+		1GM/20ML (50MG/ML)	A040743 001	Apr 26, 2007	Feb	CAHN

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL

FLUOXETINE HYDROCHLORIDE

>D>	AB1	WOCKHARDT	EQ 10MG BASE	A078143 001	Jan 16, 2008	Feb	DISC
>D>	AB1		EQ 20MG BASE	A078143 002	Jan 16, 2008	Feb	DISC
>D>	AB		EQ 40MG BASE	A078143 003	Jan 16, 2008	Feb	DISC
>A>		@ WOCKHARDT LTD	EQ 10MG BASE	A078143 001	Jan 16, 2008	Feb	DISC
>A>		@	EQ 20MG BASE	A078143 002	Jan 16, 2008	Feb	DISC
>A>		@	EQ 40MG BASE	A078143 003	Jan 16, 2008	Feb	DISC

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

@ INTL MEDICATION

10MG/ML

N018025 001

Jan DISC

TABLET; ORAL

FUROSEMIDE

>D>	AB	DAVA PHARMS INC	20MG	N018415 001	Jul 27, 1982	Feb	DISC
>A>		@	20MG	N018415 001	Jul 27, 1982	Feb	DISC
>D>	AB		40MG	N018415 002	Jul 27, 1982	Feb	DISC
>A>		@	40MG	N018415 002	Jul 27, 1982	Feb	DISC
>D>	AB		80MG	N018415 003	Nov 26, 1984	Feb	DISC
>A>		@	80MG	N018415 003	Nov 26, 1984	Feb	DISC

GADOXETATE DISODIUM

SOLUTION; INTRAVENOUS

EOVIST

>A>		BAYER HLTHCARE	2.72145GM/15ML (181.43MG/ML)	N022090 002	Feb 04, 2013	Feb	NEWA
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GLIMEPIRIDE

TABLET; ORAL

GLIMEPIRIDE

>D>	AB	COREPHARMA	1MG	A077274 001	Oct 06, 2005	Feb	DISC
>A>		@	1MG	A077274 001	Oct 06, 2005	Feb	DISC
>D>	AB		2MG	A077274 002	Oct 06, 2005	Feb	DISC
>A>		@	2MG	A077274 002	Oct 06, 2005	Feb	DISC
>D>	AB		4MG	A077274 003	Oct 06, 2005	Feb	DISC
>A>		@	4MG	A077274 003	Oct 06, 2005	Feb	DISC

>A> GLYCEROL PHENYLBUTYRATE

&gt;A&gt; LIQUID; ORAL

&gt;A&gt; RAVICTI

&gt;A&gt; + HYPERION THERAP INC 1.1GM/ML

N203284 001 Feb 01, 2013 Feb NEWA

GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

>D> AP EBEWE PHARMA EQ 0.1MG BASE/ML (EQ 0.1MG  
BASE/ML)

A078808 001 Apr 29, 2008 Feb DISC

>A> @ EQ 0.1MG BASE/ML (EQ 0.1MG  
BASE/ML)

A078808 001 Apr 29, 2008 Feb DISC

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

&gt;A&gt; AA ACTAVIS PHARMA 10MG

A091679 001 Mar 04, 2013 Feb NEWA

&gt;A&gt; AA 25MG

A091679 002 Mar 04, 2013 Feb NEWA

&gt;A&gt; AA 50MG

A091679 003 Mar 04, 2013 Feb NEWA

&gt;A&gt; AA 100MG

A091679 004 Mar 04, 2013 Feb NEWA

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL

IRBESARTAN AND HYDROCHLOROTHIAZIDE

&gt;A&gt; AB AUROBINDO PHARMA LTD 12.5MG;150MG

A203630 001 Feb 22, 2013 Feb NEWA

&gt;A&gt; AB 12.5MG;300MG

A203630 002 Feb 22, 2013 Feb NEWA

&gt;A&gt; AB LUPIN LTD 12.5MG;150MG

A201524 001 Feb 27, 2013 Feb NEWA

&gt;A&gt; AB 12.5MG;300MG

A201524 002 Feb 27, 2013 Feb NEWA

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL

LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

&gt;A&gt; AB IPCA LABS LTD 12.5MG;50MG

A201682 001 Mar 01, 2013 Feb NEWA

&gt;A&gt; AB 12.5MG;100MG

A201682 002 Mar 01, 2013 Feb NEWA

&gt;A&gt; AB 25MG;100MG

A201682 003 Mar 01, 2013 Feb NEWA

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

&gt;A&gt; AB @ WATSON LABS 50MG;75MG

A071969 001 Apr 17, 1988 Jan DISC

HYDROCORTISONE

LOTION; TOPICAL

STIE-CORT

&gt;D&gt; AT PERRIGO 1%

A089066 001 Nov 25, 1985 Feb DISC

&gt;A&gt; @ PERRIGO CO 1%

A089066 001 Nov 25, 1985 Feb DISC

HYDROCORTISONE VALERATE

OINTMENT; TOPICAL

HYDROCORTISONE VALERATE

&gt;D&gt; AB FOUGERA PHARMS 0.2%

A075085 001 Jul 31, 2001 Feb DISC

&gt;A&gt; @ 0.2%

A075085 001 Jul 31, 2001 Feb DISC

&gt;D&gt; AB TARO 0.2%

A075043 001 Aug 25, 1998 Feb CRLD

&gt;A&gt; + 0.2%

A075043 001 Aug 25, 1998 Feb CRLD

OINTMENT; TOPICAL

>D>	WESTCORT							
>D> AB	+ RANBAXY	0.2%		N018726	001	Aug 08, 1983	Feb	DISC
>A>	@	0.2%		N018726	001	Aug 08, 1983	Feb	DISC

HYDROMORPHONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL  
EXALGO  
MALLINCKRODT INC 16MG  
+ 32MG

N021217	003	Mar 01, 2010	Jan	CRLD
N021217	004	Aug 24, 2012	Jan	CRLD

ISOSORBIDE DINITRATE

TABLET; ORAL  
ISOSORBIDE DINITRATE  
PAR PHARM 5MG  
@ 5MG

A086923	001	Mar 12, 1987	Feb	DISC
A086923	001	Mar 12, 1987	Feb	DISC

ISOTRETINOIN

CAPSULE; ORAL  
ABSORICA

>D> BX	CIPHER	10MG	N021951	001	May 25, 2012	Feb	CAHN
>D> BX		20MG	N021951	002	May 25, 2012	Feb	CAHN
>D> BX		30MG	N021951	003	May 25, 2012	Feb	CAHN
>D> BX		40MG	N021951	004	May 25, 2012	Feb	CAHN
>A> BX	RANBAXY	10MG	N021951	001	May 25, 2012	Feb	CAHN
>A> BX		20MG	N021951	002	May 25, 2012	Feb	CAHN
>A> BX		30MG	N021951	003	May 25, 2012	Feb	CAHN
>A> BX		40MG	N021951	004	May 25, 2012	Feb	CAHN

LABETALOL HYDROCHLORIDE

TABLET; ORAL  
LABETALOL HYDROCHLORIDE  
AB + SANDOZ 200MG  
TRANDATE  
@ PROMETHEUS LABS 100MG  
@ 200MG

A075113	002	Aug 04, 1998	Jan	CRLD
N018716	001	May 24, 1985	Jan	DISC
N018716	002	Aug 01, 1984	Jan	DISC

LAMOTRIGINE

TABLET, EXTENDED RELEASE; ORAL  
LAMOTRIGINE  
PAR PHARM 25MG  
50MG  
100MG  
200MG  
250MG  
300MG

A201791	001	Jan 18, 2013	Jan	NEWA
A201791	002	Jan 18, 2013	Jan	NEWA
A201791	003	Jan 18, 2013	Jan	NEWA
A201791	004	Jan 18, 2013	Jan	NEWA
A201791	005	Jan 18, 2013	Jan	NEWA
A201791	006	Jan 18, 2013	Jan	NEWA

LATANOPROST

SOLUTION/DROPS; OPHTHALMIC  
LATANOPROST  
AT DR REDDYS LABS LTD 0.005%

A202077	001	Feb 11, 2013	Jan	NEWA
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LEVETIRACETAM

SOLUTION; ORAL  
LEVETIRACETAM  
HETERO DRUGS LTD 100MG/ML

A203052	001	Feb 28, 2013	Feb	NEWA
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## TABLET, EXTENDED RELEASE; ORAL

## LEVETIRACETAM

AB	VINTAGE PHARMS LLC	500MG	A202533 001 Jul 20, 2012 Jan NEWA
AB		750MG	A202533 002 Jul 20, 2012 Jan NEWA

LEVOCETIRIZINE DIHYDROCHLORIDE

## TABLET; ORAL

## LEVOCETIRIZINE DIHYDROCHLORIDE

AB	SUN PHARMA GLOBAL	5MG	A090362 001 Jan 31, 2013 Jan NEWA
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LEVOFLOXACIN

## INJECTABLE; INJECTION

## LEVOFLOXACIN

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

LEVONORGESTREL

## INTRAUTERINE DEVICE; INTRAUTERINE

## SKYLA

+	BAYER HLTHCARE	13.5MG	N203159 001 Jan 09, 2013 Jan NEWA
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## TABLET; ORAL

## LEVONORGESTREL

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

LISINOPRIL

## TABLET; ORAL

## LISINOPRIL

@	SANDOZ	2.5MG	A075999 001 Jul 01, 2002 Jan CAHN
@		5MG	A075999 002 Jul 01, 2002 Jan CAHN
@		10MG	A075999 003 Jul 01, 2002 Jan CAHN
@		20MG	A075999 004 Jul 01, 2002 Jan CAHN
@		30MG	A075999 005 Jul 01, 2002 Jan CAHN
@		40MG	A075999 006 Jul 01, 2002 Jan CAHN

LITHIUM CARBONATE

## CAPSULE; ORAL

## LITHIUM CARBONATE

>D>	AB	APOTEX INC	300MG	A076795 001 Nov 22, 2004 Feb DISC
>A>		@	300MG	A076795 001 Nov 22, 2004 Feb DISC

LORAZEPAM

## CONCENTRATE; ORAL

## LORAZEPAM

>A>	AA	LUPIN LTD	2MG/ML	A091407 001 Feb 19, 2013 Feb NEWA
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LOVASTATIN

## TABLET; ORAL

## LOVASTATIN

>D>	AB	CARLSBAD	40MG	A075991 003 Jun 05, 2002 Feb CRLD
>A>	AB	+	40MG	A075991 003 Jun 05, 2002 Feb CRLD
>D>		MEVACOR		
>D>	AB	MERCK	20MG	N019643 003 Aug 31, 1987 Feb DISC
>A>		@	20MG	N019643 003 Aug 31, 1987 Feb DISC

TABLET; ORAL

>D>	MEVACOR					
>D> AB	+ MERCK	40MG	N019643	004	Dec 14, 1988	Feb DISC
>A>	@	40MG	N019643	004	Dec 14, 1988	Feb DISC

MAFENIDE ACETATE

## FOR SOLUTION; TOPICAL

## MAFENIDE ACETATE

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

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

## SOLUTION, FOR SOLUTION;ORAL, ORAL

## SUCLEAR

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

## INJECTABLE; INJECTION

## MANNITOL 20%

@ B BRAUN 20GM/100ML

N014738 001

Jan DISC

MEFENAMIC ACID

## CAPSULE; ORAL

## MEFENAMIC ACID

AB	CYPRESS PHARM	250MG	A090359	001	Feb 05, 2013	Jan NEWA
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MELOXICAM

## TABLET; ORAL

## MELOXICAM

>D> AB	COREPHARMA	7.5MG	A077930	001	Jul 19, 2006	Feb DISC
>A>	@	7.5MG	A077930	001	Jul 19, 2006	Feb DISC
>D> AB		15MG	A077930	002	Jul 19, 2006	Feb DISC
>A>	@	15MG	A077930	002	Jul 19, 2006	Feb DISC

MEPROBAMATE

## TABLET; ORAL

## MEPROBAMATE

@ TARO 200MG  
@ 400MGA200998 001 May 23, 2011 Jan DISC  
A200998 002 May 23, 2011 Jan DISCMESALAMINE

>A>	CAPSULE, DELAYED RELEASE; ORAL					
>A>	DELZICOL					
>A>	+ WARNER CHILCOTT LLC	400MG	N204412	001	Feb 01, 2013	Feb NEWA
	SUPPOSITORY; RECTAL					
	CANASA					
>D>	APTALIS PHARMA US	1GM	N021252	002	Nov 05, 2004	Feb CRLD
>A>	+	1GM	N021252	002	Nov 05, 2004	Feb CRLD

METAPROTERENOL SULFATE

## SYRUP; ORAL

## METAPROTERENOL SULFATE

>D> AA	NOVEX	10MG/5ML	A075235	001	Jan 27, 2000	Feb DISC
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SYRUP; ORAL

## METAPROTERENOL SULFATE

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

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

## TABLET; ORAL

## PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE

AB	AUROBINDO PHARMA LTD	500MG;EQ 15MG BASE	A200823 001 Feb 13, 2013 Jan NEWA
AB		850MG;EQ 15MG BASE	A200823 002 Feb 13, 2013 Jan NEWA
AB	TORRENT PHARMS LTD	500MG;EQ 15MG BASE	A202001 001 Feb 13, 2013 Jan NEWA
AB		850MG;EQ 15MG BASE	A202001 002 Feb 13, 2013 Jan NEWA

METHOCARBAMOL

## TABLET; ORAL

## METHOCARBAMOL

@	AUSTARPHARMA LLC	500MG	A200958 001 Oct 21, 2011 Jan DISC
@		750MG	A200958 002 Oct 21, 2011 Jan DISC
>A> AA	PRINSTON INC	500MG	A086989 001 Feb CMFD
>A> AA		750MG	A086988 001 Feb CAHN
>D>	@ SOLCO HLTHCARE	500MG	A086989 001 Feb CMFD
@		500MG	A086989 001 Jan DISC
>D> AA		750MG	A086988 001 Feb CAHN

METHYCLOTHIAZIDE

## TABLET; ORAL

## METHYCLOTHIAZIDE

+ MYLAN PHARMS INC	5MG	A087672 001 Aug 17, 1982 Jan CTEC
@ WATSON LABS	5MG	A088724 001 Sep 06, 1984 Jan DISC

METHYLPHENIDATE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## METHYLIN ER

>D> AB	MALLINCKRODT	10MG	A075629 001 May 09, 2000 Feb CTEC
>A>	MALLINCKRODT INC	10MG	A075629 001 May 09, 2000 Feb CTEC

METOCLOPRAMIDE HYDROCHLORIDE

## INJECTABLE; INJECTION

## METOCLOPRAMIDE HYDROCHLORIDE

>D> AP	TEVA PARENTERAL	EQ 5MG BASE/ML	A073135 001 Nov 27, 1991 Feb DISC
>A>	@	EQ 5MG BASE/ML	A073135 001 Nov 27, 1991 Feb DISC

METOPROLOL SUCCINATE

## TABLET, EXTENDED RELEASE; ORAL

## METOPROLOL SUCCINATE

>D> AB	NESHER PHARMS	EQ 25MG TARTRATE	A077779 001 Mar 20, 2008 Feb DISC
>A>	@	EQ 25MG TARTRATE	A077779 001 Mar 20, 2008 Feb DISC

MIDAZOLAM HYDROCHLORIDE

## INJECTABLE; INJECTION

## MIDAZOLAM HYDROCHLORIDE

@ CLARIS LIFESCIENCES	EQ 1MG BASE/ML	A075637 001 Oct 31, 2000 Jan DISC
@	EQ 5MG BASE/ML	A075637 002 Oct 31, 2000 Jan DISC

MIPOMERSEN SODIUM

SOLUTION; SUBCUTANEOUS

KYNAMRO

+ GENZYME CORP

200MG/ML (200MG/ML)

N203568 001 Jan 29, 2013 Jan NEWA

MUPIROCIN CALCIUM

CREAM; TOPICAL

BACTROBAN

AB + GLAXOSMITHKLINE EQ 2% BASE  
MUPIROCIN

N050746 001 Dec 11, 1997 Jan CFTG

AB GLENMARK GENERICS EQ 2% BASE

A201587 001 Jan 24, 2013 Jan NEWA

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

MACRODANTIN

>D>	AB	ALMATICA	25MG	N016620 003	Feb	CAHN
>D>	AB		50MG	N016620 001	Feb	CAHN
>D>	AB	+	100MG	N016620 002	Feb	CAHN
>A>	AB	ALVOGEN INC	25MG	N016620 003	Feb	CAHN
>A>	AB		50MG	N016620 001	Feb	CAHN
>A>	AB	+	100MG	N016620 002	Feb	CAHN

NIZATIDINE

CAPSULE; ORAL

NIZATIDINE

>D>	AB	APOTEX	150MG	A076383 001 Jan 23, 2003 Feb DISC
>D>	AB		300MG	A076383 002 Jan 23, 2003 Feb DISC
>A>		@ APOTEX INC	150MG	A076383 001 Jan 23, 2003 Feb DISC
>A>		@	300MG	A076383 002 Jan 23, 2003 Feb DISC

NYSTATIN

SUSPENSION; ORAL

NILSTAT

>D>	AA	+ GLENMARK GENERICS	100,000 UNITS/ML	N050299 001	Feb	DISC
>A>		@	100,000 UNITS/ML	N050299 001	Feb	DISC

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

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

OSPEMIFENE

&gt;A&gt; TABLET; ORAL

&gt;A&gt; OSPHENA

>A>		+ SHIONOGI INC	60MG	N203505 001 Feb 26, 2013 Feb NEWA
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OXACILLIN SODIUM

INJECTABLE; INJECTION

OXACILLIN SODIUM

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

OXAPROZIN

TABLET; ORAL

OXAPROZIN

@ CARACO

600MG

A075844 001 Jan 03, 2002 Jan DISC

OXYMORPHONE HYDROCHLORIDE

TABLET; ORAL

OXYMORPHONE HYDROCHLORIDE

AB	AVANTHI INC	5MG	A203601 001	Jan 30, 2013	Jan	NEWA
AB		10MG	A203601 002	Jan 30, 2013	Jan	NEWA

OXYTOCIN

INJECTABLE; INJECTION

OXYTOCIN

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

INJECTABLE; INJECTION

TAXOL

@ HQ SPCLT PHARMA

6MG/ML

N020262 001 Dec 29, 1992 Jan CAHN

PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL

PIOGLITAZONE HYDROCHLORIDE

AB	ACCORD HLTHCARE	EQ 15MG BASE	A200044 001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A200044 002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A200044 003	Feb 13, 2013	Jan	NEWA
AB	AUROBINDO PHARMA LTD	EQ 15MG BASE	A200268 001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A200268 002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A200268 003	Feb 13, 2013	Jan	NEWA
AB	MACLEODS PHARMS LTD	EQ 15MG BASE	A202467 001	Feb 06, 2013	Jan	NEWA
AB		EQ 30MG BASE	A202467 002	Feb 06, 2013	Jan	NEWA
AB		EQ 45MG BASE	A202467 003	Feb 06, 2013	Jan	NEWA
AB	SANDOZ	EQ 15MG BASE	A078670 001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A078670 002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A078670 003	Feb 13, 2013	Jan	NEWA
AB	SYNTTHON PHARMS	EQ 15MG BASE	A078472 001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A078472 002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A078472 003	Feb 13, 2013	Jan	NEWA
AB	TORRENT PHARMS LTD	EQ 15MG BASE	A091298 001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A091298 002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A091298 003	Feb 13, 2013	Jan	NEWA
AB	ZYDUS PHARMS USA INC	EQ 15MG BASE	A202456 001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A202456 002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A202456 003	Feb 13, 2013	Jan	NEWA

>A>	<u>POMALIDOMIDE</u>						
>A>	CAPSULE; ORAL						
>A>	POMALYST						
>A>	CELGENE	1MG	N204026	001	Feb 08,	2013	Feb NEWA
>A>		2MG	N204026	002	Feb 08,	2013	Feb NEWA
>A>		3MG	N204026	003	Feb 08,	2013	Feb NEWA
>A>	+	4MG	N204026	004	Feb 08,	2013	Feb NEWA
<u>POTASSIUM CHLORIDE</u>							
CAPSULE, EXTENDED RELEASE; ORAL							
POTASSIUM CHLORIDE							
>A> AB	AMNEAL PHARMS	10MEQ	A202128	001	Feb 22,	2013	Feb NEWA
<u>PRAMLINTIDE ACETATE</u>							
INJECTABLE; SUBCUTANEOUS							
SYMLIN							
AMYLIN PHARMS							
EQ 1.5MG BASE/1.5ML (EQ 1MG BASE/ML)							
EQ 2.7MG BASE/2.7ML (EQ 1MG BASE/ML)							
+							
EQ 3MG BASE/5ML (EQ 600MCG BASE/ML)							
<u>PROPRANOLOL HYDROCHLORIDE</u>							
CAPSULE, EXTENDED RELEASE; ORAL							
PROPRANOLOL HYDROCHLORIDE							
>A> AB	GLATT AIR	60MG	A078065	001	Jan 26,	2007	Feb CAHN
>A> AB		80MG	A078065	002	Jan 26,	2007	Feb CAHN
>A> AB		120MG	A078065	003	Jan 26,	2007	Feb CAHN
>A> AB		160MG	A078065	004	Jan 26,	2007	Feb CAHN
>D> AB	PAR PHARM	60MG	A078065	001	Jan 26,	2007	Feb CAHN
>D> AB		80MG	A078065	002	Jan 26,	2007	Feb CAHN
>D> AB		120MG	A078065	003	Jan 26,	2007	Feb CAHN
>D> AB		160MG	A078065	004	Jan 26,	2007	Feb CAHN
<u>QUETIAPINE FUMARATE</u>							
TABLET; ORAL							
QUETIAPINE FUMARATE							
>A> AB	ACTAVIS PHARMA	EQ 25MG BASE	A201762	001	Feb 27,	2013	Feb NEWA
>A> AB		EQ 50MG BASE	A201762	002	Feb 27,	2013	Feb NEWA
>A> AB		EQ 100MG BASE	A201762	003	Feb 27,	2013	Feb NEWA
>A> AB		EQ 150MG BASE	A201762	004	Feb 27,	2013	Feb NEWA
>A> AB		EQ 200MG BASE	A201762	005	Feb 27,	2013	Feb NEWA
>A> AB		EQ 300MG BASE	A201762	006	Feb 27,	2013	Feb NEWA
>A> AB		EQ 400MG BASE	A201762	007	Feb 27,	2013	Feb NEWA
AB	ALKEM LABS LTD	EQ 25MG BASE	A201504	001	Feb 12,	2013	Jan NEWA
AB		EQ 50MG BASE	A201504	002	Feb 12,	2013	Jan NEWA
AB		EQ 100MG BASE	A201504	003	Feb 12,	2013	Jan NEWA
AB		EQ 150MG BASE	A201504	004	Feb 12,	2013	Jan NEWA
AB		EQ 200MG BASE	A201504	005	Feb 12,	2013	Jan NEWA
AB		EQ 300MG BASE	A201504	006	Feb 12,	2013	Jan NEWA
AB		EQ 400MG BASE	A201504	007	Feb 12,	2013	Jan NEWA

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

RANITIDINE HYDROCHLORIDE

>A>	AP	ZYDUS PHARMS USA INC	25MG/ML	A091534 001 Feb 22, 2013 Feb NEWA
		TABLET; ORAL		
		RANITIDINE HYDROCHLORIDE		
@	WATSON LABS	EQ 150MG BASE	A074864 001 Oct 20, 1997 Jan DISC	

@ EQ 300MG BASE A074864 002 Oct 20, 1997 Jan DISC

RIMANTADINE HYDROCHLORIDE

TABLET; ORAL

RIMANTADINE HYDROCHLORIDE

>D>	AB	COREPHARMA	100MG	A075916 001 Nov 02, 2001 Feb DISC
>A>		@	100MG	A075916 001 Nov 02, 2001 Feb DISC

RISPERIDONE

TABLET, ORALLY DISINTEGRATING; ORAL

RISPERIDONE

>A>	AB	MYLAN PHARMS INC	0.25MG	A091537 006 Feb 12, 2013 Feb NEWA
>D>		PAR PHARM	0.25MG	A077494 001 Apr 30, 2009 Feb CTEC
>A>	AB		0.25MG	A077494 001 Apr 30, 2009 Feb CTEC

ROCURONIUM BROMIDE

INJECTABLE; INJECTION

ZEMURON

@ ORGANON USA INC

10MG/ML (10MG/ML)

N020214 002 Mar 17, 1994 Jan CAHN

AP + 50MG/5ML (10MG/ML)

N020214 001 Mar 17, 1994 Jan CAHN

AP + 100MG/10ML (10MG/ML)

N020214 003 Mar 17, 1994 Jan CAHN

ROSIGLITAZONE MALEATE

TABLET; ORAL

AVANDIA

AB SB PHARMCO EQ 2MG BASE

N021071 002 May 25, 1999 Jan CFTG

AB EQ 4MG BASE

N021071 003 May 25, 1999 Jan CFTG

AB + EQ 8MG BASE

N021071 004 May 25, 1999 Jan CFTG

ROSIGLITAZONE MALEATE

AB TEVA EQ 2MG BASE

A076747 001 Jan 25, 2013 Jan NEWA

AB EQ 4MG BASE

A076747 002 Jan 25, 2013 Jan NEWA

AB EQ 8MG BASE

A076747 003 Jan 25, 2013 Jan NEWA

SAQUINAVIR MESYLATE

TABLET; ORAL

INVIRASE

&gt;A&gt; + HOFFMAN LA ROCHE EQ 500MG BASE

N021785 001 Dec 17, 2004 Feb CAHN

&gt;D&gt; + ROCHE EQ 500MG BASE

N021785 001 Dec 17, 2004 Feb CAHN

SELEGILINE HYDROCHLORIDE

TABLET; ORAL

SELEGILINE HYDROCHLORIDE

@ DAVA PHARMS INC 5MG

A074641 001 Aug 02, 1996 Jan DISC

SILDENAFIL CITRATE

TABLET; ORAL

SILDENAFIL CITRATE

&gt;A&gt; AB ACTAVIS PHARMA EQ 20MG BASE

A200149 001 Feb 25, 2013 Feb NEWA

TABLET; ORAL

SILDENAFIL CITRATE

&gt;A&gt; AB AMNEAL PHARMS EQ 20MG BASE A202025 001 Feb 28, 2013 Feb NEWA

SODIUM CHLORIDE

SOLUTION; IRRIGATION

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

@ BAXTER HLTHCARE 450MG/100ML N017864 001 Jan DISC

SULFACETAMIDE SODIUM

LOTION; TOPICAL

KLARON

>D> AB + SANOFI AVENTIS US 10% N019931 001 Dec 23, 1996 Feb CAHN  
>A> AB + VALEANT BERMUDA 10% N019931 001 Dec 23, 1996 Feb CAHNSUMATRIPTAN SUCCINATE

INJECTABLE; SUBCUTANEOUS

SUMATRIPTAN SUCCINATE

&gt;A&gt; AP SAGENT AGILA EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) A090641 001 Jul 28, 2010 Feb CAHN

&gt;D&gt; AP SAGENT STRIDES EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) A090641 001 Jul 28, 2010 Feb CAHN

SYSTEM; IONTOPHORESIS

ZECURITY

+ NUPATHE EQ 6.5MG BASE/4HR N202278 001 Jan 17, 2013 Jan NEWA

TESTOSTERONE

GEL; TRANSDERMAL

TESTOSTERONE

PERRIGO ISRAEL 25MG/2.5GM PACKET

N203098 002 Jan 31, 2013 Jan NEWA

50MG/5GM PACKET

N203098 003 Jan 31, 2013 Jan NEWA

GEL, METERED; TRANSDERMAL

TESTOSTERONE

PERRIGO ISRAEL 12.5MG/1.25GM ACTUATION

N203098 001 Jan 31, 2013 Jan NEWA

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

DELATESTRYL

AO + ENDO PHARMS 200MG/ML N009165 003 Jan CAHN  
@ 200MG/ML N009165 001 Jan CAHNTIMOLOL MALEATESOLUTION, GEL FORMING/DROPS; OPHTHALMIC  
TIMOPTIC-XEAB + VALEANT PHARMS LLC EQ 0.25% BASE N020330 001 Nov 04, 1993 Jan CAHN  
AB + EQ 0.5% BASE N020330 002 Nov 04, 1993 Jan CAHNTIZANIDINE HYDROCHLORIDE

TABLET; ORAL

TIZANIDINE HYDROCHLORIDE

&gt;D&gt; AB MYLAN PHARMS INC EQ 2MG BASE A076282 001 Dec 16, 2003 Feb DISC

&gt;A&gt; @ EQ 2MG BASE A076282 001 Dec 16, 2003 Feb DISC

&gt;D&gt; AB EQ 4MG BASE A076282 002 Dec 16, 2003 Feb DISC

&gt;A&gt; @ EQ 4MG BASE A076282 002 Dec 16, 2003 Feb DISC

TOPIRAMATE

TABLET; ORAL  
TOPIRAMATE

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

TRAMADOL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL  
RYZOLT

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

TRAMADOL HYDROCHLORIDE

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

TRAVOPROST

SOLUTION/DROPS; OPHTHALMIC  
TRAVOPROST

>A>		PAR PHARM	0.004%	A091340 001	Mar 01, 2013	Feb	NEWA
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URSODIOL

TABLET; ORAL  
URSODIOL

>A>	AB	PAR PHARM	250MG	A202540 001	Feb 14, 2013	Feb	NEWA
>A>	AB		500MG	A202540 002	Feb 14, 2013	Feb	NEWA

VALPROIC ACID

CAPSULE; ORAL  
VALPROIC ACID

>A>	AB	SUN PHARM INDs LTD	250MG	A091037 001	Feb 22, 2013	Feb	NEWA
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VERTEPORFIN

INJECTABLE; INJECTION  
VISUDYNE

+>A>	AB	VALEANT PHARMS INC	15MG/VIAL	N021119 001	Apr 12, 2000	Jan	CAHN
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WARFARIN SODIUM

TABLET; ORAL  
WARFARIN SODIUM

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

ZIDOVUDINE

TABLET; ORAL

ZIDOVUDINE

>D>	@ HEC PHARM USA INC	300MG	A202058 001 Oct 07, 2011 Feb CMFD
>A> AB		300MG	A202058 001 Oct 07, 2011 Feb CMFD
	@	300MG	A202058 001 Oct 07, 2011 Jan DISC

ZOLEDRONIC ACID

INJECTABLE; IV (INFUSION)

>A>	ZOLEDRONIC ACID		
>A> AP	ACTAVIS INC	EQ 4MG BASE/5ML	A202472 001 Mar 04, 2013 Feb NEWA
>A> AP	AGILA SPECLTS	EQ 4MG BASE/5ML	A202650 001 Mar 04, 2013 Feb NEWA
>A> AP	DR REDDYS LABS LTD	EQ 4MG BASE/5ML	A091186 001 Mar 04, 2013 Feb NEWA
>A> AP	PHARMACEUTICS	EQ 4MG BASE/5ML	A091170 001 Mar 04, 2013 Feb NEWA
>A> AP	SUN PHARMA GLOBAL	EQ 4MG BASE/5ML	A202746 001 Mar 04, 2013 Feb NEWA
>A>	+	EQ 4MG BASE/VIAL	A090018 001 Mar 04, 2013 Feb NEWA
	ZOMETA		
>D>	+	NOVARTIS	N021223 002 Mar 07, 2003 Feb CFTG
>A> AP	+	EQ 4MG BASE/5ML	N021223 002 Mar 07, 2003 Feb CFTG

ZONISAMIDE

CAPSULE; ORAL

ZONISAMIDE

>D> AB	COREPHARMA	25MG	A077876 001 Feb 21, 2007 Feb DISC
>A>	@	25MG	A077876 001 Feb 21, 2007 Feb DISC
>D> AB		50MG	A077876 002 Feb 21, 2007 Feb DISC
>A>	@	50MG	A077876 002 Feb 21, 2007 Feb DISC
>D> AB		100MG	A077876 003 Feb 21, 2007 Feb DISC
>A>	@	100MG	A077876 003 Feb 21, 2007 Feb DISC

## OTC DRUG PRODUCT LIST - 33RD EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2013

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ASPIRIN

CAPSULE; ORAL  
 ASPIRIN  
 + PLX PHARMA 325MG N203697 001 Jan 14, 2013 Jan NEWA

CETIRIZINE HYDROCHLORIDE

TABLET, CHEWABLE; ORAL  
 CHILDREN'S ZYRTEC ALLERGY  
 >D> MCNEIL CONS 5MG N021621 003 Nov 16, 2007 Feb CRLD  
 >A> + 5MG N021621 003 Nov 16, 2007 Feb CRLD  
 >D> + 10MG N021621 004 Nov 16, 2007 Feb DISC  
 >A> @ 10MG N021621 004 Nov 16, 2007 Feb DISC  
 CHILDREN'S ZYRTEC HIVES RELIEF  
 >D> MCNEIL CONS 5MG N021621 005 Nov 16, 2007 Feb CRLD  
 >A> + 5MG N021621 005 Nov 16, 2007 Feb CRLD  
 >D> + 10MG N021621 006 Nov 16, 2007 Feb DISC  
 >A> @ 10MG N021621 006 Nov 16, 2007 Feb DISC

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL  
 DEXBROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE  
 >A> AVANTHI INC 6MG;120MG A078648 001 Feb 27, 2013 Feb NEWA

FEXOFENADINE HYDROCHLORIDE

TABLET, ORALLY DISINTEGRATING; ORAL  
 CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY  
 DR REDDYS LABS LTD 30MG A202978 001 Jan 18, 2013 Jan NEWA  
 CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES  
 DR REDDYS LABS LTD 30MG A202978 002 Jan 18, 2013 Jan NEWA

LEVONORGESTREL

TABLET; ORAL  
 LEVONORGESTREL  
 LUPIN LTD 0.75MG A091328 001 Jan 23, 2013 Jan NEWA  
 >A> AB NOVEL LABS INC 1.5MG A202508 001 Feb 22, 2013 Feb NEWA

LORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL  
 LORATADINE AND PSEUDOEPHEDRINE SULFATE  
 >D> WATSON LABS FLORIDA 5MG;120MG A076208 001 Jan 28, 2004 Feb DISC  
 >A> @ WATSON LABS INC FL 5MG;120MG A076208 001 Jan 28, 2004 Feb DISC

MICONAZOLE NITRATE

CREAM; VAGINAL  
 MICONAZOLE NITRATE  
 APHENA PHARMA MD 2% A074366 001 Feb 22, 1996 Jan CAHN

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC  
 NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE  
 AKORN INC 0.025%;0.3% A202795 001 Jan 24, 2013 Jan NEWA

OXYBUTYNIN

FILM, EXTENDED RELEASE; TRANSDERMAL

OXYTROL FOR WOMEN

+ MSD CONSUMER

3.9MG/24HR

N202211 001 Jan 25, 2013 Jan NEWA

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL

POLYETHYLENE GLYCOL 3350

PAR PHARM

17GM/SCOOPFUL

A079214 001 Jan 31, 2013 Jan NEWA

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

**CUMULATIVE SUPPLEMENT NUMBER 02 FEBRUARY 2013**

NO FEBRUARY 2013 APPROVALS

## ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

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

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

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

NO FEBRUARY 2013 ADDITIONS

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2013

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See List footnote for information regarding List content

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

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2013

See List footnote for information regarding List content

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

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2013

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

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2013

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

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2013

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<u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u>						
N022426 005	>A> 5965584	Jun 19, 2016	DP U-1339		NCE	Jan 25, 2018
	>A> 6150383	Jun 19, 2016	U-1330		NC	Jan 25, 2016
	>A> 6150384	Jun 19, 2016	U-1340			
	>A> 6166042	Jun 19, 2016	U-1341			
	>A> 6166043	Jun 19, 2016	U-1342			
	>A> 6172090	Jun 19, 2016	U-1343			
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6271243	Jun 19, 2016	U-1344			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			
<u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u>						
N022426 006	>A> 5965584	Jun 19, 2016	DP U-1339		NCE	Jan 25, 2018
	>A> 6150383	Jun 19, 2016	U-1330		NC	Jan 25, 2016
	>A> 6150384	Jun 19, 2016	U-1340			
	>A> 6166042	Jun 19, 2016	U-1341			
	>A> 6166043	Jun 19, 2016	U-1342			
	>A> 6172090	Jun 19, 2016	U-1343			
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6271243	Jun 19, 2016	U-1344			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			
<u>AMOXICILLIN - MOXATAG</u>						
N050813 001	8357394	Dec 08, 2026	DP			
<u>APIXBAN - ELIQUIS</u>						
N202155 001	>A> 6413980	Dec 22, 2019	DS DP U-1200			
	>A> 6967208	Feb 03, 2023	DS DP U-1323			
	>A> 6967208	Feb 03, 2023	DS DP U-1200			
<u>APIXBAN - ELIQUIS</u>						
N202155 002	6413980	Dec 22, 2019	DS DP U-1200			
	>A> 6967208	Feb 03, 2023	DS DP U-1323			
	>A> 6967208	Feb 03, 2023	DS DP U-1200			
<u>ARIPIPRAZOLE - ABILIFY MAINTENA KIT</u>						
N202971 001				>A> NDF		Feb 28, 2016

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<u>ARIPIPRAZOLE - ABILIFY MAINTENA KIT</u>						
	N202971 002			>A> NDF		Feb 28, 2016
<u>BEDAQUILINE FUMARATE - SIRTURO</u>						
	N204384 001	7498343	Oct 02, 2024	DS DP U-1321	ODE	Dec 28, 2019
<u>BOCEPREVIR - VICTRELIS</u>						
	N202258 001			>A> M-126 >A> NPP	Feb 27, 2016 Feb 13, 2016	
<u>BUDESONIDE - UCERIS</u>						
	N203634 001	7410651	Jun 09, 2020	DP U-1325	NDF	Jan 14, 2016
		7431943	Jun 09, 2020	DP		
		8293273	Jun 09, 2020	DP		
		RE43799	Jun 09, 2020	DP U-1325		
<u>CABOZANTINIB S-MALATE - COMETRIQ</u>						
	N203756 001				ODE	Nov 29, 2019
<u>CABOZANTINIB S-MALATE - COMETRIQ</u>						
	N203756 002				ODE	Nov 29, 2019
<u>CELECOXIB - CELEBREX</u>						
	N020998 001	>A> RE44048	Jun 02, 2015	U-247		
		>A> RE44048	Jun 02, 2015	U-1352		
		>A> RE44048	Jun 02, 2015	U-1351		
		>A> RE44048	Jun 02, 2015	U-1350		
		>A> RE44048	Jun 02, 2015	U-1349		
		>A> RE44048	Jun 02, 2015	U-1348		
		>A> RE44048*PED	Dec 02, 2015			
<u>CELECOXIB - CELEBREX</u>						
	N020998 002	>A> RE44048	Jun 02, 2015	U-247		
		>A> RE44048	Jun 02, 2015	U-1352		
		>A> RE44048	Jun 02, 2015	U-1351		
		>A> RE44048	Jun 02, 2015	U-1350		
		>A> RE44048	Jun 02, 2015	U-1349		
		>A> RE44048	Jun 02, 2015	U-1348		
		>A> RE44048*PED	Dec 02, 2015			
<u>CELECOXIB - CELEBREX</u>						
	N020998 003	>A> RE44048	Jun 02, 2015	U-247		
		>A> RE44048	Jun 02, 2015	U-1352		
		>A> RE44048	Jun 02, 2015	U-1351		
		>A> RE44048	Jun 02, 2015	U-1350		
		>A> RE44048	Jun 02, 2015	U-1349		
		>A> RE44048	Jun 02, 2015	U-1348		
		>A> RE44048*PED	Dec 02, 2015			
<u>CELECOXIB - CELEBREX</u>						
	N020998 004	>A> RE44048	Jun 02, 2015	U-247		
		>A> RE44048	Jun 02, 2015	U-1352		
		>A> RE44048	Jun 02, 2015	U-1351		
		>A> RE44048	Jun 02, 2015	U-1350		
		>A> RE44048	Jun 02, 2015	U-1349		
		>A> RE44048	Jun 02, 2015	U-1348		
		>A> RE44048*PED	Dec 02, 2015			

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<u>CICLESONIDE - ALVESCO</u>						
N021658 002	>A> 8371292	Aug 25, 2027	U-1355		M-125	Dec 17, 2015
<u>CICLESONIDE - ALVESCO</u>						
N021658 003	>A> 8371292	Aug 25, 2027	U-1355		M-125	Dec 17, 2015
<u>CICLESONIDE - OMNARIS</u>						
N022004 001	>A> 8371292	Aug 25, 2027	U-1356			
<u>CICLESONIDE - ZETONNA</u>						
N202129 001	>A> 8371292	Aug 25, 2027	U-1357			
<u>CLOBAZAM - ONFI</u>						
N203993 001				>A> ODE		Oct 21, 2018
<u>CLOBETASOL PROPIONATE - CLOBETASOL PROPIONATE</u>						
A201402 001				PC		Jul 31, 2013
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 001				>A> D-135		Feb 01, 2016
				>A> PED		Aug 01, 2016
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 002				>A> D-135		Feb 01, 2016
				>A> PED		Aug 01, 2016
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 003				>A> D-135		Feb 01, 2016
				>A> PED		Aug 01, 2016
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 004				>A> D-135		Feb 01, 2016
				>A> PED		Aug 01, 2016
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 005				>A> D-135		Feb 01, 2016
				>A> PED		Aug 01, 2016
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 006				>A> D-135		Feb 01, 2016
				>A> PED		Aug 01, 2016
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N202895 001				>A> D-135		Feb 01, 2016
				>A> PED		Aug 01, 2016
<u>DEFERASIROX - EXJADE</u>						
N021882 001				I-665		Jan 23, 2016
<u>DEFERASIROX - EXJADE</u>						
N021882 002				I-665		Jan 23, 2016
<u>DEFERASIROX - EXJADE</u>						
N021882 003				I-665		Jan 23, 2016
<u>DROSPIRENONE; ETHINYL ESTRADIOL - YAZ</u>						
N021676 001	RE43916	Jun 30, 2014	U-1326			
<u>DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - BEYAZ</u>						
N022532 001	RE43916	Jun 30, 2014	U-1326			
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>						
N021427 001				M-61		Oct 18, 2015
				PED		Apr 18, 2016

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<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>						
	N021427 002				M-61 PED	Oct 18, 2015 Apr 18, 2016
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>						
	N021427 004				M-61 PED	Oct 18, 2015 Apr 18, 2016
<u>EFAVIRENZ - SUSTIVA</u>						
N020972 001	5519021	May 21, 2013	DS DP			
	5519021*PED	Nov 21, 2013				
	5663169	Sep 02, 2014		U-257		
	5663169*PED	Mar 02, 2015				
	6238695	Apr 06, 2019	DP			
	6238695*PED	Oct 06, 2019				
	6555133	Apr 06, 2019		U-248		
	6555133*PED	Oct 06, 2019				
	6639071	Feb 14, 2018	DS			
	6639071*PED	Aug 14, 2018				
	6939964	Jan 20, 2018	DS			
	6939964*PED	Jul 20, 2018				
<u>EFAVIRENZ - SUSTIVA</u>						
N020972 002	5519021	May 21, 2013	DS DP			
	5519021*PED	Nov 21, 2013				
	5663169	Sep 02, 2014		U-257		
	5663169*PED	Mar 02, 2015				
	6238695	Apr 06, 2019	DP			
	6238695*PED	Oct 06, 2019				
	6555133	Apr 06, 2019		U-248		
	6555133*PED	Oct 06, 2019				
	6639071	Feb 14, 2018	DS			
	6639071*PED	Aug 14, 2018				
	6939964	Jan 20, 2018	DS			
	6939964*PED	Jul 20, 2018				
<u>EFAVIRENZ - SUSTIVA</u>						
N020972 003	5519021	May 21, 2013	DS DP			
	5519021*PED	Nov 21, 2013				
	5663169	Sep 02, 2014		U-257		
	5663169*PED	Mar 02, 2015				
	6238695	Apr 06, 2019	DP			
	6238695*PED	Oct 06, 2019				
	6555133	Apr 06, 2019		U-248		
	6555133*PED	Oct 06, 2019				
	6639071	Feb 14, 2018	DS			
	6639071*PED	Aug 14, 2018				
	6939964	Jan 20, 2018	DS			
	6939964*PED	Jul 20, 2018				

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<u>EFAVIRENZ - SUSTIVA</u>						
N021360 001	5519021	May 21, 2013				
	5519021*PED	Nov 21, 2013				
	5663169	Sep 02, 2014				
	5663169*PED	Mar 02, 2015				
	6639071	Feb 14, 2018	DS			
	6639071*PED	Aug 14, 2018				
	6939964	Jan 20, 2018	DS			
	6939964*PED	Jul 20, 2018				
<u>EFAVIRENZ - SUSTIVA</u>						
N021360 002	5519021	May 21, 2013	DS DP			
	5519021*PED	Nov 21, 2013				
	5663169	Sep 02, 2014		U-248		
	5663169*PED	Mar 02, 2015				
	6639071	Feb 14, 2018	DS			
	6639071*PED	Aug 14, 2018				
	6939964	Jan 20, 2018	DS			
	6939964*PED	Jul 20, 2018				
<u>EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - ATRIPLA</u>						
N021937 001	5519021	May 21, 2013	DS DP			
	5519021*PED	Nov 21, 2013				
	5663169	Sep 02, 2014		U-750		
	5663169	Sep 02, 2014		U-1170		
	5663169*PED	Mar 02, 2015				
	6639071	Feb 14, 2018	DS			
	6639071*PED	Aug 14, 2018				
	6939964	Jan 20, 2018	DS			
	6939964*PED	Jul 20, 2018				
<u>EPINEPHRINE - AUVI-Q</u>						
N201739 001	>A> 7731686	Jun 01, 2026	DP			
	>A> 7731690	Jan 15, 2025	DP			
	>A> 7749194	Oct 30, 2028	DP			
	>A> 7918823	Nov 23, 2024	DP			
	>A> 7947017	Mar 12, 2028	DP			
	>A> 8016788	Mar 21, 2025	DP			
	>A> 8361029	Nov 23, 2024	DP			
<u>EPINEPHRINE - AUVI-Q</u>						
N201739 002	>A> 7731686	Jun 01, 2026	DP			
	>A> 7731690	Jan 15, 2025	DP			
	>A> 7749194	Oct 30, 2028	DP			
	>A> 7918823	Nov 23, 2024	DP			
	>A> 7947017	Mar 12, 2028	DP			
	>A> 8016788	Mar 21, 2025	DP			
	>A> 8361029	Nov 23, 2024	DP			
<u>EPOPROSTENOL SODIUM - VELETRI</u>						
N022260 001	8318802	Mar 15, 2027	DP			
<u>EPOPROSTENOL SODIUM - VELETRI</u>						
N022260 002	8318802	Mar 15, 2027	DP			

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<u>ESZOPICLONE - LUNESTA</u>						
	N021476 001				M-61 PED	Oct 10, 2015 Apr 10, 2016
<u>ESZOPICLONE - LUNESTA</u>						
	N021476 002				M-61 PED	Oct 10, 2015 Apr 10, 2016
<u>ESZOPICLONE - LUNESTA</u>						
	N021476 003				M-61 PED	Oct 10, 2015 Apr 10, 2016
<u>EVEROLIMUS - ZORTRESS</u>						
	N021560 001				>A> I-668	Feb 15, 2016
<u>EVEROLIMUS - ZORTRESS</u>						
	N021560 002				>A> I-668	Feb 15, 2016
<u>EVEROLIMUS - ZORTRESS</u>						
	N021560 003				>A> I-668	Feb 15, 2016
<u>FEBUXOSTAT - ULORIC</u>						
	N021856 001 >A> 8372872	Sep 08, 2031			U-1346	
<u>FEBUXOSTAT - ULORIC</u>						
	N021856 002 >A> 8372872	Sep 08, 2031			U-1346	
<u>FESOTERODINE FUMARATE - TOVIAZ</u>						
	N022030 001 8338478	May 11, 2019			DS DP U-913	
<u>FESOTERODINE FUMARATE - TOVIAZ</u>						
	N022030 002 8338478	May 11, 2019			DS DP U-913	
<u>FLUTICASONE FUROATE - VERAMYST</u>						
	N022051 001 8347879	Apr 01, 2027			DP	
<u>GABAPENTIN - GRALISE</u>						
	N022544 001 8333992	Oct 25, 2022			DP U-1114	
<u>GABAPENTIN - GRALISE</u>						
	N022544 002 8333992	Oct 25, 2022			DP U-1114	
<u>GADOXETATE DISODIUM - EOVI</u>						
	N022090 002				>A> NCE	Jul 03, 2013
<u>GANIRELIX ACETATE - GANIRELIX ACETATE INJECTION</u>						
	N021057 001 >A> 6653286	Jun 16, 2018			U-1354	
<u>GLYCEROL PHENYLBUTYRATE - RAVICTI</u>						
	N203284 001				>A> NE	Feb 01, 2016
<u>ICOSAPENT ETHYL - VASCEPA</u>						
	N202057 001 8357677	Feb 09, 2030			U-1287	
	8367652	Feb 09, 2030			U-1287	
	>A> 8377920	Feb 09, 2030			U-1287	
<u>IMATINIB MESYLATE - GLEEVEC</u>						
	N021588 001 7544799	Jan 16, 2019	DS DP		Y	I-666
	RE43932	Jan 16, 2019	DS DP			
	RE43932*PED	Jul 16, 2019				

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<u>IMATINIB MESYLATE - GLEEVEC</u>						
N021588 002	7544799	Jan 16, 2019	DS DP	Y	I-666	Jan 25, 2016
	RE43932	Jan 16, 2019	DS DP			
	RE43932*PED	Jul 16, 2019				
<u>INGENOL MEBUTATE - PICATO</u>						
N202833 001	>A> 8372827	Dec 18, 2026	DS DP			
	>A> 8372828	Dec 18, 2026	DS DP			
	>A> 8377919	Dec 18, 2026	DS DP			
<u>INGENOL MEBUTATE - PICATO</u>						
N202833 002	>A> 8372827	Dec 18, 2026	DS DP			
	>A> 8372828	Dec 18, 2026	DS DP			
	>A> 8377919	Dec 18, 2026	DS DP			
<u>ISOTRETINOIN - ABSORICA</u>						
N021951 001	>A> 8367102	Sep 21, 2021			U-1347	
<u>ISOTRETINOIN - ABSORICA</u>						
N021951 002	>A> 8367102	Sep 21, 2021			U-1347	
<u>ISOTRETINOIN - ABSORICA</u>						
N021951 003	>A> 8367102	Sep 21, 2021			U-1347	
<u>ISOTRETINOIN - ABSORICA</u>						
N021951 004	>A> 8367102	Sep 21, 2021			U-1347	
<u>LEVALBUTEROL HYDROCHLORIDE - LEVALBUTEROL HYDROCHLORIDE</u>						
A077756 001					>A> PC	Feb 16, 2013
<u>LEVALBUTEROL HYDROCHLORIDE - LEVALBUTEROL HYDROCHLORIDE</u>						
A077756 002					>A> PC	Feb 16, 2013
<u>LEVALBUTEROL HYDROCHLORIDE - LEVALBUTEROL HYDROCHLORIDE</u>						
A077756 003					>A> PC	Feb 16, 2013
<u>LEVOLEUCOVORIN CALCIUM - FUSILEV</u>						
N020140 001	6500829	Mar 07, 2022	DS DP			
<u>LEVOLEUCOVORIN CALCIUM - FUSILEV</u>						
N020140 002	6500829	Mar 07, 2022	DS DP			
<u>LEVOLEUCOVORIN CALCIUM - FUSILEV</u>						
N020140 003	6500829	Mar 07, 2022	DS DP			
<u>LEVONORGESTREL - SKYLA</u>						
N203159 001	5785053	Dec 05, 2015	DP		NP	Jan 09, 2016
	7252839	Nov 13, 2023	DP			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N203858 001	>A> 5712279	Feb 21, 2015	DS	U-1317	ODE	Dec 21, 2019
	>A> 7932268	Aug 19, 2027		U-1316		
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N203858 002	>A> 5712279	Feb 21, 2015	DS	U-1317	ODE	Dec 21, 2019
	>A> 7932268	Aug 19, 2027		U-1316		
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N203858 003	>A> 5712279	Feb 21, 2015	DS	U-1317	ODE	Dec 21, 2019
	>A> 7932268	Aug 19, 2027		U-1316		

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<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
N021906 001	>A> 8025899	Dec 14, 2027	DP			
	>A> 8025899*PED	Jun 14, 2028				
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
N021906 002	>A> 8025899	Dec 14, 2027	DP			
	>A> 8025899*PED	Jun 14, 2028				
<u>LOTEPREDNOL ETABONATE - LOTEMAX</u>						
N202872 001	>A> 5800807	Jan 29, 2017	DP			
<u>LUBIPROSTONE - AMITIZA</u>						
N021908 001	>A> 8389542	Nov 14, 2022	DP U-1345			
<u>MAGNESIUM SULFATE; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; POTASSIUM SULFATE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE - SUCLEAR</u>						
N203595 001				NC		Jan 18, 2016
<u>MIPOMERSEN SODIUM - KYNAMRO</u>						
N203568 001	>A> 5914396	Jun 22, 2016	DS		NCE	Jan 29, 2018
	>A> 6166197	Dec 26, 2017	DS		>A> ODE	Jan 29, 2020
	>A> 6222025	Mar 06, 2015	DS			
	>A> 6451991	Feb 11, 2017	DS			
	>A> 7015315	Mar 21, 2023	DS			
	>A> 7101993	Sep 05, 2023	DS			
	>A> 7407943	Aug 01, 2021	U-1353			
	>A> 7511131	Dec 13, 2025	DS			
<u>MUPIROCIN CALCIUM - BACTROBAN</u>						
N050703 001	>A> 5569672	Oct 29, 2013	U-1357			
<u>MUPIROCIN CALCIUM - BACTROBAN</u>						
N050746 001	>A> 5569672	Oct 29, 2013	U-1358			
<u>NEPAFENAC - NEPAFENAC</u>						
N203491 001	>A> 5475034	Jun 06, 2014	U-100			
	>A> 6403609	Jul 17, 2018	DP			
	>A> 7947295	Jun 08, 2024	DP			
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087 001				NPP		Dec 21, 2015
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087 002				NPP		Dec 21, 2015
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087 003				NPP		Dec 21, 2015
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021246 001				NPP		Dec 21, 2015
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021246 002				NPP		Dec 21, 2015
<u>OSPEMIFENE - OSPHENA</u>						
N203505 001				>A> NCE		Feb 26, 2018

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<u>OXYBUTYNIN - OXYTROL FOR WOMEN</u>						
N202211 001	>A> 5601839	Apr 26, 2015	DP U-1329		NP	Jan 25, 2016
	>A> 5834010	Apr 26, 2015	DP U-1329			
	>A> 6743441	Apr 26, 2020	DP U-1329			
	>A> 7081249	Apr 26, 2020	DP U-1329			
	>A> 7081250	Apr 26, 2020	DP U-1329			
	>A> 7081251	Apr 26, 2020	DP U-1329			
	>A> 7081252	Apr 26, 2020	DP U-1329			
	>A> 7179483	Apr 26, 2020	U-1329			
<u>PLERIXAFOR - MOZOBIL</u>						
N022311 001	RE42152	Dec 10, 2018	DP			
<u>POMALIDOMIDE - POMALYST</u>						
N204026 001				>A> NCE	Feb 08, 2018	
				>A> ODE	Feb 08, 2020	
<u>POMALIDOMIDE - POMALYST</u>						
N204026 002				>A> NCE	Feb 08, 2018	
				>A> ODE	Feb 08, 2020	
<u>POMALIDOMIDE - POMALYST</u>						
N204026 003				>A> NCE	Feb 08, 2018	
				>A> ODE	Feb 08, 2020	
<u>POMALIDOMIDE - POMALYST</u>						
N204026 004				>A> NCE	Feb 08, 2018	
				>A> ODE	Feb 08, 2020	
<u>PONATINIB HYDROCHLORIDE - ICLUSIG</u>						
N203469 001				ODE	Dec 14, 2019	
<u>PONATINIB HYDROCHLORIDE - ICLUSIG</u>						
N203469 002				ODE	Dec 14, 2019	
<u>PRALATREXATE - FOLOTYN</u>						
N022468 001	6028071	Jul 16, 2022	DS DP U-1004			
<u>PRALATREXATE - FOLOTYN</u>						
N022468 002	6028071	Jul 16, 2022	DS DP U-1004			
<u>PREGABALIN - LYRICA</u>						
N022488 001				>A> I-651	Jun 20, 2015	
<u>REGORAFENIB - STIVARGA</u>						
N203085 001				>A> I-667	Feb 25, 2016	
<u>SAPROPTERIN DIHYDROCHLORIDE - KUVAN</u>						
N022181 001	8318745	Nov 17, 2024	DP			
<u>SAQUINAVIR MESYLATE - INVIRASE</u>						
N020628 001				M-61 PED	Nov 30, 2015 May 30, 2016	
<u>SAQUINAVIR MESYLATE - INVIRASE</u>						
N021785 001				M-61 PED	Nov 30, 2015 May 30, 2016	
<u>SUMATRIPTAN SUCCINATE - SUMAVENT DOSEPRO</u>						
N022239 001	8343130	Oct 18, 2022	DP			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2013

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>SUMATRIPTAN SUCCINATE - ZECUITY</u>						
N202278 001	>A> 6745071	Feb 21, 2023	DP		NDF	Jan 17, 2016
	>A> 7973058	Apr 12, 2027		U-1328		
	>A> 8155737	Apr 12, 2027		U-1328		
	>A> 8366600	Apr 21, 2029		U-1327		
<u>TAPENTadol HYDROCHLORIDE - NUCYNTA ER</u>						
N200533 001	8114383	Oct 10, 2024	DP	Y		
<u>TAPENTadol HYDROCHLORIDE - NUCYNTA ER</u>						
N200533 002	8114383	Oct 10, 2024	DP	Y		
<u>TAPENTadol HYDROCHLORIDE - NUCYNTA ER</u>						
N200533 003	8114383	Oct 10, 2024	DP	Y		
<u>TAPENTadol HYDROCHLORIDE - NUCYNTA ER</u>						
N200533 004	8114383	Oct 10, 2024	DP	Y		
<u>TAPENTadol HYDROCHLORIDE - NUCYNTA ER</u>						
N200533 005	8114383	Oct 10, 2024	DP	Y		
<u>TEDUGLUTIDE - GATTEx KIT</u>						
N203441 001	5789379	Apr 14, 2015	DS DP	U-1320	ODE	Dec 21, 2019
	7056886	Sep 18, 2022	DP	U-1320		
	7847061	Nov 01, 2025		U-1320		
<u>TELBIVUDINE - TYZEKA</u>						
N022011 001					M-124	Jan 28, 2016
<u>TELBIVUDINE - TYZEKA</u>						
N022154 001					M-124	Jan 28, 2016
<u>TESTOSTERONE - TESTOSTERONE</u>						
N203098 001					NP	Jan 31, 2016
<u>TESTOSTERONE - TESTOSTERONE</u>						
N203098 002					NP	Jan 31, 2016
<u>TESTOSTERONE - TESTOSTERONE</u>						
N203098 003					NP	Jan 31, 2016
<u>TIGECYCLINE - TYGACIL</u>						
N021821 001	>A> 8372995	Oct 08, 2030	DP			
<u>TOBRAMYCIN - BETHKIS</u>						
N201820 001	6987094	Sep 22, 2022	DP			
	7696178	Mar 17, 2023	DP			
	7939502	Jun 14, 2022		U-1324		
<u>TRAVOPROST - TRAVATAN Z</u>						
N021994 001	>A> 8388941	Sep 20, 2027	DP			
<u>TROSPiUM CHLORIDE - TROSPiUM CHLORIDE</u>						
A091289 001					>A> PC	Apr 10, 2013
<u>UNOPROSTONE ISOPROPYL - RESCULA</u>						
N021214 001	6770675	Nov 24, 2018	DP	U-1322		

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2013

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
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## Footnote:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.

## PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 33<sup>rd</sup> Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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

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