

APPROVED DRUG PRODUCTS

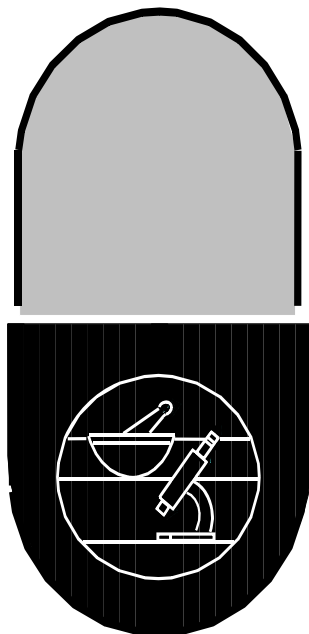
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**CUMULATIVE
SUPPLEMENT 1
JANUARY 2014**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

34th EDITION

Department of Health and Human Services

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

2014

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

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with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

34th EDITION

Cumulative Supplement 1

January 2014

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34th EDITION

**CUMULATIVE SUPPLEMENT 1
January 2014**

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

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

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

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

1.3 APPLICANT NAME CHANGES

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

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

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

1.4 LEVOTHYROXINE SODIUM

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

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

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

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

Levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of 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
LEVOTHEROID	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.

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

>D>	AA	WATSON LABS	500MG; 50MG; 40MG	A 040267	001	Jul 30, 1998	Jan DISC
>A>		@	500MG; 50MG; 40MG	A 040267	001	Jul 30, 1998	Jan DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D>	AA	MALLINCKRODT	500MG/15ML; 7.5MG/15ML	A 040418	001	Jun 27, 2001	Jan DISC
>A>		@	500MG/15ML; 7.5MG/15ML	A 040418	001	Jun 27, 2001	Jan DISC

TABLET; ORAL

>D>		ANEXSIA					
>D>	AA	MALLINCKRODT	500MG; 5MG	A 089160	001	Apr 23, 1987	Jan DISC
>A>		@	500MG; 5MG	A 089160	001	Apr 23, 1987	Jan DISC
>D>	AA		750MG; 10MG	A 040468	001	Oct 31, 2002	Jan DISC
>A>		@	750MG; 10MG	A 040468	001	Oct 31, 2002	Jan DISC
		ANEXSIA 7.5/650					
>D>	AA	MALLINCKRODT	650MG; 7.5MG	A 089725	001	Sep 30, 1987	Jan DISC
>A>		@	650MG; 7.5MG	A 089725	001	Sep 30, 1987	Jan DISC
		HYDROCODONE BITARTRATE AND ACETAMINOPHEN					
>D>	AA	MALLINCKRODT	500MG; 5MG	A 040084	002	Jun 01, 1995	Jan DISC
>A>		@	500MG; 5MG	A 040084	002	Jun 01, 1995	Jan DISC
>D>	AA		500MG; 7.5MG	A 040201	001	Feb 27, 1998	Jan DISC
>A>		@	500MG; 7.5MG	A 040201	001	Feb 27, 1998	Jan DISC
>D>	AA		500MG; 10MG	A 040201	002	Feb 27, 1998	Jan DISC
>A>		@	500MG; 10MG	A 040201	002	Feb 27, 1998	Jan DISC
>D>	AA		650MG; 10MG	A 040084	004	Oct 16, 1996	Jan DISC
>A>		@	650MG; 10MG	A 040084	004	Oct 16, 1996	Jan DISC
>D>	AA	+	660MG; 10MG	A 040084	003	Jul 29, 1996	Jan DISC
>A>		@	660MG; 10MG	A 040084	003	Jul 29, 1996	Jan DISC
>D>	AA		750MG; 7.5MG	A 040084	001	Jun 01, 1995	Jan DISC
>A>		@	750MG; 7.5MG	A 040084	001	Jun 01, 1995	Jan DISC
>D>	AA	VINTAGE PHARMS	650MG; 7.5MG	A 040155	001	Apr 14, 1997	Jan DISC
>A>		@	650MG; 7.5MG	A 040155	001	Apr 14, 1997	Jan DISC
>D>	AA		750MG; 7.5MG	A 040157	001	Apr 12, 1996	Jan DISC
>A>		@	750MG; 7.5MG	A 040157	001	Apr 12, 1996	Jan DISC
>D>	AA	WATSON LABS	500MG; 7.5MG	A 081080	001	Aug 30, 1991	Jan DISC
>A>		@	500MG; 7.5MG	A 081080	001	Aug 30, 1991	Jan DISC
>D>	AA		750MG; 7.5MG	A 081083	001	Aug 30, 1991	Jan DISC
>A>		@	750MG; 7.5MG	A 081083	001	Aug 30, 1991	Jan DISC

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

OXYCODONE AND ACETAMINOPHEN

>D>	AA	MALLINCKRODT	500MG; 5MG	A 040257	001	Aug 04, 1998	Jan DISC
>A>		@	500MG; 5MG	A 040257	001	Aug 04, 1998	Jan DISC
>D>	AA	WATSON LABS	500MG; 5MG	A 040234	001	Oct 30, 1997	Jan DISC
>A>		@	500MG; 5MG	A 040234	001	Oct 30, 1997	Jan DISC

TABLET; ORAL

OXYCODONE AND ACETAMINOPHEN

>D>	AA	WATSON LABS	500MG; 7.5MG	A 040371	001	Dec 29, 2000	Jan DISC	
>A>		@	500MG; 7.5MG	A 040371	001	Dec 29, 2000	Jan DISC	
>D>	AA		650MG; 10MG	A 040371	002	Dec 29, 2000	Jan DISC	
>A>		@	650MG; 10MG	A 040371	002	Dec 29, 2000	Jan DISC	
>D>		PERCOCET						
>D>	AA	+	VINTAGE PHARMS LLC	500MG; 7.5MG	A 040341	001	Jul 26, 1999	Jan DISC
>A>		@	500MG; 7.5MG	A 040341	001	Jul 26, 1999	Jan DISC	
>D>	AA	+		650MG; 10MG	A 040341	002	Jul 26, 1999	Jan DISC
>A>		@		650MG; 10MG	A 040341	002	Jul 26, 1999	Jan DISC

ALPRAZOLAM

TABLET, EXTENDED RELEASE; ORAL

ALPRAZOLAM

>A>	AB	ANI PHARMS INC	0.5MG	A 077725	001	Jul 31, 2006	Jan CAHN
>A>		@	0.5MG	A 077979	001	Feb 28, 2007	Jan CAHN
>A>	AB		1MG	A 077725	002	Jul 31, 2006	Jan CAHN
>A>		@	1MG	A 077979	002	Feb 28, 2007	Jan CAHN
>A>	AB		2MG	A 077725	004	Jul 31, 2006	Jan CAHN
>A>		@	2MG	A 077979	003	Feb 28, 2007	Jan CAHN

TABLET, EXTENDED RELEASE;ORAL
ALPRAZOLAM

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

AMMONIA N-13

INJECTABLE;INTRAVENOUS
AMMONIA N 13

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

INJECTABLE;INJECTION
AMPICILLIN SODIUM

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

BENDROFLUMETHIAZIDE; NADOLOL

TABLET;ORAL
NADOLOL AND BENDROFLUMETHAZIDE

>D> AB	MYLAN	5MG;40MG	A078688	001	Feb 15, 2008	Jan CTNA
>D> AB		5MG;80MG	A078688	002	Feb 15, 2008	Jan CTNA
	NADOLOL AND BENDROFLUMETHIAZIDE					
>A> AB	MYLAN	5MG;40MG	A078688	001	Feb 15, 2008	Jan CTNA
>A> AB		5MG;80MG	A078688	002	Feb 15, 2008	Jan CTNA

BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE

LOTION;TOPICAL
LOTTRISONE

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

BROMFENAC SODIUM

SOLUTION/DROPS;OPHTHALMIC
BROMDAY

>D>	+ ISTA PHARMS INC	EQ 0.09% ACID	N021664	002	Oct 16, 2010	Jan CFTG
>A> AT		EQ 0.09% ACID	N021664	002	Oct 16, 2010	Jan CFTG
	BROMFENAC SODIUM					
>D> AT	COASTAL PHARMS	EQ 0.09% ACID	A201211	001	May 11, 2011	Jan CTEC
>A> AT1		EQ 0.09% ACID	A201211	001	May 11, 2011	Jan CTEC
>A> AT	HI-TECH PHARMACAL	EQ 0.09% ACID	A203395	001	Jan 22, 2014	Jan NEWA
>D> AT	LUITPOLD	EQ 0.09% ACID	A202030	001	Jan 09, 2013	Jan CTEC
>A> AT1		EQ 0.09% ACID	A202030	001	Jan 09, 2013	Jan CTEC

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
BUPROPION HYDROCHLORIDE

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

TABLET;ORAL
BUSPIRONE HYDROCHLORIDE

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

CARISOPRODOL

TABLET;ORAL
CARISOPRODOL

>A> AA	SCIEGEN PHARMS INC	350MG	A203374	001	Jan 27, 2014	Jan NEWA
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CEFACLOXFOR SUSPENSION; ORAL
CEFACLOX

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

CEFADROXIL/CEFADROXIL HEMIHYDRATEFOR SUSPENSION; ORAL
CEFADROXIL

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

CHLORPROPAMIDETABLET; ORAL
CHLORPROPAMIDE

>A>	@	ANI PHARMS INC	100MG	A088768	001	Oct 11, 1984	Jan CAHN
>A>	@		100MG	A088812	001	Oct 19, 1984	Jan CAHN
>A>	@		100MG	A088918	001	Oct 16, 1984	Jan CAHN
>A>	AB		100MG	A088921	001	Apr 12, 1985	Jan CAHN
>A>	@		100MG	A089446	001	Nov 17, 1986	Jan CAHN
>A>	@		250MG	A088813	001	Oct 19, 1984	Jan CAHN
>A>	@		250MG	A088919	001	Oct 16, 1984	Jan CAHN
>A>	AB		250MG	A088922	001	Apr 12, 1985	Jan CAHN
>A>	@		250MG	A089447	001	Nov 17, 1986	Jan CAHN
>D>	@	BARR	100MG	A088812	001	Oct 19, 1984	Jan CAHN
>D>	@		100MG	A089446	001	Nov 17, 1986	Jan CAHN
>D>	@		250MG	A088813	001	Oct 19, 1984	Jan CAHN
>D>	@		250MG	A089447	001	Nov 17, 1986	Jan CAHN
>D>	@	DURAMED PHARMS BARR	100MG	A088918	001	Oct 16, 1984	Jan CAHN
>D>	@		250MG	A088919	001	Oct 16, 1984	Jan CAHN
>D>	AB	PLIVA	100MG	A088921	001	Apr 12, 1985	Jan CAHN
>D>	AB		250MG	A088922	001	Apr 12, 1985	Jan CAHN
>D>	@	TEVA	100MG	A088768	001	Oct 11, 1984	Jan CAHN
		GLUCAMIDE					
>A>	@	ANI PHARMS INC	250MG	A088641	001	Oct 11, 1984	Jan CAHN
>D>	@	TEVA	250MG	A088641	001	Oct 11, 1984	Jan CAHN

CIMETIDINE HYDROCHLORIDESOLUTION; ORAL
CIMETIDINE HYDROCHLORIDE

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

CLOPIDOGREL BISULFATETABLET; ORAL
CLOPIDOGREL BISULFATE

>A>	AB	MACLEODS PHARMS LTD	EQ 75MG BASE	A202928	001	Feb 10, 2014	Jan NEWA
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DAPAGLIFLOZINTABLET; ORAL
FARXIGA

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

DECITABINEPOWDER; INTRAVENOUS
DECITABINE

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

TABLET; ORAL

DESIPRAMINE HYDROCHLORIDE

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

DESMOPRESSIN ACETATE

SOLUTION; NASAL

DESMOPRESSIN ACETATE

>D> AB	SUN PHARMA GLOBAL	0.01%	A078271	001	Dec 23, 2013	Jan CMS2
	SPRAY, METERED; NASAL					
	DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)					
>A> AB	SUN PHARMA GLOBAL	0.01MG/SPRAY	A078271	001	Dec 23, 2013	Jan CMS2

DESVENLAFAXINE

TABLET, EXTENDED RELEASE; ORAL

DESVENLAFAXINE

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

DEXCHLORPHENIRAMINE MALEATE

TABLET; ORAL

DEXCHLORPHENIRAMINE MALEATE

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

DICLOFENAC POTASSIUM

FOR SOLUTION; ORAL

CAMBIA

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

DICLOFENAC SODIUM

SOLUTION; TOPICAL

PENNSAID

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

TABLET; ORAL

LANOXIN

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

DISULFIRAM

TABLET; ORAL

DISULFIRAM

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

DONEPEZIL HYDROCHLORIDE

TABLET; ORAL

DONEPEZIL HYDROCHLORIDE

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

INJECTABLE; INJECTION

DOXERCALCIFEROL

>A> AP	SANDOZ	4MCG/2ML (2MCG/ML)	A200926	001	Feb 04, 2014	Jan NEWA
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ECONAZOLE NITRATECREAM; TOPICAL
SPECTAZOLE

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

ERYTHROMYCIN STEARATETABLET; ORAL
ERYTHROMYCIN STEARATE

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

ESZOPICLONETABLET; ORAL
ESZOPICLONE

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

ETHINYL ESTRADIOL; LEVONORGESTRELTABLET; ORAL-28
LEVONORGESTREL AND ETHINYL ESTRADIOL

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

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

FLUDEOXYGLUCOSE F-18INJECTABLE; INTRAVENOUS
FLUDEOXYGLUCOSE F18

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

FLUOXETINE HYDROCHLORIDECAPSULE; ORAL
FLUOXETINE HYDROCHLORIDE

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

TABLET; ORAL
SARAFEM

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

FOLIC ACIDTABLET; ORAL
FOLIC ACID

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

TABLET; ORAL

FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE

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

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

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

INJECTABLE; SUBCUTANEOUS

COPAXONE

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

TABLET; ORAL

GLYCOPYRROLATE

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

GUANABENZ ACETATE

TABLET; ORAL

GUANABENZ ACETATE

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

ISOSORBIDE MONONITRATE

TABLET; ORAL

ISOSORBIDE MONONITRATE

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

KETOROLAC TROMETHAMINE

SOLUTION/DROPS; OPHTHALMIC

ACUVAIL

>D>		+	ALLERGAN	0.45%	N022427	001	Jul 22, 2009	Jan CFTG
>A>	AT	+		0.45%	N022427	001	Jul 22, 2009	Jan CFTG
>A>	AT		KETOROLAC TROMETHAMINE					
>A>	AT		AKORN	0.45%	A203376	001	Feb 10, 2014	Jan NEWA

LAMIVUDINE; ZIDOVUDINE

TABLET; ORAL

LAMIVUDINE AND ZIDOVUDINE

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

TABLET, DELAYED RELEASE, ORALLY DISINTEGRATING; ORAL

LANSOPRAZOLE

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

LEVOCETIRIZINE DIHYDROCHLORIDE

SOLUTION; ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

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

LIDOCAINE HYDROCHLORIDE

JELLY; TOPICAL

ANESTACON

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

LULICONAZOLECREAM; TOPICAL
LUZU

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

METHAZOLAMIDETABLET; ORAL
METHAZOLAMIDE

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

METRONIDAZOLETABLET; ORAL
METRONIDAZOLE

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

MODAFINILTABLET; ORAL
MODAFINIL

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

MORPHINE SULFATESOLUTION; ORAL
MORPHINE SULFATE

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

NAFCILLIN SODIUMINJECTABLE; INJECTION
NAFCILLIN SODIUM

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

NARATRIPTANTABLET; ORAL
NARATRIPTAN

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

NARATRIPTAN HYDROCHLORIDETABLET; ORAL
NARATRIPTAN

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

NEVIRAPINETABLET; ORAL
NEVIRAPINE

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

NICARDIPINE HYDROCHLORIDECAPSULE; ORAL
NICARDIPINE HYDROCHLORIDE

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

INJECTABLE; INJECTION
NICARDIPINE HYDROCHLORIDE

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

NIZATIDINE

CAPSULE; ORAL
NIZATIDINE

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

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ONDANSETRON HYDROCHLORIDE

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

TABLET; ORAL

ONDANSETRON HYDROCHLORIDE

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

OXANDROLONE

TABLET; ORAL
OXANDRIN

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

OXCARBAZEPINE

TABLET; ORAL
OXCARBAZEPINE

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

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION
PAMIDRONATE DISODIUM

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

PAROXETINE HYDROCHLORIDE

TABLET; ORAL
PAXIL

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

PERINDOPRIL ERBUMINE

TABLET;ORAL

PERINDOPRIL ERBUMINE

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

PHENTERMINE HYDROCHLORIDE

CAPSULE;ORAL

PHENTERMINE HYDROCHLORIDE

>A>	AA	INVAGEN PHARMS	37.5MG	A202846	001	Feb 05, 2014	Jan NEWA
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TABLET;ORAL

PHENTERMINE HYDROCHLORIDE

>A>	AA	INVAGEN PHARMS	37.5MG	A202942	001	Feb 05, 2014	Jan NEWA
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PHENYTOIN SODIUM

CAPSULE;ORAL

EXTENDED PHENYTOIN SODIUM

>A>		@ ANI PHARMS INC	100MG EXTENDED	A089441	001	Dec 18, 1986	Jan CAHN
>D>		@ PLIVA	100MG EXTENDED	A089441	001	Dec 18, 1986	Jan CAHN

PROMPT PHENYTOIN SODIUM

>A>		@ ANI PHARMS INC	100MG PROMPT	A080259	001		Jan CAHN
>D>		@ IVAX SUB TEVA PHARMS	100MG PROMPT	A080259	001		Jan CAHN

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

MIRAPEX ER

>D>	+	BOEHRINGER INGELHEIM	0.375MG	N022421	001	Feb 19, 2010	Jan CFTG
>A>	AB	+	0.375MG	N022421	001	Feb 19, 2010	Jan CFTG
>D>			0.75MG	N022421	002	Feb 19, 2010	Jan CFTG
>A>	AB		0.75MG	N022421	002	Feb 19, 2010	Jan CFTG
>D>			1.5MG	N022421	003	Feb 19, 2010	Jan CFTG
>A>	AB		1.5MG	N022421	003	Feb 19, 2010	Jan CFTG
>D>			2.25MG	N022421	006	Jun 17, 2011	Jan CFTG
>A>	AB		2.25MG	N022421	006	Jun 17, 2011	Jan CFTG
>D>			3MG	N022421	004	Feb 19, 2010	Jan CFTG
>A>	AB		3MG	N022421	004	Feb 19, 2010	Jan CFTG
>D>			3.75MG	N022421	007	Jun 17, 2011	Jan CFTG
>A>	AB		3.75MG	N022421	007	Jun 17, 2011	Jan CFTG
>D>			4.5MG	N022421	005	Feb 19, 2010	Jan CFTG
>A>	AB		4.5MG	N022421	005	Feb 19, 2010	Jan CFTG

PRAMIPEXOLE DIHYDROCHLORIDE

>A>	AB	ANCHEN PHARMS	0.375MG	A202206	001	Feb 06, 2014	Jan NEWA
>A>	AB		0.75MG	A202206	002	Feb 06, 2014	Jan NEWA
>A>	AB		1.5MG	A202206	003	Feb 06, 2014	Jan NEWA
>A>	AB		2.25MG	A202206	004	Feb 06, 2014	Jan NEWA
>A>	AB		3MG	A202206	005	Feb 06, 2014	Jan NEWA
>A>	AB		3.75MG	A202206	006	Feb 06, 2014	Jan NEWA
>A>	AB		4.5MG	A202206	007	Feb 06, 2014	Jan NEWA

PRIMAQUINE PHOSPHATE

TABLET;ORAL

PRIMAQUINE

>D>	+	SANOFI AVENTIS US	EQ 15MG BASE	N008316	001		Jan CFTG
>A>	AB	+	EQ 15MG BASE	N008316	001		Jan CFTG

PRIMAQUINE PHOSPHATE

>A>	AB	ALVOGEN INC	EQ 15MG BASE	A203924	001	Feb 03, 2014	Jan NEWA
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PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

PROCAINAMIDE HYDROCHLORIDE

>A>		@ ANI PHARMS INC	1GM	A040111	001	Dec 13, 1996	Jan CAHN
>A>		@	250MG	A088958	001	Dec 02, 1985	Jan CAHN
>A>		@	500MG	A088959	001	Dec 02, 1985	Jan CAHN
>A>		@	750MG	A089438	001	Mar 23, 1987	Jan CAHN
>D>		@ COPLEY PHARM	1GM	A040111	001	Dec 13, 1996	Jan CAHN
>D>		@	750MG	A089438	001	Mar 23, 1987	Jan CAHN
>D>		@ PLIVA	250MG	A088958	001	Dec 02, 1985	Jan CAHN

TABLET, EXTENDED RELEASE;ORAL
PROCAINAMIDE HYDROCHLORIDE

>D>	@	500MG	A088959	001	Dec 02, 1985	Jan CAHN
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PROPAFENONE HYDROCHLORIDE

TABLET;ORAL

PROPAFENONE HYDROCHLORIDE

>A>	AB	ANI PHARMS INC	150MG	A076550	001	Apr 23, 2004	Jan CAHN
>A>	AB		225MG	A076550	002	Apr 23, 2004	Jan CAHN
>A>	AB		300MG	A076550	003	Apr 23, 2004	Jan CAHN
>D>	AB	PLIVA	150MG	A076550	001	Apr 23, 2004	Jan CAHN
>D>	AB		225MG	A076550	002	Apr 23, 2004	Jan CAHN
>D>	AB		300MG	A076550	003	Apr 23, 2004	Jan CAHN

PROPRANOLOL HYDROCHLORIDE

TABLET;ORAL

>D>		INDERAL					
>D>	AB	WYETH PHARMS INC	40MG	N016418	002		Jan DISC
>A>		@	40MG	N016418	002		Jan DISC
>D>	AB		60MG	N016418	009	Oct 18, 1982	Jan DISC
>A>		@	60MG	N016418	009	Oct 18, 1982	Jan DISC
>D>	AB	+	80MG	N016418	004		Jan DISC
>A>		@	80MG	N016418	004		Jan DISC
		PROPRANOLOL HYDROCHLORIDE					
>A>		@ ANI PHARMS INC	90MG	A071977	001	Apr 06, 1988	Jan CAHN
>D>		@ PLIVA	90MG	A071977	001	Apr 06, 1988	Jan CAHN

PROPYLTHIOURACIL

TABLET;ORAL

PROPYLTHIOURACIL

>A>		@ ANI PHARMS INC	50MG	A080215	001		Jan CAHN
>D>		@ IVAX SUB TEVA PHARMS	50MG	A080215	001		Jan CAHN

REPAGLINIDE

TABLET;ORAL

REPAGLINIDE

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

RISPERIDONE

SOLUTION;ORAL

RISPERIDONE

>A>	AA	ANI PHARMS INC	1MG/ML	A076440	001	Jan 30, 2009	Jan CAHN
>D>	AA	TEVA	1MG/ML	A076440	001	Jan 30, 2009	Jan CAHN

RIZATRIPTAN BENZOATE

TABLET;ORAL

RIZATRIPTAN BENZOATE

>A>	AB	MACLEODS PHARMS LTD	EQ 5MG BASE	A203147	001	Feb 11, 2014	Jan NEWA
>A>	AB		EQ 10MG BASE	A203147	002	Feb 11, 2014	Jan NEWA

SUMATRIPTAN SUCCINATE

INJECTABLE;SUBCUTANEOUS

SUMATRIPTAN SUCCINATE

>A>	AB	DR REDDYS LABS INC	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A090495	001	Jan 29, 2014	Jan NEWA
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SUNITINIB MALATE

CAPSULE;ORAL

>A> SUNITINIB MALATE

>A> AB	MYLAN PHARMS INC	EQ 12.5MG BASE	A201275	001	Jan 30, 2014	Jan NEWA
>A> AB		EQ 25MG BASE	A201275	002	Jan 30, 2014	Jan NEWA
>A> AB		EQ 37.5MG BASE	A201275	003	Jan 30, 2014	Jan NEWA
>A> AB		EQ 50MG BASE	A201275	004	Jan 30, 2014	Jan NEWA

SUTENT

>D>	CPPI CV	EQ 12.5MG BASE	N021938	001	Jan 26, 2006	Jan CFTG
>A> AB		EQ 12.5MG BASE	N021938	001	Jan 26, 2006	Jan CFTG
>D>		EQ 25MG BASE	N021938	002	Jan 26, 2006	Jan CFTG
>A> AB		EQ 25MG BASE	N021938	002	Jan 26, 2006	Jan CFTG
>D>		EQ 37.5MG BASE	N021938	004	Mar 31, 2009	Jan CFTG
>A> AB		EQ 37.5MG BASE	N021938	004	Mar 31, 2009	Jan CFTG
>D>	+	EQ 50MG BASE	N021938	003	Jan 26, 2006	Jan CFTG
>A> AB	+	EQ 50MG BASE	N021938	003	Jan 26, 2006	Jan CFTG

TASIMELTEON

CAPSULE;ORAL

>A> HETLIOZ

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

TABLET, EXTENDED RELEASE;ORAL

THEOCHRON

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

TRANEXAMIC ACID

TABLET;ORAL

TRANEXAMIC ACID

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

GEL;TOPICAL

RETIN-A-MICRO

>A>	+	VALEANT INTL	0.08%	N020475	003	Jan 28, 2014	Jan NEWA
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VALACYCLOVIR HYDROCHLORIDE

TABLET;ORAL

VALACYCLOVIR HYDROCHLORIDE

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

VALPROIC ACID

SYRUP;ORAL

VALPROIC ACID

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

ZONISAMIDE

CAPSULE;ORAL

ZONISAMIDE

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

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE;ORAL

DEXBROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE

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

DIPHENHYDRAMINE HYDROCHLORIDE; NAPROXEN SODIUM

>A> TABLET;ORAL

>A> ALEVE PM

>A>	+ BAYER HLTHCARE	25MG;220MG	N205352	001	Jan 17, 2014	Jan NEWA
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**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT
ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

CUMULATIVE SUPPLEMENT NUMBER 1 JANUARY 2014

NO JANUARY 2014 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

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

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

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

NO JANUARY 2014 ADDITIONS

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

See List footnote for information regarding List content

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

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

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<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 001	>A> 8597876	Jun 23, 2019	U-1305			
	>A> 8597876*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 002	>A> 8597876	Jun 23, 2019	U-1305			
	>A> 8597876*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 003	>A> 8597876	Jun 23, 2019	U-1305			
	>A> 8597876*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 004	>A> 8597876	Jun 23, 2019	U-1305			
	>A> 8597876*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 005	>A> 8597876	Jun 23, 2019	U-1305			
	>A> 8597876*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 006	>A> 8597876	Jun 23, 2019	U-1305			
	>A> 8597876*PED	Dec 23, 2019				
<u>DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX</u>						
N 021038 001					>A> M-61	Jun 17, 2016
					>A> PED	Dec 17, 2016
<u>DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX</u>						
N 021038 002					>A> M-61	Jun 17, 2016
					>A> PED	Dec 17, 2016
<u>DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX</u>						
N 021038 003					>A> M-61	Jun 17, 2016
					>A> PED	Dec 17, 2016
<u>DICLOFENAC POTASSIUM - ZIPSOR</u>						
N 022202 001	>A> 6287594	Jan 15, 2019	DP			
	>A> 8623920	Feb 24, 2029	U-1482			
<u>DICLOFENAC SODIUM - PENNSAID</u>						
N 204623 001					>A> NP	Jan 16, 2017
<u>DIPHENHYDRAMINE HYDROCHLORIDE; NAPROXEN SODIUM - ALEVE PM</u>						
N 205352 001					>A> NC	Jan 17, 2017
<u>DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - BEYAZ</u>						
N 022532 001	>A> 8617597	Feb 08, 2030	DP			
<u>DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - SAFYRAL</u>						
N 022574 001	>A> 8617597	Feb 08, 2030	DP			
<u>FLUOCINONIDE - FLUOCINONIDE</u>						
A 090256 001					>A> PC	Jul 13, 2014
<u>GABAPENTIN ENACARBIL - HORIZANT</u>						
N 022399 001					>A> ODE	Jun 06, 2019
<u>GABAPENTIN ENACARBIL - HORIZANT</u>						
N 022399 002					>A> ODE	Jun 06, 2019
<u>IMATINIB MESYLATE - GLEEVEC</u>						
N 021335 001	>A> RE43932	Jan 16, 2019	DS DP			
	>A> RE43932*PED	Jul 16, 2019				
<u>IMATINIB MESYLATE - GLEEVEC</u>						
N 021335 002	>A> RE43932	Jan 16, 2019	DS DP			
	>A> RE43932*PED	Jul 16, 2019				
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 001	>A> 8626531	Oct 23, 2020	U-1210			
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 002	>A> 8626531	Oct 23, 2020	U-1210			
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 003	>A> 8626531	Oct 23, 2020	U-1210			
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 004	>A> 8626531	Oct 23, 2020	U-1210			

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

See List footnote for information regarding List content

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<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 005	>A> 8626531	Oct 23, 2020	U-1210			
<u>LENALIDOMIDE - REVLIMID</u>						
N 021880 006	>A> 8626531	Oct 23, 2020	U-1210			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 001	>A> 8618135	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 002	>A> 8618135	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 003	>A> 8618135	Mar 07, 2025	U-1316			
<u>LOXAPINE - ADASUVE</u>						
N 022549 001	>A> 7052679	Oct 26, 2021	DP			
	>A> 7537009	Oct 28, 2024	DP			
	>A> 8074644	Jul 25, 2022	DP			
<u>METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE - KOMBIGLYZE XR</u>						
N 200678 001	>A> 8628799	Jul 13, 2025	DP			
<u>METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE - KOMBIGLYZE XR</u>						
N 200678 002	>A> 8628799	Jul 13, 2025	DP			
<u>METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE - KOMBIGLYZE XR</u>						
N 200678 003	>A> 8628799	Jul 13, 2025	DP			
<u>METHYLPHENIDATE - DAYTRANA</u>						
N 021514 001	>A> 8632802	Oct 07, 2025	DP			
<u>METHYLPHENIDATE - DAYTRANA</u>						
N 021514 002	>A> 8632802	Oct 07, 2025	DP			
<u>METHYLPHENIDATE - DAYTRANA</u>						
N 021514 003	>A> 8632802	Oct 07, 2025	DP			
<u>METHYLPHENIDATE - DAYTRANA</u>						
N 021514 004	>A> 8632802	Oct 07, 2025	DP			
<u>METHYLPHENIDATE HYDROCHLORIDE - CONCERTA</u>						
N 021121 001	>A> 8629179	Jul 31, 2017	DP			
	>A> 8629179*PED	Jan 31, 2018				
<u>METHYLPHENIDATE HYDROCHLORIDE - CONCERTA</u>						
N 021121 002	>A> 8629179	Jul 31, 2017	DP			
	>A> 8629179*PED	Jan 31, 2018				
<u>METHYLPHENIDATE HYDROCHLORIDE - CONCERTA</u>						
N 021121 003	>A> 8629179	Jul 31, 2017	DP			
	>A> 8629179*PED	Jan 31, 2018				
<u>METHYLPHENIDATE HYDROCHLORIDE - CONCERTA</u>						
N 021121 004	>A> 8629179	Jul 31, 2017	DP			
	>A> 8629179*PED	Jan 31, 2018				
<u>MYCOPHENOLIC ACID - MYCOPHENOLIC ACID</u>						
A 091248 001					>A> PC	Jul 07, 2014
<u>NIACIN - NIACIN</u>						
A 076250 001					>A> PC	Mar 19, 2014
<u>NIACIN - NIACIN</u>						
A 076378 001					>A> PC	Mar 19, 2014
<u>NIACIN - NIACIN</u>						
A 076378 002					>A> PC	Mar 19, 2014
<u>NITRIC OXIDE - INOMAX</u>						
N 020845 002					>A> M-132	Dec 21, 2013
					>A> PED	Jun 21, 2014
<u>NITRIC OXIDE - INOMAX</u>						
N 020845 003					>A> M-132	Dec 21, 2013
					>A> PED	Jun 21, 2014
<u>POMALIDOMIDE - POMALYST</u>						
N 204026 001	>A> 8626531	Oct 23, 2020	U-1361			
<u>POMALIDOMIDE - POMALYST</u>						
N 204026 002	>A> 8626531	Oct 23, 2020	U-1361			

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

See List footnote for information regarding List content

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

Footnote:

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

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

PATENT AND EXCLUSIVITY TERMS

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

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

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