

APPROVED DRUG PRODUCTS

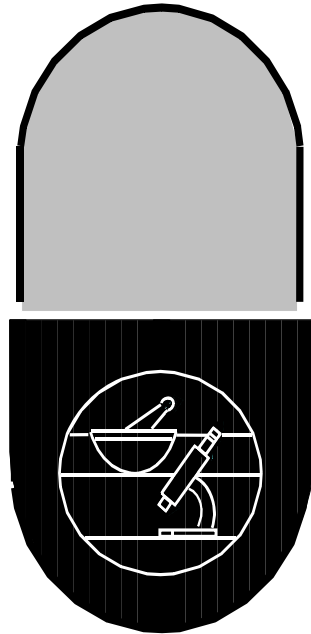
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**CUMULATIVE
SUPPLEMENT 2
FEBRUARY 2014**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

34th EDITION

Department of Health and Human Services

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

2014

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

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with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

34th EDITION

Cumulative Supplement 2

February 2014

CONTENTS

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

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34th EDITION

**CUMULATIVE SUPPLEMENT 2
February 2014**

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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

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

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

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

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

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

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

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

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

1.3 APPLICANT NAME CHANGES

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

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

<u>FORMER APPLICANT NAME</u> <u>(FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME</u> <u>(NEW ABBREVIATED NAME)</u>
WEST WARD INC (WEST WARD)	HIKMA PHARMACEUTICALS (HIKMA PHARMS)
WEST WARD PHARMACEUTICAL CORP (WEST WARD PHARMS CORP)	HIKMA PHARMACEUTICALS (HIKMA PHARMS)
WEST WARD PHARMACEUTICAL CORP (WEST WARD PHARMS)	HIKMA PHARMACEUTICALS (HIKMA PHARMS)

1.4 LEVOTHYROXINE SODIUM

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

Levothyroxine Sodium (Mylan ANDA 76187) and Levo-T (Alara NDA 21342) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets. Levo-T (Alara NDA 021342), Levothyroxine Sodium (Mylan ANDA 76187), Unithroid (Jerome Stevens NDA 021210), and Levothyroxine Sodium (Merck KGAA ANDA 76752) tablets have been determined to be therapeutically equivalent to corresponding strengths of Synthroid (Abbott NDA 021402) tablets.

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

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

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

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

1.5 AVAILABILITY OF THE EDITION

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

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable

Document Format (PDF) at the EOB home page by clicking on Publications. The PDF annual and cumulative supplements duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

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

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

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

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

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 2012) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

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

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

<u>CATEGORIES COUNTED</u>	<u>DEC 2013</u>	<u>MAR 2014</u>	<u>JUN 2014</u>	<u>SEPT 2014</u>	<u>DEC 2014</u>
DRUG PRODUCTS LISTED	15711				
SINGLE SOURCE	2517 (16.0%)				
MULTISOURCE	13194 (84.0%)				
THERAPEUTICALLY EQUIVALENT	13055 (83.1%)				
NOT THERAPEUTICALLY EQUIVALENT	139 (0.9%)				
EXCEPTIONS ¹	78 (0.5%)				
NEW MOLECULAR ENTITIES APPROVED	20				
NUMBER OF APPLICANTS	866				

¹Amino 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.

ACAMPROSATE CALCIUM

TABLET, DELAYED RELEASE;ORAL
 ACAMPROSATE CALCIUM

>A> AB MYLAN PHARMS INC 333MG A200142 001 Mar 11, 2014 Feb NEWA

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET;ORAL
 BUTALBITAL, ACETAMINOPHEN AND CAFFEINE
 @ WATSON LABS 500MG;50MG;40MG

A040267 001 Jul 30, 1998 Jan DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION;ORAL
 HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D> AA BOCA PHARMA LLC 325MG/15ML;7.5MG/15ML A040894 001 Jul 19, 2011 Feb CAHN
 @ MALLINCKRODT 500MG/15ML;7.5MG/15ML A040418 001 Jun 27, 2001 Jan DISC
 >A> AA VINTAGE PHARMS 325MG/15ML;7.5MG/15ML A040894 001 Jul 19, 2011 Feb CAHN

TABLET;ORAL
 ANEXSIA

@ MALLINCKRODT 500MG;5MG A089160 001 Apr 23, 1987 Jan DISC
 @ 750MG;10MG A040468 001 Oct 31, 2002 Jan DISC

ANEXSIA 7.5/650

@ MALLINCKRODT 650MG;7.5MG A089725 001 Sep 30, 1987 Jan DISC

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D> AA BOCA PHARMA LLC 300MG;5MG A090415 001 Jan 24, 2011 Feb CAHN
 >D> AA 300MG;7.5MG A090415 002 Jan 24, 2011 Feb CAHN
 >D> AA 300MG;10MG A090415 003 Jan 24, 2011 Feb CAHN
 @ MALLINCKRODT 500MG;5MG A040084 002 Jun 01, 1995 Jan DISC
 @ 500MG;7.5MG A040201 001 Feb 27, 1998 Jan DISC
 @ 500MG;10MG A040201 002 Feb 27, 1998 Jan DISC
 @ 650MG;10MG A040084 004 Oct 16, 1996 Jan DISC
 @ 660MG;10MG A040084 003 Jul 29, 1996 Jan DISC
 @ 750MG;7.5MG A040084 001 Jun 01, 1995 Jan DISC
 >A> AA VINTAGE PHARMS 300MG;5MG A090415 001 Jan 24, 2011 Feb CAHN
 >A> AA 300MG;7.5MG A090415 002 Jan 24, 2011 Feb CAHN
 >A> AA 300MG;10MG A090415 003 Jan 24, 2011 Feb CAHN
 @ 650MG;7.5MG A040155 001 Apr 14, 1997 Jan DISC
 @ 750MG;7.5MG A040157 001 Apr 12, 1996 Jan DISC
 @ WATSON LABS 500MG;7.5MG A081080 001 Aug 30, 1991 Jan DISC
 @ 750MG;7.5MG A081083 001 Aug 30, 1991 Jan DISC

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE;ORAL
 OXYCODONE AND ACETAMINOPHEN

@ MALLINCKRODT 500MG;5MG A040257 001 Aug 04, 1998 Jan DISC
 @ WATSON LABS 500MG;5MG A040234 001 Oct 30, 1997 Jan DISC

TABLET;ORAL
 OXYCODONE AND ACETAMINOPHEN

@ WATSON LABS 500MG;7.5MG A040371 001 Dec 29, 2000 Jan DISC
 @ 650MG;10MG A040371 002 Dec 29, 2000 Jan DISC
 PERCOCET
 @ VINTAGE PHARMS LLC 500MG;7.5MG A040341 001 Jul 26, 1999 Jan DISC
 @ 650MG;10MG A040341 002 Jul 26, 1999 Jan DISC

ACETYLCYSTEINE

SOLUTION;INHALATION, ORAL
 ACETYLCYSTEINE

AN INNOPHARMA LICENSING 10% A204674 001 Feb 11, 2014 Jan NEWA

ACYCLOVIR

CAPSULE;ORAL
 ACYCLOVIR

>A> AB CADILA PHARMS LTD 200MG A201445 001 Mar 06, 2014 Feb NEWA

ACYCLOVIR SODIUM

INJECTABLE;INJECTION
 ACYCLOVIR SODIUM

>D> AP BEDFORD EQ 1GM BASE/VIAL A074596 001 Apr 22, 1997 Feb CRLD
 >A> + EQ 1GM BASE/VIAL A074596 001 Apr 22, 1997 Feb CRLD
 >D> AP HIKMA MAPLE EQ 1GM BASE/VIAL A074913 002 Oct 15, 1997 Feb DISC
 >A> @ EQ 1GM BASE/VIAL A074913 002 Oct 15, 1997 Feb DISC

INJECTABLE; INJECTION
ACYCLOVIR SODIUM

>D>	AP		EQ 500MG BASE/VIAL	A074913	001	Oct 15, 1997	Feb	DISC
>A>		@	EQ 500MG BASE/VIAL	A074913	001	Oct 15, 1997	Feb	DISC

ADENOSINE

INJECTABLE; INJECTION
ADENOSINE

>A>	AP		3MG/ML	A078686	001	May 13, 2009	Feb	CAHN
>D>	AP		3MG/ML	A078686	001	May 13, 2009	Feb	CAHN

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM

>D>	AB		0.25MG	A090248	001	Sep 17, 2010	Feb	CAHN
>D>	AB		0.5MG	A090248	002	Sep 17, 2010	Feb	CAHN
>D>	AB		1MG	A090248	003	Sep 17, 2010	Feb	CAHN
>D>	AB		2MG	A090248	004	Sep 17, 2010	Feb	CAHN
>A>	AB		0.25MG	A090248	001	Sep 17, 2010	Feb	CAHN
>A>	AB		0.5MG	A090248	002	Sep 17, 2010	Feb	CAHN
>A>	AB		1MG	A090248	003	Sep 17, 2010	Feb	CAHN
>A>	AB		2MG	A090248	004	Sep 17, 2010	Feb	CAHN

TABLET, EXTENDED RELEASE; ORAL
ALPRAZOLAM

AB			0.5MG	A077725	001	Jul 31, 2006	Jan	CAHN
		@	0.5MG	A077979	001	Feb 28, 2007	Jan	CAHN
AB			1MG	A077725	002	Jul 31, 2006	Jan	CAHN
		@	1MG	A077979	002	Feb 28, 2007	Jan	CAHN
AB			2MG	A077725	004	Jul 31, 2006	Jan	CAHN
		@	2MG	A077979	003	Feb 28, 2007	Jan	CAHN
AB			3MG	A077725	003	Jul 31, 2006	Jan	CAHN
		@	3MG	A077979	004	Feb 28, 2007	Jan	CAHN

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL
AMANTADINE HYDROCHLORIDE

>D>	AB		100MG	A071293	001	Feb 18, 1987	Feb	CRLD
>A>	AB	+	100MG	A071293	001	Feb 18, 1987	Feb	CRLD
>D>	AB	+	100MG	A070589	001	Aug 05, 1986	Feb	CRLD
>A>	AB		100MG	A070589	001	Aug 05, 1986	Feb	CRLD

AMLODIPINE BESYLATE

TABLET; ORAL
AMLODIPINE BESYLATE

>D>	AB		EQ 2.5MG BASE	A078131	001	Sep 04, 2007	Feb	DISC
>A>		@	EQ 2.5MG BASE	A078131	001	Sep 04, 2007	Feb	DISC
>D>	AB		EQ 5MG BASE	A078131	002	Sep 04, 2007	Feb	DISC
>A>		@	EQ 5MG BASE	A078131	002	Sep 04, 2007	Feb	DISC
>D>	AB		EQ 10MG BASE	A078131	003	Sep 04, 2007	Feb	DISC
>A>		@	EQ 10MG BASE	A078131	003	Sep 04, 2007	Feb	DISC

AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM

TABLET; ORAL
AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM

>A>	AB		EQ 2.5MG BASE;EQ 10MG BASE	A203874	001	Mar 07, 2014	Feb	NEWA
>A>	AB		EQ 2.5MG BASE;EQ 20MG BASE	A203874	002	Mar 07, 2014	Feb	NEWA
>A>	AB		EQ 2.5MG BASE;EQ 40MG BASE	A203874	003	Mar 07, 2014	Feb	NEWA
>A>	AB		EQ 5MG BASE;EQ 10MG BASE	A203874	004	Mar 07, 2014	Feb	NEWA
>A>	AB		EQ 5MG BASE;EQ 20MG BASE	A203874	005	Mar 07, 2014	Feb	NEWA
>A>	AB		EQ 5MG BASE;EQ 40MG BASE	A203874	006	Mar 07, 2014	Feb	NEWA
>A>	AB		EQ 5MG BASE;EQ 80MG BASE	A203874	007	Mar 07, 2014	Feb	NEWA
>A>	AB		EQ 10MG BASE;EQ 10MG BASE	A203874	008	Mar 07, 2014	Feb	NEWA
>A>	AB		EQ 10MG BASE;EQ 20MG BASE	A203874	009	Mar 07, 2014	Feb	NEWA
>A>	AB		EQ 10MG BASE;EQ 40MG BASE	A203874	010	Mar 07, 2014	Feb	NEWA
>A>	AB		EQ 10MG BASE;EQ 80MG BASE	A203874	011	Mar 07, 2014	Feb	NEWA

AMMONIA N-13

INJECTABLE; INTRAVENOUS
AMMONIA N 13

AP			30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204506	001	Feb 07, 2014	Jan	NEWA
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AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE

CAPSULE, CAPSULE, DELAYED REL PELLETS, TABLET;ORAL
LANSOPRAZOLE, AMOXICILLIN AND CLARITHROMYCIN

>A> AB SANDOZ 500MG,N/A,N/A;N/A,500MG,N/A;N/A,N/A,30MG A 202588 001 Mar 04, 2014 Feb NEWA

AMPICILLIN SODIUM

INJECTABLE;INJECTION
AMPICILLIN SODIUM

>D> AP IBI EQ 1GM BASE/VIAL A 062719 002 May 12, 1987 Feb CAHN
>D> AP EQ 2GM BASE/VIAL A 062797 002 Jul 12, 1993 Feb CAHN
>D> AP EQ 125MG BASE/VIAL A 062797 001 Jul 12, 1993 Feb CAHN
>D> AP EQ 250MG BASE/VIAL A 062719 001 May 12, 1987 Feb CAHN
>D> AP EQ 500MG BASE/VIAL A 062719 003 May 12, 1987 Feb CAHN
>A> AP ISTITUTO BIO ITA SPA EQ 1GM BASE/VIAL A 062719 002 May 12, 1987 Feb CAHN
>A> AP EQ 2GM BASE/VIAL A 062797 002 Jul 12, 1993 Feb CAHN
AP EQ 10GM BASE/VIAL A 201404 001 Dec 20, 2013 Jan CPOT
>A> AP EQ 125MG BASE/VIAL A 062797 001 Jul 12, 1993 Feb CAHN
>A> AP EQ 250MG BASE/VIAL A 062719 001 May 12, 1987 Feb CAHN
>A> AP EQ 500MG BASE/VIAL A 062719 003 May 12, 1987 Feb CAHN

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE;INJECTION
AMPICILLIN AND SULBACTAM

>D> AP IBI EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL A 065222 001 Nov 29, 2005 Feb CAHN
>D> AP EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL A 065222 002 Nov 29, 2005 Feb CAHN
>D> AP EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL A 065314 001 Nov 27, 2006 Feb CAHN
>A> AP ISTITUTO BIO ITA SPA EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL A 065222 001 Nov 29, 2005 Feb CAHN
>A> AP EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL A 065222 002 Nov 29, 2005 Feb CAHN
>A> AP EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL A 065314 001 Nov 27, 2006 Feb CAHN

ASENAPINE MALEATE

TABLET;SUBLINGUAL
SAPHRIS

>A> FOREST LABS INC EQ 5MG BASE N 022117 001 Aug 13, 2009 Feb CAHN
>A> + EQ 10MG BASE N 022117 002 Aug 13, 2009 Feb CAHN
>D> ORGANON SUB MERCK EQ 5MG BASE N 022117 001 Aug 13, 2009 Feb CAHN
>D> + EQ 10MG BASE N 022117 002 Aug 13, 2009 Feb CAHN

AZILSARTAN KAMEDOXOMIL

TABLET;ORAL
EDARBI

>A> ARBOR PHARMS IRELAND EQ 40MG MEDOXOMIL N 200796 001 Feb 25, 2011 Feb CAHN
>A> + EQ 80MG MEDOXOMIL N 200796 002 Feb 25, 2011 Feb CAHN
>D> ARBOR PHARMS LLC EQ 40MG MEDOXOMIL N 200796 001 Feb 25, 2011 Feb CAHN
>D> + EQ 80MG MEDOXOMIL N 200796 002 Feb 25, 2011 Feb CAHN

AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE

TABLET;ORAL
EDARBYCLOR

>A> ARBOR PHARMS IRELAND EQ 40MG MEDOXOMIL;12.5MG N 202331 001 Dec 20, 2011 Feb CAHN
>A> + EQ 40MG MEDOXOMIL;25MG N 202331 002 Dec 20, 2011 Feb CAHN
>D> ARBOR PHARMS LLC EQ 40MG MEDOXOMIL;12.5MG N 202331 001 Dec 20, 2011 Feb CAHN
>D> + EQ 40MG MEDOXOMIL;25MG N 202331 002 Dec 20, 2011 Feb CAHN

BACITRACIN

OINTMENT;OPHTHALMIC
BACITRACIN

>D> AT + PERRIGO CO TENNESSEE 500 UNITS/GM A 061212 001 Feb CTEC
>A> + 500 UNITS/GM A 061212 001 Feb CTEC

BENDROFLUMETHIAZIDE; NADOLOL

TABLET;ORAL
NADOLOL AND BENDROFLUMETHIAZIDE

AB MYLAN 5MG;40MG A 078688 001 Feb 15, 2008 Jan CTNA
AB 5MG;80MG A 078688 002 Feb 15, 2008 Jan CTNA

BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE

LOTION; TOPICAL
LOTRISONE

AB + MERCK SHARP DOHME EQ 0.05% BASE; 1% N020010 001 Dec 08, 2000 Jan CAHN

BROMFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
BROMDAY

AT + ISTA PHARMS INC EQ 0.09% ACID N021664 002 Oct 16, 2010 Jan CFTG

AT1 COASTAL PHARMS EQ 0.09% ACID A201211 001 May 11, 2011 Jan CTEC

AT HI-TECH PHARMACAL EQ 0.09% ACID A203395 001 Jan 22, 2014 Jan NEWA

AT1 LUITPOLD EQ 0.09% ACID A202030 001 Jan 09, 2013 Jan CTEC

BUDESONIDE

TABLET, EXTENDED RELEASE; ORAL
UCERIS

>A> + SALIX PHARMS INC 9MG N203634 001 Jan 14, 2013 Feb CAHN

>D> + SANTARUS 9MG N203634 001 Jan 14, 2013 Feb CAHN

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
BUPROPION HYDROCHLORIDE

>D> BX WATSON LABS 300MG A077715 002 Jun 13, 2007 Feb DISC

>A> @ 300MG A077715 002 Jun 13, 2007 Feb DISC

AB3 ZYDUS PHARMS USA INC 300MG A201567 001 Jan 17, 2014 Jan NEWA

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL
BUSPIRONE HYDROCHLORIDE

AB ZYDUS PHARMS USA INC 5MG A078888 001 Feb 07, 2014 Jan NEWA

AB 10MG A078888 002 Feb 07, 2014 Jan NEWA

AB 15MG A078888 003 Feb 07, 2014 Jan NEWA

AB 30MG A078888 004 Feb 07, 2014 Jan NEWA

CAFFEINE CITRATE

SOLUTION; INTRAVENOUS
CAFFEINE CITRATE

>A> AP EXELA PHARMA SCIENCE EQ 30MG BASE/3ML (EQ 10MG BASE/ML) A077233 001 Sep 21, 2006 Feb CAHN

>D> AP PADDOCK LLC EQ 30MG BASE/3ML (EQ 10MG BASE/ML) A077233 001 Sep 21, 2006 Feb CAHN

SOLUTION; ORAL
CAFFEINE CITRATE

>A> AA EXELA PHARMA SCS LLC EQ 30MG BASE/3ML (EQ 10MG BASE/ML) A077304 001 Sep 21, 2006 Feb CAHN

>D> AA PADDOCK LLC EQ 30MG BASE/3ML (EQ 10MG BASE/ML) A077304 001 Sep 21, 2006 Feb CAHN

CALCITRIOL

INJECTABLE; INJECTION
CALCITRIOL

>D> AP TEVA PARENTERAL 0.002MG/ML A075823 002 Mar 31, 2003 Feb DISC

>A> @ 0.002MG/ML A075823 002 Mar 31, 2003 Feb DISC

CARBIDOPA

TABLET; ORAL
CARBIDOPA

>A> AB AMERIGEN PHARMS LTD 25MG A203261 001 Mar 10, 2014 Feb NEWA

LODOSYN

>D> + ATON 25MG N017830 001 Feb CFTG

>A> AB + 25MG N017830 001 Feb CFTG

CARBINOXAMINE MALEATE

SOLUTION; ORAL
CARBINOXAMINE MALEATE

>D> AA BOCA PHARMA LLC 4MG/5ML A040814 001 Feb 26, 2008 Feb CAHN

>A> AA VINTAGE PHARMS 4MG/5ML A040814 001 Feb 26, 2008 Feb CAHN

TABLET; ORAL

CARBINOXAMINE MALEATE

>D> AA BOCA PHARMA LLC 4MG A040639 002 May 30, 2008 Feb CAHN

>A> AA VINTAGE PHARMS 4MG A040639 002 May 30, 2008 Feb CAHN

CARBOPLATIN

INJECTABLE;IV (INFUSION)
CARBOPLATIN

>D>	AP	+	PHARMACHEMIE	50MG/5ML (10MG/ML)	A 077269	001	Oct 14, 2004	Feb	CAHN
>D>	AP	+		150MG/15ML (10MG/ML)	A 077269	002	Oct 14, 2004	Feb	CAHN
>D>	AP	+		450MG/45ML (10MG/ML)	A 077269	003	Oct 14, 2004	Feb	CAHN
>D>	AP	+		600MG/60ML (10MG/ML)	A 077269	004	Dec 28, 2007	Feb	CAHN
>A>	AP	+	PHARMACHEMIE BV	50MG/5ML (10MG/ML)	A 077269	001	Oct 14, 2004	Feb	CAHN
>A>	AP	+		150MG/15ML (10MG/ML)	A 077269	002	Oct 14, 2004	Feb	CAHN
>A>	AP	+		450MG/45ML (10MG/ML)	A 077269	003	Oct 14, 2004	Feb	CAHN
>A>	AP	+		600MG/60ML (10MG/ML)	A 077269	004	Dec 28, 2007	Feb	CAHN

CARISOPRODOL

TABLET;ORAL
CARISOPRODOL

AA			SCIEGEN PHARMS INC	350MG	A 203374	001	Jan 27, 2014	Jan	NEWA
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CEFACLOR

FOR SUSPENSION;ORAL
CEFACLOR

AB	+		YUNG SHIN PHARM	EQ 375MG BASE/5ML	A 065412	004	Feb 17, 2012	Jan	CRLD
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CEFADROXIL/CEFADROXIL HEMIHYDRATE

FOR SUSPENSION;ORAL
CEFADROXIL

	@		ANI PHARMS INC	EQ 125MG BASE/5ML	A 062698	001	Mar 01, 1989	Jan	CAHN
	@			EQ 250MG BASE/5ML	A 062698	002	Mar 01, 1989	Jan	CAHN
	@			EQ 250MG BASE/5ML	A 065278	001	Jan 20, 2006	Jan	CAHN
	@			EQ 500MG BASE/5ML	A 062698	003	Mar 01, 1989	Jan	CAHN
	@			EQ 500MG BASE/5ML	A 065278	002	Jan 20, 2006	Jan	CAHN

CEFTRIAZONE SODIUM

INJECTABLE;INJECTION
CEFTRIAZONE

>A>	AP		AGILA SPECLTS	EQ 10GM BASE/VIAL	A 091068	001	Jan 07, 2013	Feb	CAHN
>D>	AP		STRIDES ARCOLAB LTD	EQ 10GM BASE/VIAL	A 091068	001	Jan 07, 2013	Feb	CAHN

CHLORPROPAMIDE

TABLET;ORAL
CHLORPROPAMIDE

	@		ANI PHARMS INC	100MG	A 088768	001	Oct 11, 1984	Jan	CAHN
	@			100MG	A 088812	001	Oct 19, 1984	Jan	CAHN
>A>	@			100MG	A 088840	001	Oct 25, 1984	Feb	CAHN
	@			100MG	A 088918	001	Oct 16, 1984	Jan	CAHN
AB				100MG	A 088921	001	Apr 12, 1985	Jan	CAHN
	@			100MG	A 089446	001	Nov 17, 1986	Jan	CAHN
	@			250MG	A 088813	001	Oct 19, 1984	Jan	CAHN
	@			250MG	A 088919	001	Oct 16, 1984	Jan	CAHN
AB				250MG	A 088922	001	Apr 12, 1985	Jan	CAHN
	@			250MG	A 089447	001	Nov 17, 1986	Jan	CAHN
>D>	@		IVAX PHARMS	100MG	A 088840	001	Oct 25, 1984	Feb	CAHN
			GLUCAMIDE						
	@		ANI PHARMS INC	250MG	A 088641	001	Oct 11, 1984	Jan	CAHN

CICLOPIROX

CREAM;TOPICAL
CICLOPIROX

>D>	AB		TARO	0.77%	A 076790	001	Apr 12, 2005	Feb	DISC
>A>		@		0.77%	A 076790	001	Apr 12, 2005	Feb	DISC

CIMETIDINE HYDROCHLORIDE

SOLUTION;ORAL
CIMETIDINE HYDROCHLORIDE

AA			ANI PHARMS INC	EQ 300MG BASE/5ML	A 074610	001	Sep 26, 1996	Jan	CAHN
>A>		@		EQ 300MG BASE/5ML	A 074859	001	Jul 09, 1998	Feb	CAHN
		@		EQ 300MG BASE/5ML	A 075110	001	Jun 18, 1998	Jan	CAHN
>D>		@	TEVA PHARMS	EQ 300MG BASE/5ML	A 074859	001	Jul 09, 1998	Feb	CAHN

CIPROFLOXACINFOR SUSPENSION; ORAL
CIPRO

>D>		BAYER HLTHCARE	250MG/5ML	N020780	001	Sep 26, 1997	Feb	CFTG
>A>	AB		250MG/5ML	N020780	001	Sep 26, 1997	Feb	CFTG
>D>		+	500MG/5ML	N020780	002	Sep 26, 1997	Feb	CFTG
>A>	AB	+	500MG/5ML	N020780	002	Sep 26, 1997	Feb	CFTG
>A>		CIPROFLOXACIN						
>A>	AB	LUPIN LTD	250MG/5ML	A200563	001	Mar 05, 2014	Feb	NEWA
>A>	AB		500MG/5ML	A200563	002	Mar 05, 2014	Feb	NEWA

CISPLATININJECTABLE; INJECTION
CISPLATIN

>D>	AP	PHARMACHEMIE	1MG/ML	A074656	001	May 16, 2000	Feb	CAHN
>A>	AP	PHARMACHEMIE BV	1MG/ML	A074656	001	May 16, 2000	Feb	CAHN

CLINDAMYCIN PALMITATE HYDROCHLORIDEFOR SOLUTION; ORAL
CLINDAMYCIN PALMITATE HYDROCHLORIDE

>A>	AA	AMNEAL PHARMS	EQ 75MG BASE/5ML	A203513	001	Mar 13, 2014	Feb	NEWA
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CLINDAMYCIN PHOSPHATESOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

>D>		@ BOCA PHARMA LLC	EQ 1% BASE	A062930	001	Jun 28, 1989	Feb	CAHN
>A>		@ VINTAGE PHARMS	EQ 1% BASE	A062930	001	Jun 28, 1989	Feb	CAHN

CLONIDINE HYDROCHLORIDEINJECTABLE; INJECTION
CLONIDINE HYDROCHLORIDE

>A>	AP	ZYDUS PHARMS USA INC	1MG/10ML (0.1MG/ML)	A202601	001	Feb 20, 2014	Feb	NEWA
>A>	AP		5MG/10ML (0.5MG/ML)	A202601	002	Feb 20, 2014	Feb	NEWA

CLOPIDOGREL BISULFATETABLET; ORAL
CLOPIDOGREL BISULFATE

>A>	AB	APOTEX INC	EQ 300MG BASE	A076274	002	Mar 04, 2014	Feb	NEWA
	AB	MACLEODS PHARMS LTD	EQ 75MG BASE	A202928	001	Feb 10, 2014	Jan	NEWA

COLISTIMETHATE SODIUMINJECTABLE; INJECTION
COLISTIMETHATE SODIUM

>A>	AP	SAGENT PHARMS	EQ 150MG BASE/VIAL	A201365	001	Feb 19, 2014	Feb	NEWA
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CONIVAPTAN HYDROCHLORIDEINJECTABLE; IV (INFUSION)
VAPRISOL

>D>		@ ASTELLAS	20MG/4ML (5MG/ML)	N021697	001	Dec 29, 2005	Feb	CAHN	
>A>		@ CUMBERLAND PHARMS	20MG/4ML (5MG/ML)	N021697	001	Dec 29, 2005	Feb	CAHN	
		VAPRISOL IN 5% DEXTROSE IN PLASTIC CONTAINER							
>D>		+	ASTELLAS	20MG/100ML (0.2MG/ML)	N021697	002	Oct 08, 2008	Feb	CAHN
>A>		+	CUMBERLAND PHARMS	20MG/100ML (0.2MG/ML)	N021697	002	Oct 08, 2008	Feb	CAHN

DAPAGLIFLOZINTABLET; ORAL
FARXIGA

>A>		ASTRAZENECA AB	5MG	N202293	001	Jan 08, 2014	Feb	CAHN
>A>		+	10MG	N202293	002	Jan 08, 2014	Feb	CAHN
>D>		BRISTOL MYERS SQUIBB	5MG	N202293	001	Jan 08, 2014	Feb	CAHN
			5MG	N202293	001	Jan 08, 2014	Jan	NEWA
>D>		+	10MG	N202293	002	Jan 08, 2014	Feb	CAHN
		+	10MG	N202293	002	Jan 08, 2014	Jan	NEWA

DECITABINEPOWDER; INTRAVENOUS
DECITABINE

		+	SUN PHARMA GLOBAL	50MG/VIAL	N205582	001	Jan 28, 2014	Jan	NEWA
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DESIPRAMINE HYDROCHLORIDE

	TABLET; ORAL						
	DESIPRAMINE HYDROCHLORIDE						
	@ ANI PHARMS INC	25MG	A 071800	001	Dec 08, 1987	Jan	CAHN
	@	50MG	A 071801	001	Dec 08, 1987	Jan	CAHN
	@	75MG	A 071802	001	Dec 08, 1987	Jan	CAHN
>A>	@	100MG	A 071803	001	May 29, 1997	Feb	CAHN
>A>	@	150MG	A 071804	001	May 29, 1997	Feb	CAHN
>D>	@ BARR LABS INC	150MG	A 071804	001	May 29, 1997	Feb	CAHN
>D>	@ PLIVA	100MG	A 071803	001	May 29, 1997	Feb	CAHN

DESMOPRESSIN ACETATE

	SPRAY, METERED; NASAL						
	DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)						
AB	SUN PHARMA GLOBAL	0.01MG/SPRAY	A 078271	001	Dec 23, 2013	Jan	CMS2

DESVENLAFAXINE

	TABLET, EXTENDED RELEASE; ORAL							
	DESVENLAFAXINE							
>D>	BC	SUN PHARMA GLOBAL	50MG	N 205583	001	Jan 28, 2014	Feb	CTEC
			50MG	N 205583	001	Jan 28, 2014	Jan	NEWA
>D>	BC	+	100MG	N 205583	002	Jan 28, 2014	Feb	CTEC
	BC	+	100MG	N 205583	002	Jan 28, 2014	Jan	NEWA

DESVENLAFAXINE FUMARATE

	TABLET, EXTENDED RELEASE; ORAL							
	DESVENLAFAXINE FUMARATE							
>A>	+	SUN PHARMA GLOBAL	EQ 50MG BASE	N 205583	001	Jan 28, 2014	Feb	CTEC
>A>	+		EQ 100MG BASE	N 205583	002	Jan 28, 2014	Feb	CTEC

DEXCHLORPHENIRAMINE MALEATE

	TABLET; ORAL						
	DEXCHLORPHENIRAMINE MALEATE						
	@ ANI PHARMS INC	2MG	A 088682	001	Jan 17, 1986	Jan	CAHN

DEXTROAMPHETAMINE SULFATE

	TABLET; ORAL							
	DEXTROAMPHETAMINE SULFATE							
>A>	AA	COREPHARMA	5MG	A 090652	001	Mar 07, 2014	Feb	NEWA
>A>	AA		10MG	A 090652	002	Mar 07, 2014	Feb	NEWA

DICLOFENAC POTASSIUM

	FOR SOLUTION; ORAL							
	CAMBIA							
	+	DEPOMED INC	50MG	N 022165	001	Jun 17, 2009	Jan	CAHN

DICLOFENAC SODIUM

	SOLUTION; TOPICAL							
	PENNSAID							
	+	MALLINCKRODT INC	2%	N 204623	001	Jan 16, 2014	Jan	NEWA

DIGOXIN

	TABLET; ORAL							
	LANOXIN							
		COVIS PHARMA	0.0625MG	N 020405	001	Sep 30, 1997	Jan	CMFD
			0.1875MG	N 020405	003	Sep 30, 1997	Jan	CMFD

DILTIAZEM HYDROCHLORIDE

	INJECTABLE; INJECTION							
	DILTIAZEM HYDROCHLORIDE							
>A>	@	AGILA SPECLTS	5MG/ML	A 075375	001	Sep 30, 1999	Feb	CAHN
>D>	@	APOTEX INC	5MG/ML	A 075375	001	Sep 30, 1999	Feb	CAHN

DISULFIRAM

	TABLET; ORAL						
	DISULFIRAM						
AB	ROXANE	250MG	A 202652	001	Feb 05, 2014	Jan	NEWA
AB		500MG	A 202652	002	Feb 05, 2014	Jan	NEWA

DONEPEZIL HYDROCHLORIDE

TABLET; ORAL

DONEPEZIL HYDROCHLORIDE

AB MACLEODS PHARMS LTD 23MG A202631 001 Jan 22, 2014 Jan NEWA

DOXERCALCIFEROL

INJECTABLE; INJECTION

DOXERCALCIFEROL

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

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

DOXORUBICIN HYDROCHLORIDE

>D> AP PHARMACHEMIE 2MG/ML A063336 001 Feb 28, 1995 Feb CAHN
 >D> AP 10MG/VIAL A063097 001 May 21, 1990 Feb CAHN
 >D> AP 20MG/VIAL A063097 002 May 21, 1990 Feb CAHN
 >D> AP 50MG/VIAL A063097 003 May 21, 1990 Feb CAHN
 >D> AP 200MG/100ML A063336 004 Feb 28, 1995 Feb CAHN
 >A> AP PHARMACHEMIE BV 2MG/ML A063336 001 Feb 28, 1995 Feb CAHN
 >A> AP 10MG/VIAL A063097 001 May 21, 1990 Feb CAHN
 >A> AP 20MG/VIAL A063097 002 May 21, 1990 Feb CAHN
 >A> AP 50MG/VIAL A063097 003 May 21, 1990 Feb CAHN
 >A> AP 200MG/100ML A063336 004 Feb 28, 1995 Feb CAHN

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

>A> AB LUPIN LTD EQ 50MG BASE A204234 001 Mar 05, 2014 Feb NEWA
 >A> AB EQ 75MG BASE A204234 002 Mar 05, 2014 Feb NEWA
 >A> AB EQ 100MG BASE A204234 003 Mar 05, 2014 Feb NEWA

DOXYCYCLINE HYCLATE

TABLET, DELAYED RELEASE; ORAL

DORYX

>D> AB + MAYNE PHARMA EQ 150MG BASE N050795 003 Jun 20, 2008 Feb CRLD
 >A> AB EQ 150MG BASE N050795 003 Jun 20, 2008 Feb CRLD
 >D> EQ 200MG BASE N050795 005 Apr 11, 2013 Feb CRLD
 >A> + EQ 200MG BASE N050795 005 Apr 11, 2013 Feb CRLD

>A> DROXIDOPA

CAPSULE; ORAL

NORTHERA

>A> CHELSEA THERAPS INC 100MG N203202 001 Feb 18, 2014 Feb NEWA
 >A> 200MG N203202 002 Feb 18, 2014 Feb NEWA
 >A> + 300MG N203202 003 Feb 18, 2014 Feb NEWA

DUTASTERIDE; TAMSULOSIN HYDROCHLORIDE

CAPSULE; ORAL

DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE

>A> ANCHEN PHARMS 0.5MG; 0.4MG A202509 001 Feb 26, 2014 Feb NEWA
 JALYN
 >D> + GLAXOSMITHKLINE 0.5MG; 0.4MG N022460 001 Jun 14, 2010 Feb CFTG
 >A> AB + 0.5MG; 0.4MG N022460 001 Jun 14, 2010 Feb CFTG

ECONAZOLE NITRATE

AEROSOL, FOAM; TOPICAL

ECOZA

>D> + AMDERMA PHARMS 1% N205175 001 Oct 24, 2013 Feb CAHN
 >A> + VELDANA MEDICAL SA 1% N205175 001 Oct 24, 2013 Feb CAHN

CREAM; TOPICAL

SPECTAZOLE

@ MERZ PHARMS LLC

1% N018751 001 Dec 23, 1982 Jan CAHN

ERYTHROMYCIN STEARATE

TABLET; ORAL

ERYTHROMYCIN STEARATE

>A> @ ANI PHARMS INC EQ 250MG BASE A061461 001 Feb CAHN
 @ EQ 250MG BASE A061591 001 Jan CAHN
 >A> @ EQ 500MG BASE A061461 002 Feb CAHN
 >A> @ EQ 500MG BASE A063179 001 May 15, 1990 Feb CAHN
 >D> @ BARR EQ 500MG BASE A063179 001 May 15, 1990 Feb CAHN

TABLET;ORAL

ERYTHROMYCIN STEARATE

>D>	@	IVAX SUB TEVA PHARMS	EQ 250MG BASE	A061461	001			Feb	CAHN
>D>	@		EQ 500MG BASE	A061461	002			Feb	CAHN

ESCITALOPRAM OXALATE

TABLET;ORAL

ESCITALOPRAM OXALATE

>D>	AB	IVAX SUB TEVA PHARMS	EQ 5MG BASE	A076765	001	Mar 14, 2012		Feb	CAHN
>D>	AB		EQ 10MG BASE	A076765	002	Mar 14, 2012		Feb	CAHN
>D>	AB		EQ 20MG BASE	A076765	003	Mar 14, 2012		Feb	CAHN
>A>	AB	TEVA PHARMS USA	EQ 5MG BASE	A076765	001	Mar 14, 2012		Feb	CAHN
>A>	AB		EQ 10MG BASE	A076765	002	Mar 14, 2012		Feb	CAHN
>A>	AB		EQ 20MG BASE	A076765	003	Mar 14, 2012		Feb	CAHN

ESZOPICLONE

TABLET;ORAL

ESZOPICLONE

AB		TEVA	1MG	A091169	001	May 23, 2011		Jan	CMFD
AB			2MG	A091169	002	May 23, 2011		Jan	CMFD
AB			3MG	A091169	003	May 23, 2011		Jan	CMFD

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET;ORAL-28

LEVONORGESTREL AND ETHINYL ESTRADIOL

AB1		HAUPT PHARMA	0.02MG;0.1MG	A201108	001	Feb 05, 2014		Jan	NEWA
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ETODOLAC

CAPSULE;ORAL

ETODOLAC

>A>	@	ANI PHARMS INC	200MG	A074899	001	Jul 08, 1997		Feb	CAHN
	@		200MG	A075126	001	Sep 16, 1999		Jan	CAHN
>A>	@		300MG	A074899	002	Jul 08, 1997		Feb	CAHN
	AB		300MG	A075126	002	Sep 16, 1999		Jan	CAHN
>D>	@	IVAX SUB TEVA PHARMS	200MG	A074899	001	Jul 08, 1997		Feb	CAHN
>D>	@		300MG	A074899	002	Jul 08, 1997		Feb	CAHN

ETOMIDATE

INJECTABLE;INJECTION

ETOMIDATE

>A>	AP	AGILA SPECLTS	2MG/ML	A078289	001	Jan 02, 2009		Feb	CAHN
>D>	AP	STRIDES ARCOLAB LTD	2MG/ML	A078289	001	Jan 02, 2009		Feb	CAHN

ETOPOSIDE

INJECTABLE;INJECTION

ETOPOSIDE

>D>	@	PHARMACHEMIE	20MG/ML	A074227	001	Feb 22, 1996		Feb	CAHN
>A>	@	PHARMACHEMIE BV	20MG/ML	A074227	001	Feb 22, 1996		Feb	CAHN

FAMOTIDINE

INJECTABLE;INJECTION

FAMOTIDINE PRESERVATIVE FREE

>A>	AP	BEDFORD LABS	10MG/ML	A075825	001	Apr 17, 2001		Feb	CAHN
>D>	AP	BEN VENUE	10MG/ML	A075825	001	Apr 17, 2001		Feb	CAHN

FENOFIBRATE

TABLET;ORAL

FENOGLIDE

>D>		SALIX PHARMS INC	40MG	N022118	001	Aug 10, 2007		Feb	CAHN
>D>	+		120MG	N022118	002	Aug 10, 2007		Feb	CAHN
>A>		SANTARUS INC	40MG	N022118	001	Aug 10, 2007		Feb	CAHN
>A>	+		120MG	N022118	002	Aug 10, 2007		Feb	CAHN

FLUDEOXYGLUCOSE F-18

INJECTABLE;INTRAVENOUS

FLUDEOXYGLUCOSE F18

AP		ESSENTIAL ISOTOPES	20-300mCi/ML	A203946	001	Feb 05, 2014		Jan	NEWA
AP		LANTHEUS MEDICAL	20-200mCi/ML	A203664	001	Feb 04, 2014		Jan	NEWA
>D>	+	WEILL MEDCL COLL	10-100mCi/ML	N021768	001	Aug 05, 2004		Feb	DISC
>A>	@		10-100mCi/ML	N021768	001	Aug 05, 2004		Feb	DISC
AP		WUSM CYCLOTRON	20-300mCi/ML	A203935	001	Feb 05, 2014		Jan	NEWA

FLUDROCORTISONE ACETATE

TABLET;ORAL

FLUDROCORTISONE ACETATE

AB	HIKMA PHARMS	0.1MG	A091302	001	Jul 22, 2011	Jan CAHN
AB		0.1MG	A091302	001	Jul 22, 2011	Jan CAHN
AB		0.1MG	A091302	001	Jul 22, 2011	Jan CAHN
AB		0.1MG	A091302	001	Jul 22, 2011	Jan CAHN

FLUOXETINE HYDROCHLORIDE

CAPSULE;ORAL

FLUOXETINE HYDROCHLORIDE

AB2	ANI PHARMS INC	EQ 10MG BASE	A076287	001	May 20, 2008	Jan CAHN
AB2		EQ 20MG BASE	A076287	002	May 20, 2008	Jan CAHN

TABLET;ORAL

SARAFEM

AB1	WARNER CHILCOTT LLC	EQ 10MG BASE	N021860	001	May 19, 2006	Jan CFTG
AB1		EQ 15MG BASE	N021860	002	May 19, 2006	Jan CFTG
AB1	+	EQ 20MG BASE	N021860	003	May 19, 2006	Jan CFTG
	SELFEMRA					
AB1	TEVA PHARMS USA	EQ 10MG BASE	A200151	001	Feb 03, 2014	Jan NEWA
AB1		EQ 15MG BASE	A200151	002	Feb 03, 2014	Jan NEWA
AB1		EQ 20MG BASE	A200151	003	Feb 03, 2014	Jan NEWA

FLUPHENAZINE HYDROCHLORIDE

ELIXIR;ORAL

FLUPHENAZINE HYDROCHLORIDE

>A>	@ ANI PHARMS INC	2.5MG/5ML	A081310	001	Apr 29, 1993	Feb CAHN
>D>	@ TEVA PHARMS	2.5MG/5ML	A081310	001	Apr 29, 1993	Feb CAHN

FOLIC ACID

TABLET;ORAL

FOLIC ACID

AA	CADILA PHARMS LTD	1 MG	A202437	001	Jan 27, 2014	Jan NEWA
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FOSINOPRIL SODIUM; HYDROCHLOROTHIAZIDE

TABLET;ORAL

FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE

>A>	AB	EMCURE PHARMS INDIA	10MG;12.5MG	A079025	001	Sep 17, 2010	Feb CAIN
>A>	AB	+	20MG;12.5MG	A079025	002	Sep 17, 2010	Feb CAIN

FOSINOPRIL; HYDROCHLOROTHIAZIDE

TABLET;ORAL

FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE

>D>	AB	EMCURE PHARMS INDIA	10MG;12.5MG	A079025	001	Sep 17, 2010	Feb CAIN
>D>	AB	+	20MG;12.5MG	A079025	002	Sep 17, 2010	Feb CAIN
	AB	+	20MG;12.5MG	A079025	002	Sep 17, 2010	Jan CRLD

FOSPHENYTOIN SODIUM

INJECTABLE;INJECTION

CEREBYX

>D>		@ PARKE DAVIS	EQ 50MG PHENYTOIN NA/ML	N020450	001	Aug 05, 1996	Feb CMFD
>A>	AP		EQ 50MG PHENYTOIN NA/ML	N020450	001	Aug 05, 1996	Feb CMFD

FOSPHENYTOIN SODIUM

>A>	AP	AGILA SPECLTS	EQ 50MG PHENYTOIN NA/ML	A078736	001	Jun 08, 2010	Feb CAHN
>D>	AP	STRIDES ARCOLAB	EQ 50MG PHENYTOIN NA/ML	A078736	001	Jun 08, 2010	Feb CAHN

FUROSEMIDE

INJECTABLE;INJECTION

FUROSEMIDE

AP	CLARIS LIFESCIENCES	10MG/ML	A202747	001	Jan 27, 2014	Jan NEWA
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GABAPENTIN

TABLET;ORAL

GABAPENTIN

>A>	AB	ACI HEALTHCARE LTD	600MG	A203244	002	Jul 12, 2013	Feb CAHN
>A>	AB		800MG	A203244	001	Jul 12, 2013	Feb CAHN
>D>	AB	ALLIED PHARMA INC	600MG	A203244	002	Jul 12, 2013	Feb CAHN
>D>	AB		800MG	A203244	001	Jul 12, 2013	Feb CAHN

GLATIRAMER ACETATE

INJECTABLE;SUBCUTANEOUS
COPAXONE

+ TEVA PHARMS USA 40MG/ML N020622 003 Jan 28, 2014 Jan NEWA

GLYCOPYRROLATE

TABLET;ORAL
GLYCOPYRROLATE

>D> AA BOCA PHARMA LLC 1MG A090020 001 Oct 19, 2011 Feb CAHN
>D> AA 2MG A090020 002 Oct 19, 2011 Feb CAHN
AA STASON PHARMS 1MG A091182 001 Feb 03, 2014 Jan NEWA
AA 2MG A091182 002 Feb 03, 2014 Jan NEWA
>A> AA VINTAGE PHARMS 1MG A090020 001 Oct 19, 2011 Feb CAHN
>A> AA 2MG A090020 002 Oct 19, 2011 Feb CAHN

GUANABENZ ACETATE

TABLET;ORAL
GUANABENZ ACETATE

ANI PHARMS INC EQ 4MG BASE A074149 001 Apr 07, 1995 Jan CAHN
+ EQ 8MG BASE A074149 002 Apr 07, 1995 Jan CAHN

HALOPERIDOL DECANOATE

INJECTABLE;INJECTION
HALOPERIDOL DECANOATE

>D> @ AGILA SPECLTS EQ 50MG BASE/ML A075440 001 Feb 28, 2000 Feb CMFD
>A> AO EQ 50MG BASE/ML A075440 001 Feb 28, 2000 Feb CMFD
>D> @ EQ 100MG BASE/ML A075440 002 Feb 28, 2000 Feb CMFD
>A> AO EQ 100MG BASE/ML A075440 002 Feb 28, 2000 Feb CMFD

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

TABLET;ORAL
MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>A> AB INDICUS PHARMA 12.5MG;7.5MG A202150 001 Mar 07, 2014 Feb NEWA
>A> AB 12.5MG;15MG A202150 002 Mar 07, 2014 Feb NEWA
>A> AB 25MG;15MG A202150 003 Mar 07, 2014 Feb NEWA

HYDROCHLOROTHIAZIDE; TELMISARTAN

TABLET;ORAL
MICARDIS HCT

>D> BOEHRINGER INGELHEIM 12.5MG;40MG N021162 001 Nov 17, 2000 Feb CFTG
>A> AB 12.5MG;40MG N021162 001 Nov 17, 2000 Feb CFTG
>D> 12.5MG;80MG N021162 002 Nov 17, 2000 Feb CFTG
>A> AB 12.5MG;80MG N021162 002 Nov 17, 2000 Feb CFTG
>D> + 25MG;80MG N021162 003 Apr 19, 2004 Feb CFTG
>A> AB + 25MG;80MG N021162 003 Apr 19, 2004 Feb CFTG
>A> TELMISARTAN AND HYDROCHLOROTHIAZIDE
>A> AB ALEMBIC PHARMS LTD 12.5MG;40MG A203010 001 Feb 25, 2014 Feb NEWA
>A> AB 12.5MG;80MG A203010 002 Feb 25, 2014 Feb NEWA
>A> AB 25MG;80MG A203010 003 Feb 25, 2014 Feb NEWA
>A> AB MYLAN PHARMS INC 12.5MG;40MG A091648 001 Feb 25, 2014 Feb NEWA
>A> AB 12.5MG;80MG A091648 002 Feb 25, 2014 Feb NEWA
>A> AB 25MG;80MG A091648 003 Feb 25, 2014 Feb NEWA
>A> AB TORRENT PHARMS LTD 12.5MG;40MG A201192 001 Feb 25, 2014 Feb NEWA
>A> AB 12.5MG;80MG A201192 002 Feb 25, 2014 Feb NEWA
>A> AB 25MG;80MG A201192 003 Feb 25, 2014 Feb NEWA

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL, METERED;TOPICAL
HYDROCORTISONE ACETATE 1% AND PRAMOXINE HYDROCHLORIDE 1%

>D> @ BOCA PHARMA LLC 1%;1% A089440 001 May 17, 1988 Feb CAHN
>A> @ VINTAGE PHARMS 1%;1% A089440 001 May 17, 1988 Feb CAHN

IBANDRONATE SODIUM

INJECTABLE;INTRAVENOUS
BONIVA

>D> + ROCHE EQ 3MG BASE/3ML N021858 001 Jan 06, 2006 Feb CFTG
>A> AP + EQ 3MG BASE/3ML N021858 001 Jan 06, 2006 Feb CFTG
>A> IBANDRONATE SODIUM
>A> AP SUN PHARM INDS LTD EQ 3MG BASE/3ML A090853 001 Feb 14, 2014 Feb NEWA

INDOMETHACIN

	CAPSULE;ORAL						
>A>	TIVORBEX						
>A>		IROKO PHARMS LLC	20MG	N204768	001	Feb 24, 2014	Feb NEWA
>A>	+		40MG	N204768	002	Feb 24, 2014	Feb NEWA

INSULIN ASPART RECOMBINANT

	INJECTABLE;SUBCUTANEOUS						
>A>	NOVOLOG FLEXTOUCH						
>A>	+	NOVO NORDISK INC	300 UNITS/3ML (100 UNITS/ML)	N020986	005	Oct 31, 2013	Feb NEWA

INSULIN DETEMIR RECOMBINANT

	INJECTABLE;SUBCUTANEOUS						
>A>	LEVEMIR FLEXTOUCH						
>A>	+	NOVO NORDISK INC	300 UNITS/3ML (100 UNITS/ML)	N021536	005	Oct 31, 2013	Feb NEWA

ISOFLURANE

	LIQUID;INHALATION						
	ISOFLURANE						
>A>	AN	PIRAMAL ENT	99.9%	A074502	001	Jun 27, 1995	Feb CAHN
>D>	AN	RHODIA	99.9%	A074502	001	Jun 27, 1995	Feb CAHN

ISOSORBIDE MONONITRATE

	TABLET;ORAL						
	ISOSORBIDE MONONITRATE						
AB		ANI PHARMS INC	20MG	A075147	001	Nov 27, 1998	Jan CAHN

ISRADIPINE

	CAPSULE;ORAL						
	ISRADIPINE						
>D>	AB	MIKAH PHARMA	2.5MG	A077169	001	Apr 24, 2006	Feb DISC
>A>		@	2.5MG	A077169	001	Apr 24, 2006	Feb DISC
>D>	AB		5MG	A077169	002	Apr 24, 2006	Feb DISC
>A>		@	5MG	A077169	002	Apr 24, 2006	Feb DISC
>D>	AB	WATSON LABS	2.5MG	A077317	001	Jan 05, 2006	Feb CTEC
>A>			2.5MG	A077317	001	Jan 05, 2006	Feb CTEC
>D>	AB	+	5MG	A077317	002	Jan 05, 2006	Feb CTEC
>A>		+	5MG	A077317	002	Jan 05, 2006	Feb CTEC

KETOROLAC TROMETHAMINE

	SOLUTION/DROPS;OPHTHALMIC						
	ACUVAIL						
AT	+	ALLERGAN	0.45%	N022427	001	Jul 22, 2009	Jan CFTG
		KETOROLAC TROMETHAMINE					
>D>	AT	AKORN	0.45%	A203376	001	Feb 10, 2014	Feb DISC
>A>		@	0.45%	A203376	001	Feb 10, 2014	Feb DISC
AT			0.45%	A203376	001	Feb 10, 2014	Jan NEWA

LAMIVUDINE; ZIDOVUDINE

	TABLET;ORAL						
	LAMIVUDINE AND ZIDOVUDINE						
AB		HETERO LABS LTD V	150MG;300MG	A203259	001	Feb 03, 2014	Jan NEWA

LANSOPRAZOLE

	TABLET, DELAYED RELEASE, ORALLY DISINTEGRATING;ORAL						
	LANSOPRAZOLE						
		@ ANI PHARMS INC	15MG	A078730	001	Oct 15, 2010	Jan CAHN
		@	30MG	A078730	002	Oct 15, 2010	Jan CAHN

LEVETIRACETAM

	TABLET;ORAL						
	LEVETIRACETAM						
>D>	AB	BOCA PHARMA LLC	250MG	A077319	001	Mar 20, 2009	Feb CAHN
>D>	AB		500MG	A077319	002	Mar 20, 2009	Feb CAHN
>D>	AB		750MG	A077319	003	Mar 20, 2009	Feb CAHN
>A>	AB	VINTAGE PHARMS	250MG	A077319	001	Mar 20, 2009	Feb CAHN
>A>	AB		500MG	A077319	002	Mar 20, 2009	Feb CAHN
>A>	AB		750MG	A077319	003	Mar 20, 2009	Feb CAHN

TABLET, EXTENDED RELEASE;ORAL
LEVETIRACETAM

>D>	AB	BOCA PHARMA LLC	500MG	A201464	001	May 25, 2012	Feb	CAHN
>D>	AB		750MG	A201464	002	May 25, 2012	Feb	CAHN
>A>	AB	VINTAGE PHARMS	500MG	A201464	001	May 25, 2012	Feb	CAHN
>A>	AB		750MG	A201464	002	May 25, 2012	Feb	CAHN

LEVOCETIRIZINE DIHYDROCHLORIDE

SOLUTION;ORAL
LEVOCETIRIZINE DIHYDROCHLORIDE

AA		L PERRIGO CO	2.5MG/5ML	A091263	001	Nov 07, 2011	Jan	CAHN
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LEVORPHANOL TARTRATE

TABLET;ORAL
LEVORPHANOL TARTRATE

>D>		ROXANE	2MG	A074278	001	Mar 31, 2000	Feb	CRLD
>A>	+		2MG	A074278	001	Mar 31, 2000	Feb	CRLD

LIDOCAINE HYDROCHLORIDE

JELLY;TOPICAL
ANESTACON
@ DSM PHARMS INC
2%
SOLUTION;TOPICAL
LIDOCAINE HYDROCHLORIDE

>A>	AT	IGI LABS INC	4%	A204494	001	Mar 12, 2014	Feb	NEWA
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LOTEPREDNOL ETABONATE

GEL;OPHTHALMIC
LOTEMAX

>D>	+	BAUSCH AND LOMB	0.5%	N202872	001	Sep 28, 2012	Feb	CAHN
>A>	+	BAUSCH AND LOMB INC	0.5%	N202872	001	Sep 28, 2012	Feb	CAHN

LULICONAZOLE

CREAM;TOPICAL
LUZU
+ MEDICIS
1%

N204153	001	Nov 14, 2013	Jan	CRLD
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METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
GLUMETZA

>A>	+	SALIX PHARMS INC	1GM	N021748	002	Jun 03, 2005	Feb	CTEC
>A>			500MG	N021748	001	Jun 03, 2005	Feb	CTEC
>D>	AB3	+ SANTARUS	1GM	N021748	002	Jun 03, 2005	Feb	CTEC
>D>	AB3		500MG	N021748	001	Jun 03, 2005	Feb	CTEC

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

TABLET;ORAL
PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE

>A>	AB	TEVA PHARMS USA	500MG;EQ 15MG BASE	A091155	001	Mar 10, 2014	Feb	NEWA
>A>	AB		850MG;EQ 15MG BASE	A091155	002	Mar 10, 2014	Feb	NEWA

METHAZOLAMIDE

TABLET;ORAL
METHAZOLAMIDE

AB		ANI PHARMS INC	25MG	A040001	001	Jun 30, 1993	Jan	CAHN
AB			50MG	A040001	002	Jun 30, 1993	Jan	CAHN

METHIMAZOLE

TABLET;ORAL
METHIMAZOLE

>D>	AB	BOCA PHARMA LLC	5MG	A202068	001	Mar 07, 2012	Feb	CAHN
>D>	AB		10MG	A202068	002	Mar 07, 2012	Feb	CAHN
>A>	AB	VINTAGE PHARMS	5MG	A202068	001	Mar 07, 2012	Feb	CAHN
>A>	AB		10MG	A202068	002	Mar 07, 2012	Feb	CAHN

METHSCOPOLAMINE BROMIDE

TABLET;ORAL
METHSCOPOLAMINE BROMIDE

>D>	AA	BOCA PHARMA LLC	2.5MG	A040624	001	Dec 28, 2006	Feb	CAHN
>D>	AA		5MG	A040624	002	Dec 28, 2006	Feb	CAHN
>A>	AA	VINTAGE PHARMS	2.5MG	A040624	001	Dec 28, 2006	Feb	CAHN
>A>	AA		5MG	A040624	002	Dec 28, 2006	Feb	CAHN

METHYLERGONOVINE MALEATE

INJECTABLE; INJECTION
METHERGINE

>A>	AP	+	EDISON THERAPS LLC	0.2MG/ML	N006035	004		Feb	CAHN
>D>	AP	+	US PHARMS HOLDINGS I	0.2MG/ML	N006035	004		Feb	CAHN
			TABLET; ORAL						
			METHERGINE						
>A>	AB	+	EDISON THERAPS LLC	0.2MG	N006035	003		Feb	CAHN
>D>	AB	+	US PHARMS HOLDINGS I	0.2MG	N006035	003		Feb	CAHN

METHYLPHENIDATE HYDROCHLORIDE

TABLET; ORAL
METHYLPHENIDATE HYDROCHLORIDE

>A>	AB		COREPHARMA	5MG	A091159	001	Mar 12, 2014	Feb	NEWA
>A>	AB			10MG	A091159	002	Mar 12, 2014	Feb	NEWA
>A>	AB			20MG	A091159	003	Mar 12, 2014	Feb	NEWA

METRONIDAZOLE

TABLET; ORAL
METRONIDAZOLE

AB			UNICHEM LABS LTD	250MG	A203458	001	Jan 22, 2014	Jan	NEWA
AB				500MG	A203458	002	Jan 22, 2014	Jan	NEWA

MIVACURIUM CHLORIDE

INJECTABLE; INJECTION
MIVACURIUM CHLORIDE

>A>		@	AGILA SPECLTS	EQ 2MG BASE/ML	A078562	001	Apr 30, 2009	Feb	CAHN
>D>		@	STRIDES ARCOLAB LTD	EQ 2MG BASE/ML	A078562	001	Apr 30, 2009	Feb	CAHN

MODAFINIL

TABLET; ORAL
MODAFINIL

AB			APOTEX INC	100MG	A077667	001	Feb 03, 2014	Jan	NEWA
AB				200MG	A077667	002	Feb 03, 2014	Jan	NEWA

MORPHINE SULFATE

SOLUTION; ORAL
MORPHINE SULFATE

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

MOXIFLOXACIN HYDROCHLORIDE

TABLET; ORAL
AVELOX

>D>		+	BAYER HLTHCARE	EQ 400MG BASE	N021085	001	Dec 10, 1999	Feb	CFTG
>A>	AB	+		EQ 400MG BASE	N021085	001	Dec 10, 1999	Feb	CFTG
			MOXIFLOXACIN HYDROCHLORIDE						
>A>	AB		AUROBINDO PHARMA LTD	EQ 400MG BASE	A202632	001	Mar 04, 2014	Feb	NEWA
>A>	AB		DR REDDYS LABS LTD	EQ 400MG BASE	A076938	001	Mar 04, 2014	Feb	NEWA
>A>	AB		TEVA PHARMS USA	EQ 400MG BASE	A077437	001	Feb 18, 2014	Feb	NEWA

NAFCILLIN SODIUM

INJECTABLE; INJECTION
NAFCILLIN SODIUM

AP			ANTIBIOTICE	EQ 1GM BASE/VIAL	A090560	001	Oct 03, 2011	Jan	CPOT
AP				EQ 2GM BASE/VIAL	A090560	002	Oct 03, 2011	Jan	CPOT
>D>	AP		IBI	EQ 1GM BASE/VIAL	A090002	001	Jun 30, 2011	Feb	CAHN
>D>	AP			EQ 2GM BASE/VIAL	A090002	002	Jun 30, 2011	Feb	CAHN
>D>	AP			EQ 10GM BASE/VIAL	A090005	001	Apr 20, 2011	Feb	CAHN
>A>	AP		ISTITUTO BIO ITA SPA	EQ 1GM BASE/VIAL	A090002	001	Jun 30, 2011	Feb	CAHN
>A>	AP			EQ 2GM BASE/VIAL	A090002	002	Jun 30, 2011	Feb	CAHN
>A>	AP			EQ 10GM BASE/VIAL	A090005	001	Apr 20, 2011	Feb	CAHN

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HYDROCHLORIDE

>A>	AP		MYLAN INSTITUTIONAL	0.4MG/ML	A204997	001	Mar 06, 2014	Feb	NEWA
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NAPROXEN

TABLET;ORAL
NAPROXEN

>D>	AB	DAVA PHARMS INC	250MG	A074410	001	Apr 28, 1995	Feb	DISC
>A>		@	250MG	A074410	001	Apr 28, 1995	Feb	DISC
>D>	AB		375MG	A074410	002	Apr 28, 1995	Feb	DISC
>A>		@	375MG	A074410	002	Apr 28, 1995	Feb	DISC
>D>	AB		500MG	A074410	003	Apr 28, 1995	Feb	DISC
>A>		@	500MG	A074410	003	Apr 28, 1995	Feb	DISC

NARATRIPTAN HYDROCHLORIDE

TABLET;ORAL
NARATRIPTAN

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

NEVIRAPINE

TABLET;ORAL
NEVIRAPINE

AB		STRIDES ARCOLAB LTD	200MG	A078195	001	May 22, 2012	Jan	CAHN
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NICARDIPINE HYDROCHLORIDE

CAPSULE;ORAL
NICARDIPINE HYDROCHLORIDE

AB		ANI PHARMS INC	20MG	A074439	001	Dec 10, 1996	Jan	CAHN
AB			20MG	A074540	001	Oct 28, 1996	Jan	CAHN
AB			30MG	A074439	002	Dec 10, 1996	Jan	CAHN
AB			30MG	A074540	002	Oct 28, 1996	Jan	CAHN

INJECTABLE;INJECTION
NICARDIPINE HYDROCHLORIDE

AP		LUITPOLD	25MG/10ML (2.5MG/ML)	A090534	001	Nov 17, 2009	Jan	CAHN
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NIZATIDINE

CAPSULE;ORAL
NIZATIDINE

AB		@ ANI PHARMS INC	150MG	A075461	001	Jul 08, 2002	Jan	CAHN
AB			150MG	A075668	001	Sep 12, 2002	Jan	CAHN
AB		@	300MG	A075461	002	Jul 08, 2002	Jan	CAHN
AB			300MG	A075668	002	Sep 12, 2002	Jan	CAHN

OMEPRAZOLE; SODIUM BICARBONATE

CAPSULE;ORAL
ZEGERID

>D>	AB	SALIX PHARMS INC	20MG;1.1GM	N021849	001	Feb 27, 2006	Feb	CAHN
>D>	AB	+	40MG;1.1GM	N021849	002	Feb 27, 2006	Feb	CAHN
>A>	AB	SANTARUS INC	20MG;1.1GM	N021849	001	Feb 27, 2006	Feb	CAHN
>A>	AB	+	40MG;1.1GM	N021849	002	Feb 27, 2006	Feb	CAHN

FOR SUSPENSION;ORAL
ZEGERID

>D>	AB	SALIX PHARMS INC	20MG/PACKET;1.68GM/PACKET	N021636	001	Jun 15, 2004	Feb	CAHN
>D>	AB	+	40MG/PACKET;1.68GM/PACKET	N021636	002	Dec 21, 2004	Feb	CAHN
>A>	AB	SANTARUS INC	20MG/PACKET;1.68GM/PACKET	N021636	001	Jun 15, 2004	Feb	CAHN
>A>	AB	+	40MG/PACKET;1.68GM/PACKET	N021636	002	Dec 21, 2004	Feb	CAHN

ONDANSETRON HYDROCHLORIDE

INJECTABLE;INJECTION
ONDANSETRON HYDROCHLORIDE

		@ LANNETT	EQ 2MG BASE/ML	A090116	001	Apr 14, 2010	Jan	DISC
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TABLET;ORAL
ONDANSETRON HYDROCHLORIDE

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

OXACILLIN SODIUM

INJECTABLE;INJECTION
OXACILLIN SODIUM

>D>		@ IBI	EQ 1GM BASE/VIAL	A062798	001	Dec 11, 1995	Feb	CAHN
>D>		@	EQ 2GM BASE/VIAL	A062798	002	Dec 11, 1995	Feb	CAHN
>D>		@	EQ 125MG BASE/VIAL	A062798	003	Dec 11, 1995	Feb	CAHN
>D>		@	EQ 250MG BASE/VIAL	A062798	004	Dec 11, 1995	Feb	CAHN

INJECTABLE; INJECTION
OXACILLIN SODIUM

>D>	@	EQ 500MG BASE/VIAL	A062798	005	Dec 11, 1995	Feb	CAHN
>A>	@ ISTITUTO BIO ITA SPA	EQ 1GM BASE/VIAL	A062798	001	Dec 11, 1995	Feb	CAHN
>A>	@	EQ 2GM BASE/VIAL	A062798	002	Dec 11, 1995	Feb	CAHN
>A>	@	EQ 125MG BASE/VIAL	A062798	003	Dec 11, 1995	Feb	CAHN
>A>	@	EQ 250MG BASE/VIAL	A062798	004	Dec 11, 1995	Feb	CAHN
>A>	@	EQ 500MG BASE/VIAL	A062798	005	Dec 11, 1995	Feb	CAHN
>A>	@ MARSAM PHARMS	EQ 1GM BASE/VIAL	A062856	003	Oct 26, 1988	Feb	CAHN
>A>	@	EQ 2GM BASE/VIAL	A062856	004	Oct 26, 1988	Feb	CAHN
>A>	@	EQ 4GM BASE/VIAL	A062856	005	Oct 26, 1988	Feb	CAHN
>A>	@	EQ 250MG BASE/VIAL	A062856	001	Oct 26, 1988	Feb	CAHN
>A>	@	EQ 500MG BASE/VIAL	A062856	002	Oct 26, 1988	Feb	CAHN
>D>	@ WATSON LABS	EQ 1GM BASE/VIAL	A062856	003	Oct 26, 1988	Feb	CAHN
>D>	@	EQ 2GM BASE/VIAL	A062856	004	Oct 26, 1988	Feb	CAHN
>D>	@	EQ 4GM BASE/VIAL	A062856	005	Oct 26, 1988	Feb	CAHN
>D>	@	EQ 250MG BASE/VIAL	A062856	001	Oct 26, 1988	Feb	CAHN
>D>	@	EQ 500MG BASE/VIAL	A062856	002	Oct 26, 1988	Feb	CAHN

OXANDROLONE

TABLET; ORAL
OXANDRIN

AB	CREALTA PHARMS LLC	2.5MG	N013718	001		Jan	CAHN
AB	+	10MG	N013718	002	Nov 05, 2001	Jan	CAHN

OXCARBAZEPINE

TABLET; ORAL
OXCARBAZEPINE

@	ANI PHARMS INC	150MG	A078005	001	Dec 11, 2007	Jan	CAHN
@		300MG	A078005	002	Dec 11, 2007	Jan	CAHN
@		600MG	A078005	003	Dec 11, 2007	Jan	CAHN

OXYBUTYNIN

FILM, EXTENDED RELEASE; TRANSDERMAL
OXYBUTYNIN

>A>	AB	BARR LABS DIV TEVA	3.9MG/24HR	A090526	001	Mar 04, 2014	Feb	NEWA
>D>	+	WATSON LABS (UTAH)	3.9MG/24HR	N021351	002	Feb 26, 2003	Feb	CFTG
>A>	AB	+	3.9MG/24HR	N021351	002	Feb 26, 2003	Feb	CFTG

OXYTOCIN

SOLUTION; NASAL
SYNTOCINON

>D>	@	NOVARTIS	40USP UNITS/ML	N012285	001		Feb	CAHN
>A>	@	RETROPHIN INC	40USP UNITS/ML	N012285	001		Feb	CAHN

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION
PAMIDRONATE DISODIUM

@	MN PHARMS	30MG/VIAL	A078300	001	Mar 10, 2009	Jan	DISC
@		90MG/VIAL	A078300	002	Mar 10, 2009	Jan	DISC

PAROXETINE HYDROCHLORIDE

CAPSULE; ORAL
PAXIL

>A>	@	APOTEX TECNOLOGIES	EQ 10MG BASE	N020885	001	Oct 09, 1998	Feb	CAHN
>A>	@		EQ 20MG BASE	N020885	002	Oct 09, 1998	Feb	CAHN
>A>	@		EQ 30MG BASE	N020885	003	Oct 09, 1998	Feb	CAHN
>A>	@		EQ 40MG BASE	N020885	004	Oct 09, 1998	Feb	CAHN
>D>	@	GLAXOSMITHKLINE	EQ 10MG BASE	N020885	001	Oct 09, 1998	Feb	CAHN
>D>	@		EQ 20MG BASE	N020885	002	Oct 09, 1998	Feb	CAHN
>D>	@		EQ 30MG BASE	N020885	003	Oct 09, 1998	Feb	CAHN
>D>	@		EQ 40MG BASE	N020885	004	Oct 09, 1998	Feb	CAHN

SUSPENSION; ORAL
PAXIL

>A>	AB	+	APOTEX TECNOLOGIES	EQ 10MG BASE/5ML	N020710	001	Jun 25, 1997	Feb	CAHN
>D>	AB	+	GLAXOSMITHKLINE	EQ 10MG BASE/5ML	N020710	001	Jun 25, 1997	Feb	CAHN

TABLET; ORAL
PAXIL

AB	APOTEX TECNOLOGIES	EQ 10MG BASE	N020031	001	Dec 29, 1992	Jan	CAHN
AB		EQ 20MG BASE	N020031	002	Dec 29, 1992	Jan	CAHN
AB		EQ 30MG BASE	N020031	003	Dec 29, 1992	Jan	CAHN

TABLET;ORAL
PAXIL

AB	+		EQ 40MG BASE	N020031	005	Dec 29, 1992	Jan CAHN
		@	EQ 50MG BASE	N020031	004	Dec 29, 1992	Jan CAHN
TABLET, EXTENDED RELEASE;ORAL PAXIL CR							
>A>	AB	APOTEX TECNOLOGIES	EQ 12.5MG BASE	N020936	001	Feb 16, 1999	Feb CAHN
>A>	AB		EQ 25MG BASE	N020936	002	Feb 16, 1999	Feb CAHN
>A>	AB	+	EQ 37.5MG BASE	N020936	003	Dec 06, 2000	Feb CAHN
>D>	AB	GLAXOSMITHKLINE	EQ 12.5MG BASE	N020936	001	Feb 16, 1999	Feb CAHN
>D>	AB		EQ 25MG BASE	N020936	002	Feb 16, 1999	Feb CAHN
>D>	AB	+	EQ 37.5MG BASE	N020936	003	Dec 06, 2000	Feb CAHN

PENICILLIN G POTASSIUM

INJECTABLE;INJECTION
PENICILLIN G POTASSIUM

>D>	AP	IBI	5,000,000 UNITS/VIAL	A065448	001	Aug 18, 2009	Feb CAHN
>D>	AP		20,000,000 UNITS/VIAL	A065448	002	Aug 18, 2009	Feb CAHN
>A>	AP	ISTITUTO BIO ITA SPA	5,000,000 UNITS/VIAL	A065448	001	Aug 18, 2009	Feb CAHN
>A>	AP		20,000,000 UNITS/VIAL	A065448	002	Aug 18, 2009	Feb CAHN

PERINDOPRIL ERBUMINE

TABLET;ORAL
PERINDOPRIL ERBUMINE

AB		ANI PHARMS INC	2MG	A078138	001	Nov 10, 2009	Jan CAHN
AB			4MG	A078138	002	Nov 10, 2009	Jan CAHN
AB			8MG	A078138	003	Nov 10, 2009	Jan CAHN

PHENTERMINE HYDROCHLORIDE

CAPSULE;ORAL
PHENTERMINE HYDROCHLORIDE

>A>	AA	INVAGEN PHARMS	15MG	A202858	001	Feb 14, 2014	Feb NEWA
>A>	AA		30MG	A202858	002	Feb 14, 2014	Feb NEWA
	AA		37.5MG	A202846	001	Feb 05, 2014	Jan NEWA
TABLET;ORAL PHENTERMINE HYDROCHLORIDE							
AA		INVAGEN PHARMS	37.5MG	A202942	001	Feb 05, 2014	Jan NEWA

PHENYTOIN SODIUM

CAPSULE;ORAL
EXTENDED PHENYTOIN SODIUM

	@	ANI PHARMS INC	100MG EXTENDED	A089441	001	Dec 18, 1986	Jan CAHN
PROMPT PHENYTOIN SODIUM							
	@	ANI PHARMS INC	100MG PROMPT	A080259	001		Jan CAHN

PINDOLOL

TABLET;ORAL
PINDOLOL

>D>		@ MUTUAL PHARM	5MG	A074063	001	Jan 27, 1994	Feb CMFD
>A>	AB		5MG	A074063	001	Jan 27, 1994	Feb CMFD
>D>		@	10MG	A074063	002	Jan 27, 1994	Feb CMFD
>A>	AB		10MG	A074063	002	Jan 27, 1994	Feb CMFD
>D>		MYLAN PHARMS INC	5MG	A074019	001	Sep 03, 1992	Feb CTEC
>A>	AB		5MG	A074019	001	Sep 03, 1992	Feb CTEC
>D>		+	10MG	A074019	002	Sep 03, 1992	Feb CTEC
>A>	AB	+	10MG	A074019	002	Sep 03, 1992	Feb CTEC

PIPERACILLIN SODIUM

INJECTABLE;INJECTION
PIPERACILLIN

>D>	+	IBI	EQ 2GM BASE/VIAL	A065114	001	Nov 14, 2003	Feb CAHN
>D>	+		EQ 3GM BASE/VIAL	A065114	002	Nov 14, 2003	Feb CAHN
>D>	+		EQ 4GM BASE/VIAL	A065114	003	Nov 14, 2003	Feb CAHN
>D>	+		EQ 40GM BASE/VIAL	A065157	001	Jul 12, 2004	Feb CAHN
>A>	+	ISTITUTO BIO ITA SPA	EQ 2GM BASE/VIAL	A065114	001	Nov 14, 2003	Feb CAHN
>A>	+		EQ 3GM BASE/VIAL	A065114	002	Nov 14, 2003	Feb CAHN
>A>	+		EQ 4GM BASE/VIAL	A065114	003	Nov 14, 2003	Feb CAHN
>A>	+		EQ 40GM BASE/VIAL	A065157	001	Jul 12, 2004	Feb CAHN

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE; INJECTION

PIPERACILLIN AND TAZOBACTAM

>D>	AP	IBI	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	A065523	001	May 31, 2011	Feb	CAHN
>D>	AP		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	A065523	002	May 31, 2011	Feb	CAHN
>D>	AP		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A065523	003	May 31, 2011	Feb	CAHN
>D>	AP		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A090498	001	May 31, 2011	Feb	CAHN
>A>	AP	ISTITUTO BIO ITA SPA	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	A065523	001	May 31, 2011	Feb	CAHN
>A>	AP		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	A065523	002	May 31, 2011	Feb	CAHN
>A>	AP		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A065523	003	May 31, 2011	Feb	CAHN
>A>	AP		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A090498	001	May 31, 2011	Feb	CAHN

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE ANHYDROUS

FOR SUSPENSION; ORAL

CO-LAV

>D>		@ BOCA PHARMA LLC	240GM/BOT;2.98GM/BOT;6.72GM/BOT;5. 84GM/BOT;22.72GM/BOT	A073428	001	Jan 28, 1992	Feb	CAHN
>A>		@ VINTAGE PHARMS	240GM/BOT;2.98GM/BOT;6.72GM/BOT;5. 84GM/BOT;22.72GM/BOT	A073428	001	Jan 28, 1992	Feb	CAHN
>D>		@ BOCA PHARMA LLC	236GM/BOT;2.97GM/BOT;6.74GM/BOT;5. 86GM/BOT;22.74GM/BOT	A073433	001	Apr 28, 1992	Feb	CAHN
>A>		@ VINTAGE PHARMS	236GM/BOT;2.97GM/BOT;6.74GM/BOT;5. 86GM/BOT;22.74GM/BOT	A073433	001	Apr 28, 1992	Feb	CAHN

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

MIRAPEX ER

AB	+	BOEHRINGER INGELHEIM	0.375MG	N022421	001	Feb 19, 2010	Jan	CFTG
AB			0.75MG	N022421	002	Feb 19, 2010	Jan	CFTG
AB			1.5MG	N022421	003	Feb 19, 2010	Jan	CFTG
AB			2.25MG	N022421	006	Jun 17, 2011	Jan	CFTG
AB			3MG	N022421	004	Feb 19, 2010	Jan	CFTG
AB			3.75MG	N022421	007	Jun 17, 2011	Jan	CFTG
AB			4.5MG	N022421	005	Feb 19, 2010	Jan	CFTG
			PRAMIPEXOLE DIHYDROCHLORIDE					
AB		ANCHEN PHARMS	0.375MG	A202206	001	Feb 06, 2014	Jan	NEWA
AB			0.75MG	A202206	002	Feb 06, 2014	Jan	NEWA
AB			1.5MG	A202206	003	Feb 06, 2014	Jan	NEWA
AB			2.25MG	A202206	004	Feb 06, 2014	Jan	NEWA
AB			3MG	A202206	005	Feb 06, 2014	Jan	NEWA
AB			3.75MG	A202206	006	Feb 06, 2014	Jan	NEWA
AB			4.5MG	A202206	007	Feb 06, 2014	Jan	NEWA

PRAMLINTIDE ACETATE

INJECTABLE; SUBCUTANEOUS

SYMLIN

>D>		AMYLIN PHARMS LLC	EQ 1.5MG BASE/1.5ML (EQ 1MG BASE/ML)	N021332	002	Sep 25, 2007	Feb	CAHN
>D>	+		EQ 2.7MG BASE/2.7ML (EQ 1MG BASE/ML)	N021332	003	Sep 25, 2007	Feb	CAHN
>D>	@		EQ 3MG BASE/5ML (EQ 600MCG BASE/ML)	N021332	001	Mar 16, 2005	Feb	CAHN
>A>		ASTRAZENECA AB	EQ 1.5MG BASE/1.5ML (EQ 1MG BASE/ML)	N021332	002	Sep 25, 2007	Feb	CAHN
>A>	+		EQ 2.7MG BASE/2.7ML (EQ 1MG BASE/ML)	N021332	003	Sep 25, 2007	Feb	CAHN
>A>	@		EQ 3MG BASE/5ML (EQ 600MCG BASE/ML)	N021332	001	Mar 16, 2005	Feb	CAHN

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE

>D>	AT	BAUSCH AND LOMB	EQ 0.23% PHOSPHATE;10%	A074449	001	Dec 29, 1995	Feb	CRLD
>A>	AT	+	EQ 0.23% PHOSPHATE;10%	A074449	001	Dec 29, 1995	Feb	CRLD

SOLUTION/DROPS;OPHTHALMIC
 >D> VASOCIDIN
 >D> AT + NOVARTIS EQ 0.23% PHOSPHATE;10% N018988 001 Aug 26, 1988 Feb DISC
 >A> @ EQ 0.23% PHOSPHATE;10% N018988 001 Aug 26, 1988 Feb DISC

PRIMAQUINE PHOSPHATE

TABLET;ORAL
 PRIMAQUINE
 AB + SANOFI AVENTIS US EQ 15MG BASE N008316 001 Jan CFTG
 PRIMAQUINE PHOSPHATE
 AB ALVOGEN INC EQ 15MG BASE A203924 001 Feb 03, 2014 Jan NEWA
 >A> AB BAYSHORE PHARMS LLC EQ 15MG BASE A204476 001 Feb 25, 2014 Feb NEWA

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
 PROCAINAMIDE HYDROCHLORIDE
 @ ANI PHARMS INC 1GM A040111 001 Dec 13, 1996 Jan CAHN
 @ 250MG A088958 001 Dec 02, 1985 Jan CAHN
 @ 500MG A088959 001 Dec 02, 1985 Jan CAHN
 @ 750MG A089438 001 Mar 23, 1987 Jan CAHN

PROPAPENONE HYDROCHLORIDE

TABLET;ORAL
 PROPAPENONE HYDROCHLORIDE
 AB ANI PHARMS INC 150MG A076550 001 Apr 23, 2004 Jan CAHN
 AB 225MG A076550 002 Apr 23, 2004 Jan CAHN
 AB 300MG A076550 003 Apr 23, 2004 Jan CAHN

PROPRANOLOL HYDROCHLORIDE

TABLET;ORAL
 INDERAL
 @ WYETH PHARMS INC 40MG N016418 002 Jan DISC
 @ 60MG N016418 009 Oct 18, 1982 Jan DISC
 @ 80MG N016418 004 Jan DISC
 PROPRANOLOL HYDROCHLORIDE
 @ ANI PHARMS INC 90MG A071977 001 Apr 06, 1988 Jan CAHN

PROPYLTHIOURACIL

TABLET;ORAL
 PROPYLTHIOURACIL
 @ ANI PHARMS INC 50MG A080215 001 Jan CAHN

RALOXIFENE HYDROCHLORIDE

TABLET;ORAL
 EVISTA
 >D> + LILLY 60MG N020815 001 Dec 09, 1997 Feb CFTG
 >A> AB + 60MG N020815 001 Dec 09, 1997 Feb CFTG
 >A> RALOXIFENE HYDROCHLORIDE
 >A> AB TEVA PHARMS USA 60MG A078193 001 Mar 04, 2014 Feb NEWA

RANITIDINE HYDROCHLORIDE

TABLET, EFFERVESCENT;ORAL
 >D> ZANTAC 25
 >D> + GLAXO GRP LTD EQ 25MG BASE N020251 003 Apr 01, 2004 Feb DISC
 >A> @ EQ 25MG BASE N020251 003 Apr 01, 2004 Feb DISC

REPAGLINIDE

TABLET;ORAL
 REPAGLINIDE
 AB ACTAVIS TOTOWA 0.5MG A090008 001 Jan 22, 2014 Jan NEWA
 AB 1MG A090008 002 Jan 22, 2014 Jan NEWA
 AB 2MG A090008 003 Jan 22, 2014 Jan NEWA
 AB AUROBINDO PHARMA LTD 0.5MG A203820 001 Jan 22, 2014 Jan NEWA
 AB 1MG A203820 002 Jan 22, 2014 Jan NEWA
 AB 2MG A203820 003 Jan 22, 2014 Jan NEWA
 AB MYLAN PHARMS INC 1MG A090252 002 Jan 22, 2014 Jan NEWA
 AB 2MG A090252 003 Jan 22, 2014 Jan NEWA
 AB PADDOCK LLC 1MG A201189 002 Jan 22, 2014 Jan NEWA
 AB 2MG A201189 003 Jan 22, 2014 Jan NEWA
 AB SANDOZ 1MG A078555 002 Jan 22, 2014 Jan NEWA
 AB 2MG A078555 003 Jan 22, 2014 Jan NEWA

RIFABUTIN

		CAPSULE;ORAL							
		MYCOBUTIN							
>D>	+	PHARMACIA AND UPJOHN	150MG		N050689	001	Dec 23, 1992	Feb	CFTG
>A>	AB	+	150MG		N050689	001	Dec 23, 1992	Feb	CFTG
>A>		RIFABUTIN							
>A>	AB	LUPIN LTD	150MG		A090033	001	Feb 24, 2014	Feb	NEWA

RISPERIDONE

		SOLUTION;ORAL							
		RISPERIDONE							
AA		ANI PHARMS INC	1MG/ML		A076440	001	Jan 30, 2009	Jan	CAHN
		TABLET;ORAL							
		RISPERIDONE							
>A>	AB	CARACO	0.25MG		A078036	001	Mar 10, 2014	Feb	NEWA
>A>	AB		0.5MG		A078036	002	Mar 10, 2014	Feb	NEWA
>A>	AB		1MG		A078036	003	Mar 10, 2014	Feb	NEWA
>A>	AB		2MG		A078036	004	Mar 10, 2014	Feb	NEWA
>A>	AB		3MG		A078036	005	Mar 10, 2014	Feb	NEWA
>A>	AB		4MG		A078036	006	Mar 10, 2014	Feb	NEWA

RIZATRIPTAN BENZOATE

		TABLET;ORAL							
		RIZATRIPTAN BENZOATE							
AB		MACLEODS PHARMS LTD	EQ 5MG BASE		A203147	001	Feb 11, 2014	Jan	NEWA
AB			EQ 10MG BASE		A203147	002	Feb 11, 2014	Jan	NEWA

SIMEPREVIR

		CAPSULE;ORAL							
		OLYSIO							
>D>	+	JANSSEN RES AND DEV	150MG		N205123	001	Nov 22, 2013	Feb	CAIN

SIMEPREVIR SODIUM

		CAPSULE;ORAL							
		OLYSIO							
>A>	+	JANSSEN RES AND DEV	EQ 150MG BASE		N205123	001	Nov 22, 2013	Feb	CAIN

SOMATROPIN RECOMBINANT

		INJECTABLE;INJECTION							
		ACCRETROPIN							
>D>	@	CANGENE	5MG/ML (5MG/ML)		N021538	001	Jan 23, 2008	Feb	CAHN
>A>	@	EMERGENT	5MG/ML (5MG/ML)		N021538	001	Jan 23, 2008	Feb	CAHN

SPIRONOLACTONE

		TABLET;ORAL							
		SPIRONOLACTONE							
>A>	AB	ORION CORP ORION	25MG		A202187	001	Mar 06, 2014	Feb	NEWA
>A>	AB		50MG		A202187	002	Mar 06, 2014	Feb	NEWA
>A>	AB		100MG		A202187	003	Mar 06, 2014	Feb	NEWA

SUMATRIPTAN SUCCINATE

		INJECTABLE;SUBCUTANEOUS							
		SUMATRIPTAN SUCCINATE							
AB		DR REDDYS LABS INC	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)		A090495	001	Jan 29, 2014	Jan	NEWA

SUNITINIB MALATE

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

TASIMELTEON

CAPSULE;ORAL
HETLIOZ

+ VANDA PHARMS INC 20MG N205677 001 Jan 31, 2014 Jan NEWA

TEMOZOLOMIDE

CAPSULE;ORAL
TEMOZOLOMIDE

>A> AB SUN PHARMA GLOBAL 5MG A201742 001 Feb 12, 2014 Feb NEWA
>A> AB 20MG A201742 002 Feb 12, 2014 Feb NEWA
>A> AB 100MG A201742 003 Feb 12, 2014 Feb NEWA
>A> AB 140MG A201742 004 Feb 12, 2014 Feb NEWA
>A> AB 180MG A201742 005 Feb 12, 2014 Feb NEWA
>A> AB 250MG A201742 006 Feb 12, 2014 Feb NEWA

THEOPHYLLINE

TABLET, EXTENDED RELEASE;ORAL
THEOCHRON

@ CARACO 300MG A087400 002 Jan 11, 1983 Jan DISC

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE;ORAL
THIORIDAZINE HYDROCHLORIDE

>A> @ ANI PHARMS INC 100MG/ML A089603 001 Nov 09, 1987 Feb CAHN
>D> @ TEVA PHARMS 100MG/ML A089603 001 Nov 09, 1987 Feb CAHN

TABLET;ORAL
THIORIDAZINE HYDROCHLORIDE

>A> @ ANI PHARMS INC 10MG A088270 001 Apr 14, 1983 Feb CAHN
>A> @ 10MG A088493 001 May 17, 1985 Feb CAHN
>A> @ 15MG A088271 001 Apr 14, 1983 Feb CAHN
>A> @ 25MG A088272 001 Apr 14, 1983 Feb CAHN
>A> @ 50MG A088194 001 Apr 14, 1983 Feb CAHN
>A> @ 100MG A088273 001 Oct 03, 1983 Feb CAHN
>A> @ 100MG A088456 001 May 17, 1985 Feb CAHN
>D> @ IVAX PHARMS 10MG A088270 001 Apr 14, 1983 Feb CAHN
>D> @ 15MG A088271 001 Apr 14, 1983 Feb CAHN
>D> @ 25MG A088272 001 Apr 14, 1983 Feb CAHN
>D> @ 50MG A088194 001 Apr 14, 1983 Feb CAHN
>D> @ 100MG A088273 001 Oct 03, 1983 Feb CAHN
>D> @ TEVA 10MG A088493 001 May 17, 1985 Feb CAHN
>D> @ 100MG A088456 001 May 17, 1985 Feb CAHN

TRANEXAMIC ACID

INJECTABLE;INJECTION
TRANEXAMIC ACID

AP ACIC FINE CHEMS 100MG/ML A202436 001 Feb 11, 2014 Jan NEWA

TABLET;ORAL
TRANEXAMIC ACID

AB APOTEX INC 650 MG A202286 001 Jan 27, 2014 Jan NEWA

TRAVOPROST

SOLUTION/DROPS;OPHTHALMIC
TRAVOPROST

>D> PAR PHARM 0.004% A091340 001 Mar 01, 2013 Feb CRLD
>A> + 0.004% A091340 001 Mar 01, 2013 Feb CRLD

TRETINOIN

GEL;TOPICAL
RETIN-A-MICRO

+ VALEANT INTL 0.08% N020475 003 Jan 28, 2014 Jan NEWA

SOLUTION;TOPICAL
RETIN-A

>D> AT + VALEANT INTL 0.05% N016921 001 Feb CTEC
>A> + 0.05% N016921 001 Feb CTEC
>D> TRETINOIN
>D> AT WOCHKHARDT 0.05% A075260 001 Jan 25, 1999 Feb DISC
>A> @ 0.05% A075260 001 Jan 25, 1999 Feb DISC

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL

VALACYCLOVIR HYDROCHLORIDE

AB	CIPLA LTD	EQ 1GM BASE	A077135	002	May 24, 2010	Jan	CAHN
AB		EQ 500MG BASE	A077135	001	May 24, 2010	Jan	CAHN

VALPROIC ACID

SYRUP; ORAL

VALPROIC ACID

AA	ANI PHARMS INC	250MG/5ML	A073178	001	Aug 25, 1992	Jan	CAHN
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VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

VANCOMYCIN HYDROCHLORIDE

>A>	AP	AGILA SPECLTS	EQ 10GM BASE/VIAL	A091554	001	Sep 19, 2011	Feb	CAHN
>D>	AP	STRIDES ARCOLAB LTD	EQ 10GM BASE/VIAL	A091554	001	Sep 19, 2011	Feb	CAHN

ZICONOTIDE

INJECTABLE; INTRATHECAL

PRIALT

>D>	@	JAZZ PHARMS INTL	200MCG/2ML (100MCG/ML)	N021060	003	Dec 28, 2004	Feb	CAIN
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ZICONOTIDE ACETATE

INJECTABLE; INTRATHECAL

PRIALT

>A>	@	JAZZ PHARMS INTL	200MCG/2ML (100MCG/ML)	N021060	003	Dec 28, 2004	Feb	CAIN
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ZOLMITRIPTAN

TABLET; ORAL

ZOLMITRIPTAN

>A>	AB	TEVA PHARMS USA	2.5MG	A090861	001	Mar 04, 2014	Feb	NEWA
>A>	AB		5MG	A090861	002	Mar 04, 2014	Feb	NEWA

ZONISAMIDE

CAPSULE; ORAL

ZONISAMIDE

AB	ANI PHARMS INC	25MG	A077639	001	Dec 22, 2005	Jan	CAHN	
	@	25MG	A077641	003	Dec 22, 2005	Jan	CAHN	
AB		50MG	A077639	002	Dec 22, 2005	Jan	CAHN	
	@	50MG	A077641	002	Dec 22, 2005	Jan	CAHN	
AB		100MG	A077639	003	Dec 22, 2005	Jan	CAHN	
	@	100MG	A077641	001	Dec 22, 2005	Jan	CAHN	
>D>	AB	SANDOZ	25MG	A077644	001	Dec 22, 2005	Feb	DISC
>A>	@	25MG	A077644	001	Dec 22, 2005	Feb	DISC	
>D>	AB		50MG	A077644	002	Dec 22, 2005	Feb	DISC
>A>	@	50MG	A077644	002	Dec 22, 2005	Feb	DISC	
>D>	AB		100MG	A077644	003	Dec 22, 2005	Feb	DISC
>A>	@	100MG	A077644	003	Dec 22, 2005	Feb	DISC	

>D> ACETAMINOPHEN; DEKBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

>D> TABLET, EXTENDED RELEASE;ORAL

>D> DRIXORAL PLUS

>D> + SCHERING PLOUGH 500MG;3MG;60MG

N019453 001 May 22, 1987 Feb DISC

>A> @ 500MG;3MG;60MG

N019453 001 May 22, 1987 Feb DISC

CETIRIZINE HYDROCHLORIDE

TABLET;ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

>A> IPCA LABS LTD 5MG

A202277 002 Mar 11, 2014 Feb NEWA

>A> 10MG

A202277 004 Mar 11, 2014 Feb NEWA

CETIRIZINE HYDROCHLORIDE HIVES

>A> IPCA LABS LTD 5MG

A202277 001 Mar 11, 2014 Feb NEWA

>A> 10MG

A202277 003 Mar 11, 2014 Feb NEWA

TABLET, CHEWABLE;ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

>D> CARACO 5MG

A077631 004 Jan 11, 2008 Feb DISC

>A> @ 5MG

A077631 004 Jan 11, 2008 Feb DISC

>D> 10MG

A077631 003 Jan 11, 2008 Feb DISC

>A> @ 10MG

A077631 003 Jan 11, 2008 Feb DISC

>D> CETIRIZINE HYDROCHLORIDE HIVES RELIEF

>D> CARACO 5MG

A077631 001 Jan 11, 2008 Feb DISC

>A> @ 5MG

A077631 001 Jan 11, 2008 Feb DISC

>D> 10MG

A077631 002 Jan 11, 2008 Feb DISC

>A> @ 10MG

A077631 002 Jan 11, 2008 Feb DISC

DEKBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE;ORAL

DEKBROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE

+ AVANTHI INC 6MG;120MG

A078648 001 Feb 27, 2013 Jan CRLD

DISOPHROL

@ SCHERING PLOUGH 6MG;120MG

N013483 004 Sep 13, 1982 Jan DISC

DRIXORAL

@ SCHERING PLOUGH 6MG;120MG

N013483 003 Sep 13, 1982 Jan DISC

DIPHENHYDRAMINE HYDROCHLORIDE; NAPROXEN SODIUM

TABLET;ORAL

ALEVE PM

+ BAYER HLTHCARE 25MG;220MG

N205352 001 Jan 17, 2014 Jan NEWA

MINOXIDIL

AEROSOL, FOAM;TOPICAL

>A> WOMEN'S ROGAINE

>A> + JOHNSON AND JOHNSON 5%

N021812 002 Feb 28, 2014 Feb NEWA

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

CUMULATIVE SUPPLEMENT NUMBER 2 FEBRUARY 2014

NO FEBRUARY 2014 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

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

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

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

NO FEBRUARY 2014 ADDITIONS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2014

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>ACETYLCYSTEINE - ACETADOTE</u>						
N 021539 001	>A> 8653061	Aug 24, 2025	U-1373			
<u>ACYCLOVIR; HYDROCORTISONE - XERESE</u>						
N 022436 001	>A> 6514980	Jan 24, 2019	DP U-1006		NPP	Jan 22, 2017
	>A> 6514980	Jan 24, 2019	DP U-1484			
	>A> 7223387	May 13, 2023	DP U-1006			
	>A> 7223387	May 13, 2023	DP U-1484			
	>A> RE39264	Aug 02, 2016	DP U-1006			
	>A> RE39264	Aug 02, 2016	DP U-1484			
<u>ALISKIREN HEMIFUMARATE - TEKTURNA</u>						
N 021985 001	8617595	Feb 19, 2026	DP			
<u>ALISKIREN HEMIFUMARATE - TEKTURNA</u>						
N 021985 002	8617595	Feb 19, 2026	DP			
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>						
N 022545 001	8613949	Dec 21, 2029	DP			
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>						
N 022545 002	8613949	Dec 21, 2029	DP			
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>						
N 022545 003	8613949	Dec 21, 2029	DP			
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>						
N 022545 004	8613949	Dec 21, 2029	DP			
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>						
N 200045 001	8618174	Nov 15, 2021	DP			
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>						
N 200045 002	8618174	Nov 15, 2021	DP			
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>						
N 200045 003	8618174	Nov 15, 2021	DP			
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>						
N 200045 004	8618174	Nov 15, 2021	DP			
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>						
N 200045 005	8618174	Nov 15, 2021	DP			
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT</u>						
N 022107 001	8618172	Jul 13, 2028	DP			
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT</u>						
N 022107 002	8618172	Jul 13, 2028	DP			
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT</u>						
N 022107 003	8618172	Jul 13, 2028	DP			
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT</u>						
N 022107 004	8618172	Jul 13, 2028	DP			
<u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u>						
N 022426 001	>A> 8637079	Jan 23, 2029	DP			
<u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u>						
N 022426 002	>A> 8637079	Jan 23, 2029	DP			
<u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u>						
N 022426 003	>A> 8637079	Jan 23, 2029	DP			
<u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u>						
N 022426 004	>A> 8637079	Jan 23, 2029	DP			
<u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u>						
N 022426 005	>A> 8637079	Jan 23, 2029	DP			
<u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u>						
N 022426 006	>A> 8637079	Jan 23, 2029	DP			
<u>ALVIMOPAN - ENTEREG</u>						
N 021775 001	>A> 8645160	Jun 18, 2029	U-1485			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2014

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>ARIPRAZOLE - ABILIFY</u>						
N 021436 001	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
	>A> 8642760	Sep 25, 2022	DS			
	>A> 8642760*PED	Mar 25, 2023				
<u>ARIPRAZOLE - ABILIFY</u>						
N 021436 002	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
	>A> 8642760	Sep 25, 2022	DS			
	>A> 8642760*PED	Mar 25, 2023				
<u>ARIPRAZOLE - ABILIFY</u>						
N 021436 003	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
	>A> 8642760	Sep 25, 2022	DS			
	>A> 8642760*PED	Mar 25, 2023				
<u>ARIPRAZOLE - ABILIFY</u>						
N 021436 004	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
	>A> 8642760	Sep 25, 2022	DS			
	>A> 8642760*PED	Mar 25, 2023				
<u>ARIPRAZOLE - ABILIFY</u>						
N 021436 005	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
	>A> 8642760	Sep 25, 2022	DS			
	>A> 8642760*PED	Mar 25, 2023				
<u>ARIPRAZOLE - ABILIFY</u>						
N 021436 006	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
	>A> 8642760	Sep 25, 2022	DS			
	>A> 8642760*PED	Mar 25, 2023				
<u>ARIPRAZOLE - ABILIFY</u>						
N 021713 001	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
<u>ARIPRAZOLE - ABILIFY</u>						
N 021729 002	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
	>A> 8642760	Sep 25, 2022	DS			
	>A> 8642760*PED	Mar 25, 2023				
<u>ARIPRAZOLE - ABILIFY</u>						
N 021729 003	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
	>A> 8642760	Sep 25, 2022	DS			
	>A> 8642760*PED	Mar 25, 2023				
<u>ARIPRAZOLE - ABILIFY</u>						
N 021729 004	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
	>A> 8642760	Sep 25, 2022	DS			
	>A> 8642760*PED	Mar 25, 2023				
<u>ARIPRAZOLE - ABILIFY</u>						
N 021729 005	>A> 8642600	Jan 28, 2022	U-1492			
	>A> 8642600*PED	Jul 28, 2022				
	>A> 8642760	Sep 25, 2022	DS			
	>A> 8642760*PED	Mar 25, 2023				
<u>BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE - ACANYA</u>						
N 050819 001	>A> 8663699	Jun 03, 2029	U-124			
<u>BIMATOPROST - LATISSE</u>						
N 022369 001	>A> 8263054	Jan 15, 2023	U-1277			
	>A> 8632760	Jan 15, 2023	U-1487			
<u>BORTEZOMIB - VELCADE</u>						
N 021602 001				>A> ODE		Jun 20, 2015
<u>BROMOCRIPTINE MESYLATE - CYCLOSET</u>						
N 020866 001	8613947	Apr 30, 2032	DP U-976			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2014

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
N 021929 001	8616196	Apr 07, 2029	DP			
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
N 021929 002	8616196	Apr 07, 2029	DP			
<u>CABAZITAXEL - JEVTANA KIT</u>						
N 201023 001	>A> 5847170	Mar 26, 2021	DS DP			
<u>CLEVIDIPINE - CLEVIPREX</u>						
N 022156 001	>A> 8658676	Oct 10, 2031	DP			
<u>CLEVIDIPINE - CLEVIPREX</u>						
N 022156 002	>A> 8658676	Oct 10, 2031	DP			
<u>CLEVIDIPINE - CLEVIPREX</u>						
N 022156 003	>A> 5739152	Apr 14, 2015	DP U-893			
	>A> 5856346	Jan 05, 2021	DS DP U-893			
	>A> 8658676	Oct 10, 2031	DP			
<u>COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - STRIBILD</u>						
N 203100 001	8633219	Oct 11, 2031	DP U-257		>A> NP	Aug 27, 2015
<u>CYCLOSPORINE - RESTASIS</u>						
N 050790 001	8633162	Aug 27, 2024	U-1479			
	8642556	Aug 27, 2024	DP			
	8648048	Aug 27, 2024	U-1483			
<u>DABRAFENIB MESYLATE - TAFINLAR</u>						
N 202806 001					I-678 ODE	Jan 08, 2017 Jan 09, 2021
<u>DABRAFENIB MESYLATE - TAFINLAR</u>						
N 202806 002					I-678 ODE	Jan 08, 2017 Jan 09, 2021
<u>DAPAGLIFLOZIN - FARXIGA</u>						
N 202293 001					NCE	Jan 08, 2019
<u>DAPAGLIFLOZIN - FARXIGA</u>						
N 202293 002					NCE	Jan 08, 2019
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 001	8597876	Jun 23, 2019	U-1305			
	8597876*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 002	8597876	Jun 23, 2019	U-1305			
	8597876*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 003	8597876	Jun 23, 2019	U-1305			
	8597876*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 004	8597876	Jun 23, 2019	U-1305			
	8597876*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 005	8597876	Jun 23, 2019	U-1305			
	8597876*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 006	8597876	Jun 23, 2019	U-1305			
	8597876*PED	Dec 23, 2019				
<u>DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX</u>						
N 021038 001					M-61 PED	Jun 17, 2016 Dec 17, 2016
<u>DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX</u>						
N 021038 002	>A> 8648106	Jan 04, 2032	DP		M-61 PED	Jun 17, 2016 Dec 17, 2016
	>A> 8648106*PED	Jul 04, 2032				
<u>DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX</u>						
N 021038 003	>A> 8648106	Jan 04, 2032	DP		M-61 PED	Jun 17, 2016 Dec 17, 2016
	>A> 8648106*PED	Jul 04, 2032				
<u>DEXMETHYLPHENIDATE HYDROCHLORIDE - DEXMETHYLPHENIDATE HYDROCHLORIDE</u>						
A 078992 003					>A> PC	May 18, 2014

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2014

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>DICLOFENAC EPOLAMINE - FLECTOR</u>						
N 021234 001	>A> 5607690	Apr 13, 2019	DP			
<u>DICLOFENAC POTASSIUM - ZIPSOR</u>						
N 022202 001	6287594	Jan 15, 2019	DP			
	8623920	Feb 24, 2029	U-1482			
<u>DICLOFENAC SODIUM - PENNSAID</u>						
N 204623 001	>A> 8217078	Jul 10, 2029	U-1477		NP	Jan 16, 2017
	>A> 8252838	Apr 21, 2028	DP U-1489			
	>A> 8546450	Aug 09, 2030	U-1435			
	>A> 8546450	Aug 09, 2030	U-1436			
	>A> 8563613	Oct 17, 2027	DP U-1488			
	>A> 8618164	Jul 10, 2029	U-1477			
<u>DIPHENHYDRAMINE HYDROCHLORIDE; NAPROXEN SODIUM - ALEVE PM</u>						
N 205352 001					NC	Jan 17, 2017
<u>DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - BEYAZ</u>						
N 022532 001	8617597	Feb 08, 2030	DP			
<u>DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - SAFYRAL</u>						
N 022574 001	8617597	Feb 08, 2030	DP			
<u>DROXIDOPA - NORTHERA</u>						
N 203202 001				>A> NCE		Feb 18, 2019
				>A> ODE		Feb 18, 2021
<u>DROXIDOPA - NORTHERA</u>						
N 203202 002				>A> NCE		Feb 18, 2019
				>A> ODE		Feb 18, 2021
<u>DROXIDOPA - NORTHERA</u>						
N 203202 003				>A> NCE		Feb 18, 2019
				>A> ODE		Feb 18, 2021
<u>ESOMEPRAZOLE SODIUM - NEXIUM IV</u>						
N 021689 001				>A> D-138		Mar 04, 2017
				>A> I-679		Mar 04, 2017
<u>ESOMEPRAZOLE SODIUM - NEXIUM IV</u>						
N 021689 002				>A> D-138		Mar 04, 2017
				>A> I-679		Mar 04, 2017
<u>EZETIMIBE - ZETIA</u>						
N 021445 001	>A> 7612058	Oct 30, 2025	U-1027			
	>A> 7612058	Oct 30, 2025	U-1173			
	>A> 7612058*PED	Apr 30, 2026				
<u>FENTANYL - SUBSYS</u>						
N 202788 001	>A> 8486972	Apr 27, 2030	DP			
	>A> 8486973	Apr 27, 2030	U-55			
<u>FENTANYL - SUBSYS</u>						
N 202788 002	>A> 8486972	Apr 27, 2030	DP			
	>A> 8486973	Apr 27, 2030	U-55			
<u>FENTANYL - SUBSYS</u>						
N 202788 003	>A> 8486972	Apr 27, 2030	DP			
	>A> 8486973	Apr 27, 2030	U-55			
<u>FENTANYL - SUBSYS</u>						
N 202788 004	>A> 8486972	Apr 27, 2030	DP			
	>A> 8486973	Apr 27, 2030	U-55			
<u>FENTANYL - SUBSYS</u>						
N 202788 005	>A> 8486972	Apr 27, 2030	DP			
	>A> 8486973	Apr 27, 2030	U-55			
<u>FENTANYL - SUBSYS</u>						
N 202788 006	>A> 8486972	Apr 27, 2030	DP			
	>A> 8486973	Apr 27, 2030	U-55			
<u>FENTANYL - SUBSYS</u>						
N 202788 007	>A> 8486972	Apr 27, 2030	DP			
	>A> 8486973	Apr 27, 2030	U-55			
<u>FLUOCINONIDE - FLUOCINONIDE</u>						
A 090256 001					PC	Jul 13, 2014

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2014

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>FLUTICASONE FUROATE - VERAMYST</u>						
N 022051 001	>A> 8147461	Oct 15, 2028	DP			
<u>FLUTICASONE FUROATE; VILANTEROL TRIFENATATE - BREO ELLIPTA</u>						
N 204275 001					>A> NP	May 10, 2016
<u>GABAPENTIN ENACARBIL - HORIZANT</u>						
N 022399 001					ODE	Jun 06, 2019
<u>GABAPENTIN ENACARBIL - HORIZANT</u>						
N 022399 002					ODE	Jun 06, 2019
<u>GLATIRAMER ACETATE - COPAXONE</u>						
N 020622 003	>A> 6054430	May 24, 2014	DS			
	>A> 6342476	May 24, 2014		U-441		
	>A> 6362161	May 24, 2014	DS			
	>A> 7199098	May 24, 2014	DS			
	>A> 8232250	Aug 19, 2030		U-441		
	>A> 8367605	May 24, 2014	DS			
	>A> 8399413	Sep 06, 2030		U-441		
<u>GLYCEROL PHENYLBUTYRATE - RAVICTI</u>						
N 203284 001	>A> 8642012	Sep 22, 2030		U-1383		
<u>HEXAMINOLEVULINATE HYDROCHLORIDE - CYSVIEW KIT</u>						
N 022555 001	>A> 7348361	Nov 06, 2020	DP	U-1087		
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 001	>A> 6228398	Nov 01, 2019	DP			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 002	>A> 6228398	Nov 01, 2019	DP			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 003	>A> 6228398	Nov 01, 2019	DP			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 004	>A> 6228398	Nov 01, 2019	DP			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 005	>A> 6228398	Nov 01, 2019	DP			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 006	>A> 6228398	Nov 01, 2019	DP			
<u>IBRUTINIB - IMBRUVICA</u>						
N 205552 001	>A> 8476284	Dec 28, 2026		U-1456	>A> I-680	Feb 12, 2017
	>A> 8476284	Dec 28, 2026		U-1491	>A> ODE	Feb 12, 2021
	>A> 8497277	Dec 28, 2026		U-1456		
	>A> 8497277	Dec 28, 2026		U-1491		
<u>ICOSAPENT ETHYL - VASCEPA</u>						
N 202057 001					>A> NP	Jul 26, 2015
<u>IMATINIB MESYLATE - GLEEVEC</u>						
N 021335 001	RE43932	Jan 16, 2019	DS DP			
	RE43932*PED	Jul 16, 2019				
<u>IMATINIB MESYLATE - GLEEVEC</u>						
N 021335 002	RE43932	Jan 16, 2019	DS DP			
	RE43932*PED	Jul 16, 2019				
<u>INDOMETHACIN - TIVORBEX</u>						
N 204768 001					>A> NP	Feb 24, 2017
<u>INDOMETHACIN - TIVORBEX</u>						
N 204768 002					>A> NP	Feb 24, 2017
<u>INSULIN ASPART RECOMBINANT - NOVOLOG FLEXTOUCH</u>						
N 020986 005	>A> 6899699	Jan 02, 2022	DP			
	>A> 7686786	Aug 03, 2026	DP			
<u>INSULIN DETEMIR RECOMBINANT - LEVEMIR FLEXTOUCH</u>						
N 021536 005	>A> 6899699	Jan 02, 2022	DP			
	>A> 7686786	Aug 03, 2026	DP			
<u>KETOROLAC TROMETHAMINE - ACULAR LS</u>						
N 021528 001	>A> 8648107	May 28, 2024	DP			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2014

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N 022115 001	>A> 8637512	Jun 14, 2028	DP			
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N 022115 002	>A> 8637512	Jun 14, 2028	DP			
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N 022115 003	>A> 8637512	Jun 14, 2028	DP			
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N 022115 004	>A> 8637512	Jun 14, 2028	DP			
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N 022115 005	>A> 8637512	Jun 14, 2028	DP			
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N 022115 006	>A> 8637512	Jun 14, 2028	DP			
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 001	8626531	Oct 23, 2020	U-1210			
	>A> 8648095	May 15, 2023	U-1216			
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 002	8626531	Oct 23, 2020	U-1210			
	>A> 8648095	May 15, 2023	U-1216			
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 003	8626531	Oct 23, 2020	U-1210			
	>A> 8648095	May 15, 2023	U-1216			
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 004	8626531	Oct 23, 2020	U-1210			
	>A> 8648095	May 15, 2023	U-1216			
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 005	8626531	Oct 23, 2020	U-1210			
	>A> 8648095	May 15, 2023	U-1216			
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 006	8626531	Oct 23, 2020	U-1210			
	>A> 8648095	May 15, 2023	U-1216			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 001	8618135	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 002	8618135	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 003	8618135	Mar 07, 2025	U-1316			
<u>LOXAPINE - ADASUVE</u>						
N 022549 001	7052679	Oct 26, 2021	DP			
	7537009	Oct 28, 2024	DP			
	8074644	Jul 25, 2022	DP			
<u>METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE - KOMBIGLYZE XR</u>						
N 200678 001	8628799	Jul 13, 2025	DP		>A> M-134	May 24, 2016
<u>METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE - KOMBIGLYZE XR</u>						
N 200678 002					>A> M-134	May 24, 2016
<u>METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE - KOMBIGLYZE XR</u>						
N 200678 003					>A> M-134	May 24, 2016
<u>METHYLPHENIDATE - DAYTRANA</u>						
N 021514 001	8632802	Oct 07, 2025	DP			
<u>METHYLPHENIDATE - DAYTRANA</u>						
N 021514 002	8632802	Oct 07, 2025	DP			
<u>METHYLPHENIDATE - DAYTRANA</u>						
N 021514 003	8632802	Oct 07, 2025	DP			
<u>METHYLPHENIDATE - DAYTRANA</u>						
N 021514 004	8632802	Oct 07, 2025	DP			
<u>METHYLPHENIDATE HYDROCHLORIDE - CONCERTA</u>						
N 021121 001	8629179	Jul 31, 2017	DP			
	8629179*PED	Jan 31, 2018				

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2014

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>METHYLPHENIDATE HYDROCHLORIDE - CONCERTA</u>						
N 021121 002	8629179	Jul 31, 2017	DP			
	8629179*PED	Jan 31, 2018				
<u>METHYLPHENIDATE HYDROCHLORIDE - CONCERTA</u>						
N 021121 003	8629179	Jul 31, 2017	DP			
	8629179*PED	Jan 31, 2018				
<u>METHYLPHENIDATE HYDROCHLORIDE - CONCERTA</u>						
N 021121 004	8629179	Jul 31, 2017	DP			
	8629179*PED	Jan 31, 2018				
<u>MINOXIDIL - WOMEN'S ROGAINE</u>						
N 021812 002					>A> NP	Feb 28, 2017
<u>MYCOPHENOLIC ACID - MYCOPHENOLIC ACID</u>						
A 091248 001					PC	Jul 07, 2014
<u>NIACIN - NIACIN</u>						
A 076250 001					PC	Mar 19, 2014
<u>NIACIN - NIACIN</u>						
A 076378 001					PC	Mar 19, 2014
<u>NIACIN - NIACIN</u>						
A 076378 002					PC	Mar 19, 2014
<u>NITRIC OXIDE - INOMAX</u>						
N 020845 002					M-132 PED	Dec 21, 2013 Jun 21, 2014
<u>NITRIC OXIDE - INOMAX</u>						
N 020845 003					M-132 PED	Dec 21, 2013 Jun 21, 2014
<u>OSPEMIFENE - OSPHENA</u>						
N 203505 001	>A> 8642079	Mar 01, 2028	DP			
<u>OXYCODONE HYDROCHLORIDE - OXECTA</u>						
N 202080 001	>A> 8637540	Nov 26, 2023	DP			
<u>OXYCODONE HYDROCHLORIDE - OXECTA</u>						
N 202080 002	>A> 8637540	Nov 26, 2023	DP			
<u>PAROXETINE MESYLATE - BRISDELLE</u>						
N 204516 001	>A> 8658663	Apr 06, 2029	DS DP U-904			
<u>PERFLUTREN - DEFINITY</u>						
N 021064 001	>A> 8658205	Apr 20, 2019	DP			
<u>POMALIDOMIDE - POMALYST</u>						
N 204026 001	8626531	Oct 23, 2020			U-1361	
<u>POMALIDOMIDE - POMALYST</u>						
N 204026 002	8626531	Oct 23, 2020			U-1361	
<u>POMALIDOMIDE - POMALYST</u>						
N 204026 003	8626531	Oct 23, 2020			U-1361	
<u>POMALIDOMIDE - POMALYST</u>						
N 204026 004	8626531	Oct 23, 2020			U-1361	
<u>RALTEGRAVIR POTASSIUM - ISENTRESS</u>						
N 205786 001	7169780	Oct 03, 2023	DS DP			
	7217713	Oct 21, 2022			U-257	
	7435734	Oct 21, 2022			U-257	
	7754731	Mar 11, 2029	DS DP		U-257	
<u>REGORAFENIB - STIVARGA</u>						
N 203085 001	>A> 8637553	Jul 08, 2029	DS DP			
<u>RIFAXIMIN - XIFAXAN</u>						
N 021361 001	8642573	Oct 02, 2029			U-1481	
<u>RIFAXIMIN - XIFAXAN</u>						
N 022554 001	8642573	Oct 02, 2029			U-1481	
<u>ROFLUMILAST - DALIRESP</u>						
N 022522 001	8618142	Mar 08, 2024	DP			
<u>SAXAGLIPTIN HYDROCHLORIDE - ONGLYZA</u>						
N 022350 001					>A> M-134	May 24, 2016

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2014

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>SAXAGLIPTIN HYDROCHLORIDE - ONGLYZA</u>						
N 022350	002				>A> M-134	May 24, 2016
<u>SILDENAFIL CITRATE - REVATIO</u>						
N 021845	001				>A> D-137 >A> M-133	Jan 31, 2017 Jan 31, 2017
<u>SILDENAFIL CITRATE - REVATIO</u>						
N 022473	001				>A> D-137 >A> M-133	Jan 31, 2017 Jan 31, 2017
<u>SILDENAFIL CITRATE - REVATIO</u>						
N 203109	001				>A> D-137 >A> M-133	Jan 31, 2017 Jan 31, 2017
<u>SIROLIMUS - SIROLIMUS</u>						
A 201676	003				PC	Jul 15, 2014
<u>SOFOSBUVIR - SOVALDI</u>						
N 204671	001	8618076	Dec 11, 2030	DS DP U-1470		
		8633309	Mar 26, 2029	DS DP U-1470		
<u>SORAFENIB TOSYLATE - NEXAVAR</u>						
N 021923	001	8618141	Feb 11, 2023		U-1480	
<u>TASIMELTEON - HETLIOZ</u>						
N 205677	001	>A> 5856529	Dec 09, 2017	DS DP U-1486	NCE >A> ODE	Jan 31, 2019 Jan 31, 2021
<u>TEMOZOLOMIDE - TEMODAR</u>						
N 022277	001	8623868	Feb 21, 2023		DP	
<u>TEMSIROLIMUS - TORISEL</u>						
N 022088	001	>A> 5362718	Feb 15, 2019	DS DP		Y
		>A> 5362718*PED	Aug 15, 2019			
		>A> RE44768	Feb 15, 2019	DS DP		
		>A> RE44768*PED	Aug 15, 2019			
<u>THALIDOMIDE - THALOMID</u>						
N 020785	001	8626531	Oct 23, 2020		U-1465	
<u>THALIDOMIDE - THALOMID</u>						
N 020785	002	8626531	Oct 23, 2020		U-1465	
<u>THALIDOMIDE - THALOMID</u>						
N 020785	003	8626531	Oct 23, 2020		U-1465	
<u>THALIDOMIDE - THALOMID</u>						
N 020785	004	8626531	Oct 23, 2020		U-1465	
<u>TOLVAPTAN - SAMSCA</u>						
N 022275	001	>A> 5753677	May 19, 2020		U-978	
<u>TOLVAPTAN - SAMSCA</u>						
N 022275	002	>A> 5753677	May 19, 2020		U-978	
<u>TOLVAPTAN - SAMSCA</u>						
N 022275	003	>A> 5753677	May 19, 2020		U-978	
<u>TOPIRAMATE - TROKENDI XR</u>						
N 201635	001	>A> 8663683	Nov 16, 2027	DS	U-106	
<u>TOPIRAMATE - TROKENDI XR</u>						
N 201635	002	>A> 8663683	Nov 16, 2027	DS	U-106	
<u>TOPIRAMATE - TROKENDI XR</u>						
N 201635	003	>A> 8663683	Nov 16, 2027	DS	U-106	
<u>TOPIRAMATE - TROKENDI XR</u>						
N 201635	004	>A> 8663683	Nov 16, 2027	DS	U-106	
<u>TRAMETINIB DIMETHYL SULFOXIDE - MEKINIST</u>						
N 204114	001				I-678 ODE	Jan 08, 2017 Jan 08, 2021
<u>TRAMETINIB DIMETHYL SULFOXIDE - MEKINIST</u>						
N 204114	002				I-678 ODE	Jan 08, 2017 Jan 08, 2021

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2014

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>TRAMETINIB DIMETHYL SULFOXIDE - MEKINIST</u>						
N 204114	003				I-678 ODE	Jan 08, 2017 Jan 08, 2021
<u>TREPROSTINIL - REMODULIN</u>						
N 021272	001	>A> 8653137 >A> 8658694	Sep 05, 2028 Sep 05, 2028	U-1437 U-1437		
<u>TREPROSTINIL - REMODULIN</u>						
N 021272	002	>A> 8653137 >A> 8658694	Sep 05, 2028 Sep 05, 2028	U-1437 U-1437		
<u>TREPROSTINIL - REMODULIN</u>						
N 021272	003	>A> 8653137 >A> 8658694	Sep 05, 2028 Sep 05, 2028	U-1437 U-1437		
<u>TREPROSTINIL - REMODULIN</u>						
N 021272	004	>A> 8653137 >A> 8658694	Sep 05, 2028 Sep 05, 2028	U-1437 U-1437		
<u>UMECLIDINIUM BROMIDE; VILANTEROL TRIFENATATE - ANORO ELLIPTA</u>						
N 203975	001				>A> NP	Dec 18, 2016
<u>VANDETANIB - CAPRELSA</u>						
N 022405	001	>A> 8642608	Feb 06, 2022	U-1490		
<u>VANDETANIB - CAPRELSA</u>						
N 022405	002	>A> 8642608	Feb 06, 2022	U-1490		
<u>VARDENAFIL HYDROCHLORIDE - STAXYN</u>						
N 200179	001	8613950	Dec 23, 2028	DP		
<u>ZICONOTIDE ACETATE - PRIALT</u>						
N 021060	001	>A> 8653033 >A> 8653033	Oct 01, 2024 Oct 01, 2024	U-48 U-55		
<u>ZICONOTIDE ACETATE - PRIALT</u>						
N 021060	002	>A> 8653033 >A> 8653033	Oct 01, 2024 Oct 01, 2024	U-48 U-55		
<u>ZICONOTIDE ACETATE - PRIALT</u>						
N 021060	003	>A> 8653033 >A> 8653033	Oct 01, 2024 Oct 01, 2024	U-48 U-55		
<u>ZICONOTIDE ACETATE - PRIALT</u>						
N 021060	004	>A> 8653033 >A> 8653033	Oct 01, 2024 Oct 01, 2024	U-48 U-55		

Footnote:

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

2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.

PATENT AND EXCLUSIVITY TERMS

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

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

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