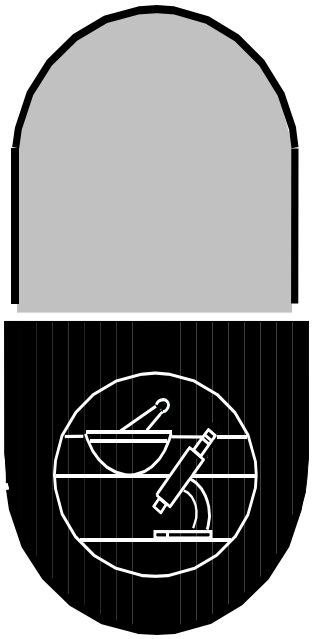
CUMULATIVE SUPPLEMENT 2
FEBRUARY 2015



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

35th 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

2015

Prepared By
Office of Generic Drugs
Office of Medical Products and Tobacco
Center for Drug Evaluation and Research
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CUMULATIVE SUPPLEMENT 2
February 2015

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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: 301-595-1446.

mail to: FDA/CDER Orange Book Staff
Office of Generic Drugs
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 cwill be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

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

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)

1.4 LEVOTHYROXINE SODIUM

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

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

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

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

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

Trade Name	Applicant	Potency	TE Code	Appl No	Product No
UNITHROID	STEVENS J	0.025MG	AB1	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB1	76187	001
LEVOXYL	KING PHARMS	0.025MG	AB1	21301	001
SYNTHROID	ABBOTT	0.025MG	AB1	21402	001
LEVO-T	ALARA PHARM	0.025MG	AB1	21342	001
SYNTHROID	ABBOTT	0.025MG	AB2	21402	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB2	76187	001
LEVO-T	ALARA PHARM	0.025MG	AB2	21342	001
UNITHROID	STEVENS J	0.025MG	AB2	21210	001
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 (December of the previous Annual Edition) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

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

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

CATEGORIES COUNTED	DEC 2014	MAR 2015	JUN 2015	SEPT 2015	DEC 2015
DRUG PRODUCTS LISTED	16150				
SINGLE SOURCE	2572 (15.9%)				

MULTISOURCE	13578 (84.1%)
THERAPEUTICALLY EQUIVALENT	13443 (83.2%)
NOT THERAPEUTICALLY EQUIVALENT	135 (0.8%)
EXCEPTIONS[1]	77 (0.5%)
NEW MOLECULAR ENTITIES APPROVED	13
NUMBER OF APPLICANTS	927

[1]Amino acid-containing products of varying composition (see Introduction, page xx of the List).

1.7 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The application number preceded by "N" is a New Drug Application (NDA or innovator). The application number preceded by an "A" is an Abbreviated New Drug Application (ANDA or generic). The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

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

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET;ORAL
FIORICET

>A>		@	ACTAVIS LABS UT INC	325MG;50MG;40MG	A088616	001	Nov 09, 1984	Feb	CAHN
>D>		@	WATSON PHARMS	325MG;50MG;40MG	A088616	001	Nov 09, 1984	Feb	CAHN

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE;ORAL
FIORICET W/ CODEINE

AB	+		ACTAVIS LABS UT INC	325MG;50MG;40MG;30MG	N020232	001	Jul 30, 1992	Jan	CAHN

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET;ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D>		+	MIKART	325MG;2.5MG	A040846	001	Jun 09, 2010	Feb	CTEC
>A>	AA	+		325MG;2.5MG	A040846	001	Jun 09, 2010	Feb	CTEC

NORCO

>A>	AA		ACTAVIS LABS FL INC	325MG;2.5MG	A040148	004	Jul 07, 2014	Feb	NEWA
>A>	AA			325MG;5MG	A040148	005	Jul 07, 2014	Feb	NEWA

ALFUZOSIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
ALFUZOSIN HYDROCHLORIDE

>D>	AB		WOCKHARDT LTD	10MG	A090221	001	Aug 10, 2012	Feb	DISC
>A>		@		10MG	A090221	001	Aug 10, 2012	Feb	DISC

AMANTADINE HYDROCHLORIDE

CAPSULE;ORAL
AMANTADINE HYDROCHLORIDE

	AB		BANNER LIFE SCIENCES	100MG	A078720	001	May 29, 2008	Jan	CAHN

AMINO ACIDS

INJECTABLE;INJECTION
BRANCHAMIN 4% IN PLASTIC CONTAINER

>D>			BAXTER HLTHCARE	4% (4GM/100ML)	N018684	001	Sep 28, 1984	Feb	DISC
>A>		@		4% (4GM/100ML)	N018684	001	Sep 28, 1984	Feb	DISC

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE;INJECTION
TRAVASOL 3.5% SULFITE FREE W/ ELECTROLYTES IN PLASTIC CONTAINER

>D>			BAXTER HLTHCARE	3.5%;51MG/100ML;131MG/100ML;218MG/100ML;35MG/100ML	N020177	001	Oct 23, 1995	Feb	DISC
>A>		@		3.5%;51MG/100ML;131MG/100ML;218MG/100ML;35MG/100ML	N020177	001	Oct 23, 1995	Feb	DISC

AMLODIPINE BESYLATE; PERINDOPRIL ARGININE

TABLET;ORAL
PRESTALIA

			SYMPLMED PHARMS LLC	EQ 2.5MG BASE;3.5MG	N205003	001	Jan 21, 2015	Jan	NEWA
				EQ 5MG BASE;7MG	N205003	002	Jan 21, 2015	Jan	NEWA
		+		EQ 10MG BASE;14MG	N205003	003	Jan 21, 2015	Jan	NEWA

AMMONIA N-13

INJECTABLE;INTRAVENOUS
AMMONIA N 13

			NCM USA BRONX LLC	3.75-260mCi/mL	A204515	001	Feb 04, 2015	Jan	NEWA

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE;ORAL
FIORINAL

	AA	+	ACTAVIS LABS UT INC	325MG;50MG;40MG	N017534	005	Apr 16, 1986	Jan	CAHN

TABLET;ORAL
FIORINAL

		@	ACTAVIS LABS UT INC	325MG;50MG;40MG	N017534	003	Apr 16, 1986	Jan	CAHN

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE;ORAL

FIORINAL W/CODEINE

AB	+	ACTAVIS LABS UT INC	325MG;50MG;40MG;30MG	N019429	003	Oct 26, 1990	Jan	CAHN

ATAZANAVIR SULFATE; COBICISTAT

TABLET;ORAL

EVOTAZ

	+	BRISTOL MYERS SQUIBB	EQ 300MG BASE;150MG	N206353	001	Jan 29, 2015	Jan	NEWA

ATENOLOL

TABLET;ORAL

TENORMIN

>A> AB		ALVOGEN IPCO SARL	25MG	N018240	004	Apr 09, 1990	Feb	CAHN
>A> AB			50MG	N018240	001		Feb	CAHN
>A> AB	+		100MG	N018240	002		Feb	CAHN
>D> AB		ASTRAZENECA	25MG	N018240	004	Apr 09, 1990	Feb	CAHN
>D> AB			50MG	N018240	001		Feb	CAHN
>D> AB	+		100MG	N018240	002		Feb	CAHN

ATENOLOL; CHLORTHALIDONE

TABLET;ORAL

TENORETIC 100

>A> AB	+	ALVOGEN IPCO SARL	100MG;25MG	N018760	001	Jun 08, 1984	Feb	CAHN
>D> AB	+	ASTRAZENECA	100MG;25MG	N018760	001	Jun 08, 1984	Feb	CAHN

TENORETIC 50

>A> AB		ALVOGEN IPCO SARL	50MG;25MG	N018760	002	Jun 08, 1984	Feb	CAHN
>D> AB		ASTRAZENECA	50MG;25MG	N018760	002	Jun 08, 1984	Feb	CAHN

ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

TABLET;ORAL

MOTOFEN

>A>	+	SEBELA IRELAND LTD	0.025MG;1MG	N017744	002		Feb	CAHN
>D>	+	VALEANT	0.025MG;1MG	N017744	002		Feb	CAHN

MOTOFEN HALF-STRENGTH

>A>	@	SEBELA IRELAND LTD	0.025MG;0.5MG	N017744	001		Feb	CAHN
>D>	@	VALEANT	0.025MG;0.5MG	N017744	001		Feb	CAHN

>A> AVIBACTAM SODIUM; CEFTAZIDIME

>A> POWDER;IV (INFUSION)

>A> AVYCAZ

>A>	+	CEREXA INC	EQ 0.5GM BASE;2GM/VIAL	N206494	001	Feb 25, 2015	Feb	NEWA

BENAZEPRIL HYDROCHLORIDE

TABLET;ORAL

BENAZEPRIL HYDROCHLORIDE

AB		AMNEAL PHARMS LLC	5MG	A076820	001	Feb 03, 2006	Jan	CAHN
AB			10MG	A076820	002	Feb 03, 2006	Jan	CAHN
AB			20MG	A076820	003	Feb 03, 2006	Jan	CAHN
AB			40MG	A076820	004	Feb 03, 2006	Jan	CAHN

BENZONATATE

CAPSULE;ORAL

BENZONATATE

AA		APOTEX INC	100MG	A091310	001	Jan 16, 2015	Jan	NEWA
AA			200MG	A091310	002	Jan 16, 2015	Jan	NEWA
AA		BANNER LIFE SCIENCES	100MG	A081297	001	Jan 29, 1993	Jan	CAHN
AA			200MG	A081297	002	Oct 30, 2007	Jan	CAHN

BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE

GEL;TOPICAL

ONEXTON

	+	DOW PHARM	3.75%;EQ 1.2% BASE	N050819	002	Nov 24, 2014	Jan	CRLD

BETHANECHOL CHLORIDE

TABLET;ORAL

BETHANECHOL CHLORIDE

>D>	@	LANNETT HOLDINGS INC	5MG	A040703	001	Mar 27, 2008	Feb	CMFD
>A> AA			5MG	A040703	001	Mar 27, 2008	Feb	CMFD
>D>	@		50MG	A040677	001	Mar 27, 2008	Feb	CMFD
>A> AA			50MG	A040677	001	Mar 27, 2008	Feb	CMFD

TABLET;ORAL
DUVOID

AA		WELLSPRING PHARM	10MG	A086262	001			Jan CMFD

BEXAROTENE
CAPSULE;ORAL
BEXAROTENE

	@	BANNER LIFE SCIENCES	75MG	A203174	001	Aug 12, 2014		Jan CAHN

BIMATOPROST
SOLUTION/DROPS;OPHTHALMIC
BIMATOPROST

>A>								
>A> AT	+	LUPIN LTD	0.03%	A203991	001	Feb 20, 2015		Feb NEWA

BROMFENAC SODIUM
SOLUTION/DROPS;OPHTHALMIC
BROMFENAC SODIUM

AT1		PADDOCK LLC	EQ 0.09% ACID	A201941	001	Feb 10, 2015		Jan NEWA

BUPRENORPHINE HYDROCHLORIDE
TABLET;SUBLINGUAL
BUPRENORPHINE HYDROCHLORIDE

>A> AB		ACTAVIS ELIZABETH	EQ 2MG BASE	A090819	001	Feb 19, 2015		Feb NEWA
>A> AB			EQ 8MG BASE	A090819	002	Feb 19, 2015		Feb NEWA
>A> AB		MYLAN PHARMS INC	EQ 2MG BASE	A201066	001	Mar 06, 2015		Feb NEWA
>A> AB			EQ 8MG BASE	A201066	002	Mar 06, 2015		Feb NEWA

BUPROPION HYDROBROMIDE
TABLET, EXTENDED RELEASE;ORAL
APLENZIN

>D>		VALEANT BERMUDA	174MG	N022108	001	Apr 23, 2008		Feb CAHN
>D>			348MG	N022108	002	Apr 23, 2008		Feb CAHN
>D>	+		522MG	N022108	003	Apr 23, 2008		Feb CAHN
>A>		VALEANT PHARMS NORTH	174MG	N022108	001	Apr 23, 2008		Feb CAHN
>A>			348MG	N022108	002	Apr 23, 2008		Feb CAHN
>A>	+		522MG	N022108	003	Apr 23, 2008		Feb CAHN

CALCITRIOL
CAPSULE;ORAL
CALCITRIOL

AB		BANNER LIFE SCIENCES	0.25MCG	A091174	001	May 24, 2013		Jan CAHN
AB			0.5MCG	A091174	002	May 24, 2013		Jan CAHN
AB		STRIDES PHARMA	0.25MCG	A091356	001	Dec 12, 2014		Jan CAHN
AB			0.5MCG	A091356	002	Dec 12, 2014		Jan CAHN

CALCIUM ACETATE
TABLET;ORAL
CALCIUM ACETATE

AB		ZYDUS PHARMS USA INC	EQ 169MG CALCIUM	A202885	001	Jan 22, 2015		Jan NEWA

CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE
INJECTABLE;INJECTION
PRISMASOL B22GK 2/0 IN PLASTIC CONTAINER

	+	GAMBRO RENAL PRODS	N/A/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.157GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML)	N021703	010	Oct 10, 2008		Jan CPOT

PRISMASOL B22GK 2/2.5 IN PLASTIC CONTAINER

	@	GAMBRO RENAL PRODS	3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.157GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML)	N021703	012	Oct 10, 2008		Jan CPOT

PRISMASOL B22GK 4/0 IN PLASTIC CONTAINER

	+	GAMBRO RENAL PRODS	N/A/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML)	N021703	011	Oct 10, 2008		Jan CPOT

PRISMASOL B22GK 4/2.5 IN PLASTIC CONTAINER

	+	GAMBRO RENAL PRODS	3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML)	N021703	013	Oct 10, 2008		Jan CPOT

INJECTABLE;INJECTION

PRISMASOL BGK 0/2.5 IN PLASTIC CONTAINER

+	GAMBRO RENAL PRODS	3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	006	Oct 25, 2006	Jan CPOT

PRISMASOL BGK 2/0 IN PLASTIC CONTAINER

+	GAMBRO RENAL PRODS	N/A/1000ML;20GM/1000ML;5.4GM/1000ML;2.03GM/1000ML;0.157GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	002	Oct 25, 2006	Jan CPOT

PRISMASOL BGK 2/3.5 IN PLASTIC CONTAINER

+	GAMBRO RENAL PRODS	5.15GM/1000ML;20GM/1000ML;5.4GM/1000ML;2.03GM/1000ML;0.157GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	003	Oct 25, 2006	Jan CPOT

PRISMASOL BGK 4/0 IN PLASTIC CONTAINER

@	GAMBRO RENAL PRODS	N/A/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	005	Oct 25, 2006	Jan CPOT

PRISMASOL BGK 4/0/1.2 IN PLASTIC CONTAINER

+	GAMBRO RENAL PRODS	N/A/1000ML;20GM/1000ML;5.4GM/1000ML;2.44GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	015	Oct 10, 2008	Jan CPOT

PRISMASOL BGK 4/2.5 IN PLASTIC CONTAINER

+	GAMBRO RENAL PRODS	3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	004	Oct 25, 2006	Jan CPOT

PRISMASOL BGK 4/3.5 IN PLASTIC CONTAINER

@	GAMBRO RENAL PRODS	5.15GM/1000ML;20GM/1000ML;5.4GM/1000ML;2.03GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	008	Oct 25, 2006	Jan CPOT

PRISMASOL BK 0/0 IN PLASTIC CONTAINER

@	GAMBRO RENAL PRODS	N/A/1000ML;N/A/1000ML;5.4GM/1000ML;3.05GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	007	Oct 25, 2006	Jan CPOT

PRISMASOL BK 0/0/1.2 IN PLASTIC CONTAINER

+	GAMBRO RENAL PRODS	N/A/1000ML;N/A/1000ML;5.4GM/1000ML;2.44GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	014	Oct 10, 2008	Jan CPOT

PRISMASOL BK 0/3.5 IN PLASTIC CONTAINER

+	GAMBRO RENAL PRODS	5.15GM/1000ML;N/A/1000ML;5.4GM/1000ML;2.03GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	001	Oct 25, 2006	Jan CPOT

PRISMASOL BK 4/2.5 IN PLASTIC CONTAINER

@	GAMBRO RENAL PRODS	3.68GM/1000ML;N/A/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N	021703	009	Oct 25, 2006	Jan CPOT

>D> CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE

>D> INJECTABLE;INJECTION

>D> PHOXILLUM B22K 4/0 IN PLASTIC CONTAINER

>D> +	GAMBRO LUNDIA	N/A/1000ML;N/A/1000ML;N/A/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;6.95GM/1000ML;0.187GM/1000ML (5000ML)	N	207026	002	Jan 13, 2015	Feb CAIN
+		N/A/1000ML;N/A/1000ML;N/A/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;6.95GM/1000ML;0.187GM/1000ML (5000ML)	N	207026	002	Jan 13, 2015	Jan NEWA

>D> PHOXILLUM BK 4/2.5 IN PLASTIC CONTAINER

>D> +	GAMBRO LUNDIA	3.68GM/1000ML;N/A/1000ML;N/A/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.34GM/1000ML;0.187GM/1000ML (5000ML)	N	207026	001	Jan 13, 2015	Feb CAIN
+		3.68GM/1000ML;N/A/1000ML;N/A/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.34GM/1000ML;0.187GM/1000ML (5000ML)	N	207026	001	Jan 13, 2015	Jan NEWA

>A>		CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE							
>A>		INJECTABLE;INJECTION							
>A>		PHOXILLUM B22K 4/0 IN PLASTIC CONTAINER							
>A>	+	GAMBRO LUNDIA	N/A/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;6.95GM/1000ML;0.187GM/1000ML (5000ML)	N207026	002	Jan 13, 2015	Feb CAIN		
>A>		PHOXILLUM BK 4/2.5 IN PLASTIC CONTAINER							
>A>	+	GAMBRO LUNDIA	3.68GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.34GM/1000ML;0.187	N207026	001	Jan 13, 2015	Feb CAIN		
		CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE							
		TABLET;ORAL							
		CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE							
>A>	AB	MACLEODS PHARMS LTD	16MG;12.5MG	A204100	001	Feb 27, 2015	Feb NEWA		
>A>	AB		32MG;12.5MG	A204100	002	Feb 27, 2015	Feb NEWA		
>A>	AB		32MG;25MG	A204100	003	Feb 27, 2015	Feb NEWA		
		CARBIDOPA; LEVODOPA							
		CAPSULE, EXTENDED RELEASE;ORAL							
		RYTARY							
		IMPAX LABS INC	23.75MG;95MG	N203312	001	Jan 07, 2015	Jan NEWA		
			36.25MG;145MG	N203312	002	Jan 07, 2015	Jan NEWA		
			48.75MG;195MG	N203312	003	Jan 07, 2015	Jan NEWA		
	+		61.25MG;245MG	N203312	004	Jan 07, 2015	Jan NEWA		
		SUSPENSION;ENTERAL							
		DUOPA							
	+	ABBVIE INC	4.63MG/ML;20MG/ML	N203952	001	Jan 09, 2015	Jan NEWA		
		CEFAZOLIN SODIUM							
		INJECTABLE;INJECTION							
		CEFAZOLIN SODIUM							
	AP	FACTA FARMA	EQ 1GM BASE/VIAL	A063207	001	Dec 27, 1991	Jan CAHN		
	AP		EQ 10GM BASE/VIAL	A063209	001	Dec 27, 1991	Jan CAHN		
	AP	+	EQ 20GM BASE/VIAL	A063209	002	Apr 30, 1999	Jan CAHN		
	AP		EQ 500MG BASE/VIAL	A063214	001	Dec 27, 1991	Jan CAHN		
		CEFTRIAXONE SODIUM							
		INJECTABLE;INJECTION							
		CEFTRIAXONE							
	AP	FACTA FARMA	EQ 10GM BASE/VIAL	A065269	001	Feb 28, 2007	Jan CAHN		
		INJECTABLE;INTRAMUSCULAR, INTRAVENOUS							
		CEFTRIAXONE							
		@ FACTA FARMA	EQ 1GM BASE/VIAL	A065268	001	Feb 28, 2007	Jan CAHN		
		@	EQ 2GM BASE/VIAL	A065268	002	Feb 28, 2007	Jan CAHN		
		CEFUROXIME SODIUM							
		INJECTABLE;INJECTION							
		CEFUROXIME SODIUM							
	AP	FACTA FARMA	EQ 1.5GM BASE/VIAL	A064125	002	May 30, 1997	Jan CAHN		
	AP		EQ 7.5GM BASE/VIAL	A064124	001	May 30, 1997	Jan CAHN		
		INJECTABLE;INTRAMUSCULAR, INTRAVENOUS							
		CEFUROXIME SODIUM							
	AB	FACTA FARMA	EQ 750MG BASE/VIAL	A064125	001	May 30, 1997	Jan CAHN		
		CELECOXIB							
		CAPSULE;ORAL							
		CELECOXIB							
	AB	MYLAN PHARMS INC	100MG	A078857	002	Feb 11, 2015	Jan NEWA		
	AB		200MG	A078857	003	Feb 11, 2015	Jan NEWA		
	AB		400MG	A078857	004	Feb 11, 2015	Jan NEWA		
	AB	WATSON LABS INC	50MG	A200562	001	Feb 11, 2015	Jan NEWA		
	AB		100MG	A200562	002	Feb 11, 2015	Jan NEWA		
	AB		200MG	A200562	003	Feb 11, 2015	Jan NEWA		
	AB		400MG	A200562	004	Feb 11, 2015	Jan NEWA		

CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE

SOLUTION;ORAL

HYDROCODONE BITARTRATE AND CHLORPHENIRAMINE MALEATE

AA			TRIS PHARMA INC	4MG/5ML;5MG/5ML	A206438	001	Jan 27, 2015	Jan NEWA

VITUZ

AA	+		CYPRESS PHARM	4MG/5ML;5MG/5ML	N204307	001	Feb 20, 2013	Jan CFTG

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE;INJECTION

CHLORPROMAZINE HYDROCHLORIDE

>A>		+	EUROHLTH INTL SARL	25MG/ML	A083329	001		Feb CAHN
>D>		+	HIKMA MAPLE	25MG/ML	A083329	001		Feb CAHN

CISATRACURIUM BESYLATE

INJECTABLE;INJECTION

CISATRACURIUM BESYLATE

>A>	AP		FRESENIUS KABI USA	EQ 2MG BASE/ML	A203183	001	Feb 26, 2015	Feb NEWA

CISATRACURIUM BESYLATE PRESERVATIVE FREE

>A>	AP		FRESENIUS KABI USA	EQ 2MG BASE/ML	A203182	001	Feb 26, 2015	Feb NEWA
>A>	AP			EQ 10MG BASE/ML	A203182	002	Feb 26, 2015	Feb NEWA

CLARITHROMYCIN

TABLET, EXTENDED RELEASE;ORAL

BIAXIN XL

		@	ABBVIE	500MG	N050775	001	Mar 03, 2000	Jan DISC

CLARITHROMYCIN

AB		+	TEVA	500MG	A065154	001	May 18, 2005	Jan CRLD

CLINDAMYCIN PHOSPHATE

SOLUTION;TOPICAL

CLINDAMYCIN PHOSPHATE

		@	BOCA PHARMA LLC	EQ 1% BASE	A062944	001	Jan 11, 1989	Jan CAHN

CLOBETASOL PROPIONATE

OINTMENT;TOPICAL

CLOBETASOL PROPIONATE

>A>	AB		G AND W LABS INC	0.05%	A074089	001	Feb 16, 1994	Feb CAHN
>D>	AB		TEVA PHARMS	0.05%	A074089	001	Feb 16, 1994	Feb CAHN

COBICISTAT; DARUNAVIR ETHANOLATE

TABLET;ORAL

PREZCOBIX

		+	JANSSEN PRODS	150MG;EQ 800MG BASE	N205395	001	Jan 29, 2015	Jan NEWA

CODEINE SULFATE

SOLUTION;ORAL

CODEINE SULFATE

		@	ROXANE	30MG/5ML	N202245	001	Jun 30, 2011	Jan DISC

COLCHICINE

CAPSULE;ORAL

MITIGARE

			HIKMA INTL PHARMS	0.6MG	N204820	001	Sep 26, 2014	Jan CAHN

CYANOCOBALAMIN

INJECTABLE;INJECTION

CYANOCOBALAMIN

>A>		@	EUROHLTH INTL SARL	1MG/ML	A080515	002		Feb CAHN
>D>		@	HIKMA MAPLE	1MG/ML	A080515	002		Feb CAHN

DECITABINE

INJECTABLE;INTRAVENOUS

DACOGEN

AP		+	OTSUKA PHARM CO LTD	50MG/VIAL	N021790	001	May 02, 2006	Jan CAHN

DESMOPRESSIN ACETATE

TABLET;ORAL

DDAVP

	AB		FERRING PHARMS INC	0.1MG	N019955	001	Sep 06, 1995	Jan CAHN
	AB	+		0.2MG	N019955	002	Sep 06, 1995	Jan CAHN

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE;INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

>A>	AP	+	EUROHLTH INTL SARL	EQ 10MG PHOSPHATE/ML	A087702	001	Sep 07, 1982	Feb CAHN
>D>	AP	+	HIKMA MAPLE	EQ 10MG PHOSPHATE/ML	A087702	001	Sep 07, 1982	Feb CAHN

DEXMEDETOMIDINE HYDROCHLORIDE

INJECTABLE;INJECTION

PRECEDEX

			HOSPIRA	EQ 80MCG BASE/20ML (EQ 4MCG BASE/ML)	N021038	004	Nov 14, 2014	Jan NEWA

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE;INJECTION

MD-76R

>A>	AP	+	LIEBEL-FLARSHEIM	66%;10%	N019292	001	Sep 29, 1989	Feb CAHN
>D>	AP	+	MALLINCKRODT	66%;10%	N019292	001	Sep 29, 1989	Feb CAHN

SOLUTION;ORAL, RECTAL

MD-GASTROVIEW

	AA		LIEBEL-FLARSHEIM	66%;10%	A087388	001		Jan CAHN

DIGOXIN

INJECTABLE;INJECTION

DIGOXIN

>A>	AP		EUROHLTH INTL SARL	0.25MG/ML	A083391	001		Feb CAHN
>D>	AP		HIKMA MAPLE	0.25MG/ML	A083391	001		Feb CAHN

TABLET;ORAL

DIGOXIN

	AB		MYLAN PHARMS INC	0.125MG	A040282	001	Dec 23, 1999	Jan CTEC
	AB			0.25MG	A040282	002	Dec 23, 1999	Jan CTEC
>D>		@	SUN PHARM INDS INC	0.125MG	A076363	001	Jan 31, 2003	Feb CMFD
>A>	AB			0.125MG	A076363	001	Jan 31, 2003	Feb CMFD
>D>		@		0.25MG	A076363	002	Jan 31, 2003	Feb CMFD
>A>	AB			0.25MG	A076363	002	Jan 31, 2003	Feb CMFD

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

DILACOR XR

>D>								
>D>	AB2		WATSON LABS	120MG	N020092	001	May 29, 1992	Feb DISC
>A>		@		120MG	N020092	001	May 29, 1992	Feb DISC
>D>	AB2			180MG	N020092	002	May 29, 1992	Feb DISC
>A>		@		180MG	N020092	002	May 29, 1992	Feb DISC
>D>	AB2	+		240MG	N020092	003	May 29, 1992	Feb DISC
>A>		@		240MG	N020092	003	May 29, 1992	Feb DISC

DILTIAZEM HYDROCHLORIDE

>D>	AB2		MYLAN	240MG	A075124	001	Mar 18, 1998	Feb CRLD
>A>	AB2	+		240MG	A075124	001	Mar 18, 1998	Feb CRLD

TIAZAC

>D>	AB4		VALEANT INTL	120MG	N020401	001	Sep 11, 1995	Feb CAHN
>D>	AB4			180MG	N020401	002	Sep 11, 1995	Feb CAHN
>D>	AB4			240MG	N020401	003	Sep 11, 1995	Feb CAHN
>D>	AB4			300MG	N020401	004	Sep 11, 1995	Feb CAHN
>D>	AB4			360MG	N020401	005	Sep 11, 1995	Feb CAHN
>D>	AB4	+		420MG	N020401	006	Oct 16, 1998	Feb CAHN
>A>	AB4		VALEANT PHARMS NORTH	120MG	N020401	001	Sep 11, 1995	Feb CAHN
>A>	AB4			180MG	N020401	002	Sep 11, 1995	Feb CAHN
>A>	AB4			240MG	N020401	003	Sep 11, 1995	Feb CAHN
>A>	AB4			300MG	N020401	004	Sep 11, 1995	Feb CAHN
>A>	AB4			360MG	N020401	005	Sep 11, 1995	Feb CAHN
>A>	AB4	+		420MG	N020401	006	Oct 16, 1998	Feb CAHN

DISULFIRAM

TABLET;ORAL

DISULFIRAM

>A> AB		MYLAN PHARMS INC	250MG	A203916	001	Mar 04, 2015	Feb	NEWA
>A> AB			500MG	A203916	002	Mar 04, 2015	Feb	NEWA

DONEPEZIL HYDROCHLORIDE

TABLET;ORAL

DONEPEZIL HYDROCHLORIDE

AB		HETERO LABS LTD V	5MG	A203034	001	Jan 30, 2015	Jan	NEWA
AB			10MG	A203034	002	Jan 30, 2015	Jan	NEWA

DOXEPIN HYDROCHLORIDE

CAPSULE;ORAL

DOXEPIN HYDROCHLORIDE

AB	+	MYLAN PHARMS INC	EQ 100MG BASE	A070791	005	May 13, 1986	Jan	CRLD
	+	PAR PHARM	EQ 150MG BASE	A071669	001	Nov 09, 1987	Jan	CRLD

EDOXABAN TOSYLATE

TABLET;ORAL

SAVAYSA

		DAIICHI SANKYO	EQ 15MG BASE	N206316	001	Jan 08, 2015	Jan	NEWA
			EQ 30MG BASE	N206316	002	Jan 08, 2015	Jan	NEWA
	+		EQ 60MG BASE	N206316	003	Jan 08, 2015	Jan	NEWA

EMPAGLIFLOZIN; LINAGLIPTIN

TABLET;ORAL

GLYXAMBI

		BOEHRINGER INGELHEIM	10MG;5MG	N206073	001	Jan 30, 2015	Jan	NEWA
	+		25MG;5MG	N206073	002	Jan 30, 2015	Jan	NEWA

ERGOCALCIFEROL

CAPSULE;ORAL

VITAMIN D

AA		BANNER LIFE SCIENCES	50,000 IU	A080704	001		Jan	CAHN

ESMOLOL HYDROCHLORIDE

INJECTABLE;INJECTION

ESMOLOL HYDROCHLORIDE

>A> AP		LUITPOLD	10MG/ML	A201126	001	Feb 20, 2015	Feb	NEWA

ESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED REL PELLETS;ORAL

ESOMEPRAZOLE MAGNESIUM

AB		IVAX SUB TEVA PHARMS	EQ 20MG BASE	A078003	001	Jan 26, 2015	Jan	NEWA
AB			EQ 40MG BASE	A078003	002	Jan 26, 2015	Jan	NEWA

NEXIUM

AB		ASTRAZENECA PHARMS	EQ 20MG BASE	N021153	001	Feb 20, 2001	Jan	CFTG
AB	+		EQ 40MG BASE	N021153	002	Feb 20, 2001	Jan	CFTG

ESTRADIOL

FILM, EXTENDED RELEASE;TRANSDERMAL

MINIVELLE

		NOVEN	0.025MG/24HR	N203752	005	Sep 23, 2014	Jan	NEWA

ESZOPICLONE

TABLET;ORAL

ESZOPICLONE

AB		MACLEODS PHARMS LTD	1MG	A202929	001	Jan 30, 2015	Jan	NEWA
AB			2MG	A202929	002	Jan 30, 2015	Jan	NEWA
AB			3MG	A202929	003	Jan 30, 2015	Jan	NEWA

ETHAMBUTOL HYDROCHLORIDE

TABLET;ORAL

ETHAMBUTOL HYDROCHLORIDE

AB		VERSAPHARM INC	100MG	A075095	001	Nov 30, 1999	Jan	CMFD
AB			400MG	A075095	002	Nov 30, 1999	Jan	CMFD

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET;ORAL

>A>			ASHLYNA						
>A>	AB		GLENMARK GENERICS	0.03MG,0.01MG;0.15MG,N/A	A203163	001	Feb 23, 2015	Feb	NEWA

ETHINYL ESTRADIOL; NORELGESTROMIN

FILM, EXTENDED RELEASE;TRANSDERMAL

>D>			ORTHO EVRA						
>D>	AB	+	JANSSEN PHARMS	0.035MG/24HR;0.15MG/24HR	N021180	001	Nov 20, 2001	Feb	DISC
>A>		@		0.035MG/24HR;0.15MG/24HR	N021180	001	Nov 20, 2001	Feb	DISC
			XULANE						
>D>	AB		MYLAN TECHNOLOGIES	0.035MG/24HR;0.15MG/24HR	A200910	001	Apr 16, 2014	Feb	CRLD
>A>	AB	+		0.035MG/24HR;0.15MG/24HR	A200910	001	Apr 16, 2014	Feb	CRLD

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET;ORAL-21

			NORINYL 1+35 21-DAY						
>A>	AB		ACTAVIS LABS UT INC	0.035MG;1MG	N017565	001		Feb	CAHN
>D>	AB		WATSON LABS	0.035MG;1MG	N017565	001		Feb	CAHN
			TRI-NORINYL 21-DAY						
>A>		@	ACTAVIS LABS UT INC	0.035MG,0.035MG,0.035MG;0.5MG,1MG, 0.5MG	N018977	001	Apr 13, 1984	Feb	CAHN
>D>		@	WATSON LABS	0.035MG,0.035MG,0.035MG;0.5MG,1MG, 0.5MG	N018977	001	Apr 13, 1984	Feb	CAHN

TABLET;ORAL-28

			NORINYL 1+35 28-DAY						
>A>	AB		ACTAVIS LABS UT INC	0.035MG;1MG	N017565	002		Feb	CAHN
>D>	AB		WATSON LABS	0.035MG;1MG	N017565	002		Feb	CAHN
			TRI-NORINYL 28-DAY						
>A>	AB	+	ACTAVIS LABS UT INC	0.035MG,0.035MG,0.035MG;0.5MG,1MG, 0.5MG	N018977	002	Apr 13, 1984	Feb	CAHN
>D>	AB	+	WATSON LABS	0.035MG,0.035MG,0.035MG;0.5MG,1MG, 0.5MG	N018977	002	Apr 13, 1984	Feb	CAHN

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET;ORAL

>A>			LARIN 24 FE						
>A>	AB		NOVAST LABS LTD	0.02MG;1MG	A202994	001	Feb 18, 2015	Feb	NEWA
			LOESTRIN 24 FE						
		@	WARNER CHILCOTT	0.02MG;1MG	N021871	001	Feb 17, 2006	Jan	DISC
			NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE						
	AB	+	AMNEAL PHARMS	0.02MG;1MG	A078267	001	Sep 01, 2009	Jan	CRLD

TABLET;ORAL-21

			NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL						
>A>	AB		FAMY CARE LTD	0.03MG;1.5MG	A202770	001	Feb 19, 2015	Feb	NEWA

TABLET;ORAL-28

			NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL						
>A>	AB		FAMY CARE LTD	0.03MG;1.5MG	A202741	001	Feb 20, 2015	Feb	NEWA

ETHINYL ESTRADIOL; NORGESTREL

TABLET;ORAL-28

			LOW-OGESTREL-28						
>D>		@	WATSON LABS	0.03MG;0.3MG	A075288	002	Jul 28, 1999	Feb	CMFD
>A>	AB			0.03MG;0.3MG	A075288	002	Jul 28, 1999	Feb	CMFD

ETHOSUXIMIDE

CAPSULE;ORAL

			ETHOSUXIMIDE						
	AB		BANNER LIFE SCIENCES	250MG	A040430	001	Oct 28, 2002	Jan	CAHN

FAMOTIDINE

TABLET;ORAL

			PEPCID						
>D>	AB		MARATHON PHARMS	20MG	N019462	001	Oct 15, 1986	Feb	CAHN
>D>	AB	+		40MG	N019462	002	Oct 15, 1986	Feb	CAHN
>A>	AB		VALEANT PHARMS NORTH	20MG	N019462	001	Oct 15, 1986	Feb	CAHN
>A>	AB	+		40MG	N019462	002	Oct 15, 1986	Feb	CAHN

FENTANYL CITRATE

INJECTABLE;INJECTION

FENTANYL CITRATE PRESERVATIVE FREE

>A>	AP	+	EUROHLTH INTL SARL	EQ 0.05MG BASE/ML	N019101	001	Jul 11, 1984	Feb	CAHN
>D>	AP	+	HIKMA MAPLE	EQ 0.05MG BASE/ML	N019101	001	Jul 11, 1984	Feb	CAHN

FERRIC CITRATE

TABLET;ORAL

AURYXIA

		+	KERYX BIOPHARMS	EQ 210MG IRON	N205874	001	Sep 05, 2014	Jan	CTNA

FERRIC PYROPHOSPHATE CITRATE

SOLUTION;IV (INFUSION)

TRIFERIC

		+	ROCKWELL MEDICAL INC	27.2MG IRON/5ML (5.44MG IRON/ML)	N206317	001	Jan 23, 2015	Jan	NEWA

FLUDEOXYGLUCOSE F-18

INJECTABLE;INTRAVENOUS

FLUDEOXYGLUCOSE F 18

			UNIV NORTH DAKOTA	4-500mCi/ML	A203994	001	Feb 04, 2015	Jan	NEWA

FLUOROURACIL

CREAM;TOPICAL

CARAC

>D>		+	VALEANT BERMUDA	0.5%	N020985	001	Oct 27, 2000	Feb	CAHN
>A>		+	VALEANT PHARMS NORTH	0.5%	N020985	001	Oct 27, 2000	Feb	CAHN

GADOVERSETAMIDE

INJECTABLE;INJECTION

OPTIMARK

>A>		+	LIEBEL-FLARSHEIM	16.545GM/50ML (330.9MG/ML)	N020975	001	Dec 08, 1999	Feb	CAHN
>A>		+		1654.5MG/5ML (330.9MG/ML)	N020937	001	Dec 08, 1999	Feb	CAHN
>A>		+		3309MG/10ML (330.9MG/ML)	N020937	002	Dec 08, 1999	Feb	CAHN
>A>		+		4963.5MG/15ML (330.9MG/ML)	N020937	003	Dec 08, 1999	Feb	CAHN
>A>		+		6618MG/20ML (330.9MG/ML)	N020937	004	Dec 08, 1999	Feb	CAHN
>D>		+	MALLINCKRODT	16.545GM/50ML (330.9MG/ML)	N020975	001	Dec 08, 1999	Feb	CAHN
>D>		+		1654.5MG/5ML (330.9MG/ML)	N020937	001	Dec 08, 1999	Feb	CAHN
>D>		+		3309MG/10ML (330.9MG/ML)	N020937	002	Dec 08, 1999	Feb	CAHN
>D>		+		4963.5MG/15ML (330.9MG/ML)	N020937	003	Dec 08, 1999	Feb	CAHN
>D>		+		6618MG/20ML (330.9MG/ML)	N020937	004	Dec 08, 1999	Feb	CAHN

OPTIMARK IN PLASTIC CONTAINER

>A>		+	LIEBEL-FLARSHEIM	3309MG/10ML (330.9MG/ML)	N020976	002	Dec 08, 1999	Feb	CAHN
>A>		+		4963.5MG/15ML (330.9MG/ML)	N020976	003	Dec 08, 1999	Feb	CAHN
>A>		+		6618MG/20ML (330.9MG/ML)	N020976	004	Dec 08, 1999	Feb	CAHN
>A>		+		9927MG/30ML (330.9MG/ML)	N020976	001	Dec 08, 1999	Feb	CAHN
>D>		+	MALLINCKRODT	3309MG/10ML (330.9MG/ML)	N020976	002	Dec 08, 1999	Feb	CAHN
>D>		+		4963.5MG/15ML (330.9MG/ML)	N020976	003	Dec 08, 1999	Feb	CAHN
>D>		+		6618MG/20ML (330.9MG/ML)	N020976	004	Dec 08, 1999	Feb	CAHN
>D>		+		9927MG/30ML (330.9MG/ML)	N020976	001	Dec 08, 1999	Feb	CAHN

GRANISETRON HYDROCHLORIDE

INJECTABLE;INJECTION

GRANISETRON HYDROCHLORIDE

	AP		BANNER LIFE SCIENCES	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A078863	001	Jun 30, 2008	Jan	CAHN
	AP			EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A078880	001	Jun 30, 2008	Jan	CAHN

GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE

	AP		BANNER LIFE SCIENCES	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A078863	002	Jun 30, 2008	Jan	CAHN

HYDRALAZINE HYDROCHLORIDE

INJECTABLE;INJECTION

HYDRALAZINE HYDROCHLORIDE

>D>	AP		AKORN	20MG/ML	A040730	001	Apr 21, 2009	Feb	CRLD
>A>	AP	+		20MG/ML	A040730	001	Apr 21, 2009	Feb	CRLD
>D>	AP	+	LUITPOLD	20MG/ML	A040136	001	Jun 30, 1997	Feb	CRLD
>A>	AP			20MG/ML	A040136	001	Jun 30, 1997	Feb	CRLD

HYDROCHLOROTHIAZIDE

CAPSULE;ORAL

MICROZIDE

>A> AB	+	ACTAVIS LABS UT INC	12.5MG	N020504	001	Dec 27, 1996	Feb CAHN
>D> AB	+	WATSON LABS	12.5MG	N020504	001	Dec 27, 1996	Feb CAHN

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET;ORAL

ZESTORETIC

>A> AB		ALVOGEN IPCO SARL	12.5MG;10MG	N019888	003	Nov 18, 1993	Feb CAHN
>A> AB	+		12.5MG;20MG	N019888	001	Sep 20, 1990	Feb CAHN
>A> AB	+		25MG;20MG	N019888	002	Jul 20, 1989	Feb CAHN
>D> AB		ASTRAZENECA	12.5MG;10MG	N019888	003	Nov 18, 1993	Feb CAHN
>D> AB	+		12.5MG;20MG	N019888	001	Sep 20, 1990	Feb CAHN
>D> AB	+		25MG;20MG	N019888	002	Jul 20, 1989	Feb CAHN

HYDROCORTISONE

TABLET;ORAL

HYDROCORTISONE

>A> AB		HIKMA INTL PHARMS	5MG	A083365	002	Feb 23, 2015	Feb NEWA
>A> AB			10MG	A083365	003	Feb 23, 2015	Feb NEWA
>D>	@		20MG	A083365	001		Feb CMFD
>A> AB			20MG	A083365	001		Feb CMFD

ILOPERIDONE

TABLET;ORAL

FANAPT

	+	VANDA PHARMS INC	1MG	N022192	001	May 06, 2009	Jan CAHN
			2MG	N022192	002	May 06, 2009	Jan CAHN
			4MG	N022192	003	May 06, 2009	Jan CAHN
			6MG	N022192	004	May 06, 2009	Jan CAHN
			8MG	N022192	005	May 06, 2009	Jan CAHN
			10MG	N022192	006	May 06, 2009	Jan CAHN
			12MG	N022192	007	May 06, 2009	Jan CAHN

INSULIN GLARGINE

>A> SOLUTION;SUBCUTANEOUS

>A> TOUJEO SOLOSTAR

>A>	+	SANOFI US SERVICES	300UNITS/ML (300UNITS/ML)	N206538	001	Feb 25, 2015	Feb NEWA

INSULIN GLARGINE RECOMBINANT

>A> SOLUTION;SUBCUTANEOUS

>A> TOUJEO SOLOSTAR

>A>	+	SANOFI US SERVICES	300UNITS/ML (300UNITS/ML)	N206538	001	Feb 25, 2015	Feb NEWA

IOPAMIDOL

INJECTABLE;INJECTION

IOPAMIDOL-250

	@	FRESENIUS KABI USA	51%	A074679	001	Apr 02, 1997	Jan DISC

IOPAMIDOL-300

	@	FRESENIUS KABI USA	61%	A074679	002	Apr 02, 1997	Jan DISC

IOPAMIDOL-370

	@	FRESENIUS KABI USA	76%	A074679	003	Apr 02, 1997	Jan DISC

ISOVUE-200

>D> AP	+	BRACCO	41%	N018735	006	Jul 07, 1987	Feb CTEC
>A>	+		41%	N018735	006	Jul 07, 1987	Feb CTEC

ISOVUE-250

>D> AP	+	BRACCO	51%	N018735	007	Jul 06, 1992	Feb CTEC
>A>	+		51%	N018735	007	Jul 06, 1992	Feb CTEC
>D> AP	+		51%	N020327	002	Oct 12, 1994	Feb CTEC
>A>	+		51%	N020327	002	Oct 12, 1994	Feb CTEC

ISOVUE-300

>D> AP	+	BRACCO	61%	N020327	003	Oct 12, 1994	Feb CTEC
>A>	+		61%	N020327	003	Oct 12, 1994	Feb CTEC

ISOVUE-370

>D> AP	+	BRACCO	76%	N020327	004	Oct 12, 1994	Feb CTEC
>A>	+		76%	N020327	004	Oct 12, 1994	Feb CTEC

IOTHALAMATE MEGLUMINE

INJECTABLE;INJECTION

CONRAY

>A>	+	LIEBEL-FLARSHEIM	60%	N013295	001			Feb CAHN
>D>	+	MALLINCKRODT	60%	N013295	001			Feb CAHN

CONRAY 30

>A>	+	LIEBEL-FLARSHEIM	30%	N016983	001			Feb CAHN
>D>	+	MALLINCKRODT	30%	N016983	001			Feb CAHN

CONRAY 43

>A>	+	LIEBEL-FLARSHEIM	43%	N013295	002			Feb CAHN
>D>	+	MALLINCKRODT	43%	N013295	002			Feb CAHN

SOLUTION;INTRAVESICAL

CYSTO-CONRAY II

>A>		LIEBEL-FLARSHEIM	17.2%	N017057	002			Feb CAHN
>D>		MALLINCKRODT	17.2%	N017057	002			Feb CAHN

IOVERSOL

INJECTABLE;INJECTION

OPTIRAY 160

>A>	@	LIEBEL-FLARSHEIM	34%	N019710	003	Dec 30, 1988		Feb CAHN
>D>	@	MALLINCKRODT	34%	N019710	003	Dec 30, 1988		Feb CAHN

OPTIRAY 240

>A>	+	LIEBEL-FLARSHEIM	51%	N019710	002	Dec 30, 1988		Feb CAHN
>A>	@		51%	N020923	001	May 28, 1998		Feb CAHN
>D>	+	MALLINCKRODT	51%	N019710	002	Dec 30, 1988		Feb CAHN
>D>	@		51%	N020923	001	May 28, 1998		Feb CAHN

OPTIRAY 300

>A>	+	LIEBEL-FLARSHEIM	64%	N019710	004	Jan 22, 1992		Feb CAHN
>A>	+		64%	N020923	004	May 13, 1999		Feb CAHN
>D>	+	MALLINCKRODT	64%	N019710	004	Jan 22, 1992		Feb CAHN
>D>	+		64%	N020923	004	May 13, 1999		Feb CAHN

OPTIRAY 320

>A>	+	LIEBEL-FLARSHEIM	68%	N019710	001	Dec 30, 1988		Feb CAHN
>A>	@		68%	N020923	002	May 29, 1998		Feb CAHN
>D>	+	MALLINCKRODT	68%	N019710	001	Dec 30, 1988		Feb CAHN
>D>	@		68%	N020923	002	May 29, 1998		Feb CAHN

OPTIRAY 350

>A>	+	LIEBEL-FLARSHEIM	74%	N019710	005	Jan 22, 1992		Feb CAHN
>A>	+		74%	N020923	003	May 28, 1998		Feb CAHN
>D>	+	MALLINCKRODT	74%	N019710	005	Jan 22, 1992		Feb CAHN
>D>	+		74%	N020923	003	May 28, 1998		Feb CAHN

IRBESARTAN

TABLET;ORAL

IRBESARTAN

>A>	AB	JUBILANT GENERICS	75MG	A203534	001	Feb 23, 2015		Feb NEWA
>A>	AB		150MG	A203534	002	Feb 23, 2015		Feb NEWA
>A>	AB		300MG	A203534	003	Feb 23, 2015		Feb NEWA

ISOSORBIDE DINITRATE

TABLET;ORAL

ISORDIL

>D>	AB	VALEANT BERMUDA	5MG	N012093	007	Jul 29, 1988		Feb CAHN
>D>	@		10MG	N012093	002	Jul 29, 1988		Feb CAHN
>D>	@		20MG	N012093	006	Jul 29, 1988		Feb CAHN
>D>	@		30MG	N012093	005	Jul 29, 1988		Feb CAHN
>D>	+		40MG	N012093	001	Jul 29, 1988		Feb CAHN
>A>	AB	VALEANT PHARMS NORTH	5MG	N012093	007	Jul 29, 1988		Feb CAHN
>A>	@		10MG	N012093	002	Jul 29, 1988		Feb CAHN
>A>	@		20MG	N012093	006	Jul 29, 1988		Feb CAHN
>A>	@		30MG	N012093	005	Jul 29, 1988		Feb CAHN
>A>	+		40MG	N012093	001	Jul 29, 1988		Feb CAHN

ISOTRETINOIN

CAPSULE;ORAL

ABSORICA

>A>		RANBAXY	25MG	N021951	005	Aug 15, 2014		Feb NEWA
>A>			35MG	N021951	006	Aug 15, 2014		Feb NEWA

ZENATANE

>A>	AB	DR REDDYS LABS LTD	30MG	A202099	004	Feb 23, 2015		Feb NEWA

KETOROLAC TROMETHAMINE

SPRAY, METERED;NASAL

SPRIX

		+	EGALET US INC	15.75MG/SPRAY	N022382	001	May 14, 2010	Jan CAHN

KETOROLAC TROMETHAMINE; PHENYLEPHRINE HYDROCHLORIDE

SOLUTION;IRRIGATION

OMIDRIA

>D>		+	OMEROS	EQ 2.88MG BASE/ML;EQ 10.16MG BASE/ML	N205388	001	May 30, 2014	Feb CPOT
>A>		+		EQ 4.24MG BASE/ML;EQ 12.4MG BASE/ML	N205388	001	May 30, 2014	Feb CPOT

LABETALOL HYDROCHLORIDE

TABLET;ORAL

LABETALOL HYDROCHLORIDE

	AB		MUTUAL PHARM	100MG	A075215	001	Jul 29, 1999	Jan CMFD
	AB			200MG	A075215	002	Jul 29, 1999	Jan CMFD
	AB			300MG	A075215	003	Jul 29, 1999	Jan CMFD

>A> LAMIVUDINE; RALTEGRAVIR POTASSIUM

>A> TABLET;ORAL

>A> DUTREBIS

>A>		+	MERCK SHARP DOHME	150MG;EQ 300MG BASE	N206510	001	Feb 06, 2015	Feb NEWA

>A> LENVATINIB MESYLATE

>A> CAPSULE;ORAL

>A> LENVIMA

>A>			EISAI INC	EQ 4MG BASE	N206947	001	Feb 13, 2015	Feb NEWA
>A>		+		EQ 10MG BASE	N206947	002	Feb 13, 2015	Feb NEWA

LEVETIRACETAM

TABLET, EXTENDED RELEASE;ORAL

LEVETIRACETAM

>A>			APOTEX INC	1GM	A202958	001	Feb 25, 2015	Feb NEWA

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET;ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

>A>	AB		APOTEX INC	5MG	A203027	001	Feb 13, 2015	Feb NEWA

LEVOLEUCOVORIN CALCIUM

SOLUTION;IV (INFUSION)

>A> LEVOLEUCOVORIN CALCIUM

>A>			SANDOZ	EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML)	A203563	001	Mar 09, 2015	Feb NEWA
>A>				EQ 250MG BASE/25ML (EQ 10MG BASE/ML)	A203563	002	Mar 09, 2015	Feb NEWA

LEVONORGESTREL

INTRAUTERINE DEVICE;INTRAUTERINE

>A> LILETTA

>A>			MEDICINES360	52MG	N206229	001	Feb 26, 2015	Feb NEWA

LIDOCAINE HYDROCHLORIDE

INJECTABLE;INJECTION

LIDOCAINE HYDROCHLORIDE PRESERVATIVE FREE

>A>		@	EUROHLTH INTL SARL	1%	A084625	001		Feb CAHN
>A>		@		2%	A084625	002		Feb CAHN
>D>		@	HIKMA MAPLE	1%	A084625	001		Feb CAHN
>D>		@		2%	A084625	002		Feb CAHN

JELLY;TOPICAL

ANESTACON

		@	BANNER LIFE SCIENCES	2%	A080429	001		Jan CAHN

LIDOCAINE; PRILOCAINE

CREAM;TOPICAL

EMLA

>A>	AB	+	ACTAVIS LABS UT INC	2.5%;2.5%	N019941	001	Dec 30, 1992	Feb CAHN
>D>	AB	+	WATSON LABS INC	2.5%;2.5%	N019941	001	Dec 30, 1992	Feb CAHN

LISINOPRIL

TABLET;ORAL

ZESTRIL

>A>	AB		ALVOGEN IPCO SARL	2.5MG	N019777	005	Apr 29, 1993	Feb CAHN
>A>	AB			5MG	N019777	001	May 19, 1988	Feb CAHN
>A>	AB			10MG	N019777	002	May 19, 1988	Feb CAHN
>A>	AB			20MG	N019777	003	May 19, 1988	Feb CAHN
>A>	AB			30MG	N019777	006	Jan 20, 1999	Feb CAHN
>A>	AB	+		40MG	N019777	004	May 19, 1988	Feb CAHN
>D>	AB		ASTRAZENECA	2.5MG	N019777	005	Apr 29, 1993	Feb CAHN
>D>	AB			5MG	N019777	001	May 19, 1988	Feb CAHN
>D>	AB			10MG	N019777	002	May 19, 1988	Feb CAHN
>D>	AB			20MG	N019777	003	May 19, 1988	Feb CAHN
>D>	AB			30MG	N019777	006	Jan 20, 1999	Feb CAHN
>D>	AB	+		40MG	N019777	004	May 19, 1988	Feb CAHN

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE;ORAL

LITHIUM CARBONATE

>D>	AB		HIKMA INTL PHARMS	450MG	A076490	001	Jun 17, 2003	Feb DISC
>A>		@		450MG	A076490	001	Jun 17, 2003	Feb DISC

LOMUSTINE

CAPSULE;ORAL

GLEOSTINE

			CORDEN PHARMA	5MG	N017588	004	Dec 19, 2014	Jan NEWA

LOSARTAN POTASSIUM

TABLET;ORAL

LOSARTAN POTASSIUM

>D>		@	WATSON LABS	25MG	A091129	001	Oct 06, 2010	Feb CMFD
>A>	AB			25MG	A091129	001	Oct 06, 2010	Feb CMFD
>D>		@		50MG	A091129	002	Oct 06, 2010	Feb CMFD
>A>	AB			50MG	A091129	002	Oct 06, 2010	Feb CMFD
>D>		@		100MG	A091129	003	Oct 06, 2010	Feb CMFD
>A>	AB			100MG	A091129	003	Oct 06, 2010	Feb CMFD

MEMANTINE HYDROCHLORIDE

TABLET;ORAL

MEMANTINE HYDROCHLORIDE

	AB		MYLAN PHARMS INC	5MG	A079225	001	Jan 30, 2015	Jan NEWA
	AB			10MG	A079225	002	Jan 30, 2015	Jan NEWA

MEPERIDINE HYDROCHLORIDE

INJECTABLE;INJECTION

MEPERIDINE HYDROCHLORIDE

>A>	AP		EUROHLTH INTL SARL	25MG/ML	A080445	001		Feb CAHN
>A>	AP			50MG/ML	A080445	002		Feb CAHN
>A>	AP			75MG/ML	A080445	003		Feb CAHN
>A>	AP			100MG/ML	A080445	004		Feb CAHN
>D>	AP		HIKMA MAPLE	25MG/ML	A080445	001		Feb CAHN
>D>	AP			50MG/ML	A080445	002		Feb CAHN
>D>	AP			75MG/ML	A080445	003		Feb CAHN
>D>	AP			100MG/ML	A080445	004		Feb CAHN

METAXALONE

TABLET;ORAL

METAXALONE

>A>			COREPHARMA	400MG	A040486	001	Feb 27, 2015	Feb NEWA

METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

RITALIN LA

>D>	AB1	+	NOVARTIS	40MG	N021284	003	Jun 05, 2002	Feb CRLD
>A>	AB1			40MG	N021284	003	Jun 05, 2002	Feb CRLD
>D>				60MG	N021284	005	Oct 27, 2014	Feb CRLD
>A>		+		60MG	N021284	005	Oct 27, 2014	Feb CRLD

TABLET, CHEWABLE;ORAL

METHYLIN

>D>			MALLINCKRODT	2.5MG	N021475	001	Apr 15, 2003	Feb CFTG
>A>	AB			2.5MG	N021475	001	Apr 15, 2003	Feb CFTG

		TABLET, CHEWABLE;ORAL						
		METHYLIN						
>D>			5MG	N021475	002	Apr 15, 2003	Feb	CFTG
>A>	AB		5MG	N021475	002	Apr 15, 2003	Feb	CFTG
>D>	+		10MG	N021475	003	Apr 15, 2003	Feb	CFTG
>A>	AB +		10MG	N021475	003	Apr 15, 2003	Feb	CFTG
>A>		METHYLPHENIDATE HYDROCHLORIDE						
>A>	AB	NOVEL LABS INC	2.5MG	A204115	001	Feb 25, 2015	Feb	NEWA
>A>	AB		5MG	A204115	002	Feb 25, 2015	Feb	NEWA
>A>	AB		10MG	A204115	003	Feb 25, 2015	Feb	NEWA
		METRONIDAZOLE						
		CREAM;TOPICAL						
		NORITATE						
>D>	+	VALEANT BERMUDA	1%	N020743	001	Sep 26, 1997	Feb	CAHN
>A>	+	VALEANT PHARMS NORTH	1%	N020743	001	Sep 26, 1997	Feb	CAHN
		GEL;VAGINAL						
		METRONIDAZOLE						
>A>	+	ACTAVIS LABS UT INC	1.3%	N205223	001	Mar 24, 2014	Feb	CAHN
>D>	+	WATSON LABS INC	1.3%	N205223	001	Mar 24, 2014	Feb	CAHN
>A>		NUVESSA						
>A>	+	ACTAVIS LABS UT INC	1.3%	N205223	001	Mar 24, 2014	Feb	CTNA
		MIGLITOL						
		TABLET;ORAL						
		GLYSET						
>D>		PHARMACIA AND UPJOHN	25MG	N020682	001	Dec 18, 1996	Feb	CFTG
>A>	AA		25MG	N020682	001	Dec 18, 1996	Feb	CFTG
>D>			50MG	N020682	002	Dec 18, 1996	Feb	CFTG
>A>	AA		50MG	N020682	002	Dec 18, 1996	Feb	CFTG
>D>	+		100MG	N020682	003	Dec 18, 1996	Feb	CFTG
>A>	AA +		100MG	N020682	003	Dec 18, 1996	Feb	CFTG
>A>		MIGLITOL						
>A>	AA	ORIENT PHARMA CO LTD	25MG	A203965	001	Feb 24, 2015	Feb	NEWA
>A>	AA		50MG	A203965	002	Feb 24, 2015	Feb	NEWA
>A>	AA		100MG	A203965	003	Feb 24, 2015	Feb	NEWA
		MILRINONE LACTATE						
		INJECTABLE;INJECTION						
		MILRINONE LACTATE						
	AP	BEDFORD	EQ 1MG BASE/ML	A075660	001	May 28, 2002	Jan	CRLD
	AP +	HIKMA FARMACEUTICA	EQ 1MG BASE/ML	A077966	001	Dec 03, 2010	Jan	CRLD
		MIVACURIUM CHLORIDE						
		SOLUTION;INTRAVENOUS						
		MIVACRON						
		ABBVIE	EQ 10MG BASE/5ML (EQ 2MG BASE/ML)	N020098	004	Jan 22, 1992	Jan	NEWA
	+		EQ 20MG BASE/10ML (EQ 2MG BASE/ML)	N020098	005	Jan 22, 1992	Jan	NEWA
		MONTELUKAST SODIUM						
		TABLET, CHEWABLE;ORAL						
		MONTELUKAST SODIUM						
>A>	AB	JUBILANT GENERICS	EQ 4MG BASE	A203795	001	Feb 27, 2015	Feb	NEWA
>A>	AB		EQ 5MG BASE	A203795	002	Feb 27, 2015	Feb	NEWA
>A>	AB	MACLEODS PHARMS LTD	EQ 4MG BASE	A203582	001	Mar 12, 2015	Feb	NEWA
>A>	AB		EQ 5MG BASE	A203582	002	Mar 12, 2015	Feb	NEWA
		MOXIFLOXACIN HYDROCHLORIDE						
		SOLUTION/DROPS;OPHTHALMIC						
		MOXIFLOXACIN HYDROCHLORIDE						
>A>	AT	WATSON LABS INC	EQ 0.5% BASE	A202525	001	Mar 06, 2015	Feb	NEWA
		NEOSTIGMINE METHYLSULFATE						
		SOLUTION;INTRAVENOUS						
		NEOSTIGMINE METHYLSULFATE						
		FRESENIUS KABI USA	5MG/10ML (0.5MG/ML)	N203629	001	Jan 08, 2015	Jan	NEWA
			10MG/10ML (1MG/ML)	N203629	002	Jan 08, 2015	Jan	NEWA

NIMODIPINE

CAPSULE;ORAL

NIMODIPINE

AB	+	BANNER LIFE SCIENCES	30MG	A076740	001	Jan 17, 2008	Jan CAHN

OLANZAPINE

TABLET, ORALLY DISINTEGRATING;ORAL

OLANZAPINE

>A> AB		MACLEODS PHARMS LTD	5MG	A203044	001	Feb 20, 2015	Feb NEWA
>A> AB			10MG	A203044	002	Feb 20, 2015	Feb NEWA
>A> AB			15MG	A203044	003	Feb 20, 2015	Feb NEWA
>A> AB			20MG	A203044	004	Feb 20, 2015	Feb NEWA
>A> AB		ORCHID HLTHCARE	5MG	A202937	001	Mar 02, 2015	Feb NEWA
>A> AB			10MG	A202937	002	Mar 02, 2015	Feb NEWA
>A> AB			15MG	A202937	003	Mar 02, 2015	Feb NEWA
>A> AB			20MG	A202937	004	Mar 02, 2015	Feb NEWA

OLAPARIB

CAPSULE;ORAL

LYNPARZA

		ASTRAZENECA PHARMS	50MG	N206162	001	Dec 19, 2014	Jan CTNA

OLOPATADINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

PAZEO

	+	ALCON RES LTD	EQ 0.7% BASE	N206276	001	Jan 30, 2015	Jan NEWA

ONDANSETRON HYDROCHLORIDE

INJECTABLE;INJECTION

ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE

	@	TARO PHARMS IRELAND	EQ 2MG BASE/ML	A078014	001	Mar 21, 2008	Jan DISC

OXYTOCIN

INJECTABLE;INJECTION

OXYTOCIN

>A> AP	+	EUROHLTH INTL SARL	10USP UNITS/ML (10USP UNITS/ML)	N018243	001		Feb CAHN
>A> AP	+		100USP UNITS/10ML (10USP UNITS/ML)	N018243	002	Jan 10, 2007	Feb CAHN
>D> AP	+	HIKMA MAPLE	10USP UNITS/ML (10USP UNITS/ML)	N018243	001		Feb CAHN
>D> AP	+		100USP UNITS/10ML (10USP UNITS/ML)	N018243	002	Jan 10, 2007	Feb CAHN

>A> PALBOCICLIB

>A> CAPSULE;ORAL

>A> IBRANCE

>A>		PFIZER INC	75MG	N207103	001	Feb 03, 2015	Feb NEWA
>A>			100MG	N207103	002	Feb 03, 2015	Feb NEWA
>A>	+		125MG	N207103	003	Feb 03, 2015	Feb NEWA

>A> PANOBINOSTAT

>A> CAPSULE;ORAL

>A> FARYDAK

>A>		NOVARTIS PHARMS CORP	10MG	N205353	001	Feb 23, 2015	Feb NEWA
>A>			15MG	N205353	002	Feb 23, 2015	Feb NEWA
>A>	+		20MG	N205353	003	Feb 23, 2015	Feb NEWA

PARICALCITOL

CAPSULE;ORAL

PARICALCITOL

AB		BANNER LIFE SCIENCES	1MCG	A202539	001	Mar 27, 2014	Jan CAHN
AB			2MCG	A202539	002	Mar 27, 2014	Jan CAHN
AB			4MCG	A202539	003	Mar 27, 2014	Jan CAHN

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE;ORAL

PENTOXIFYLLINE

>D> AB		VALEANT BERMUDA	400MG	A075028	001	Jul 20, 1998	Feb CAHN
>A> AB		VALEANT PHARMS	400MG	A075028	001	Jul 20, 1998	Feb CAHN

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE;ORAL

BONTRIL

		@	VALEANT	105MG	A088021	001	Sep 21, 1982	Jan DISC

PHENDIMETRAZINE TARTRATE

		+	SANDOZ	105MG	N018074	001		Jan CTEC

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

PHENYLEPHRINE HYDROCHLORIDE

			AKORN INC	2.5%	N207926	001	Jan 15, 2015	Jan NEWA
				10%	N207926	002	Jan 15, 2015	Jan NEWA

PHENYTOIN SODIUM

INJECTABLE;INJECTION

PHENYTOIN SODIUM

>A>	AP	+	EUROHLTH INTL SARL	50MG/ML	A084307	001		Feb CAHN
>D>	AP	+	HIKMA MAPLE	50MG/ML	A084307	001		Feb CAHN

PIRBUTEROL ACETATE

AEROSOL, METERED;INHALATION

MAXAIR

		@	MEDICIS	EQ 0.2MG BASE/INH	N020014	001	Nov 30, 1992	Jan DISC

PIRFENIDONE

CAPSULE;ORAL

ESBRIET

>A>		+	GENENTECH INC	267MG	N022535	001	Oct 15, 2014	Feb CAHN
>D>		+	INTERMUNE INC	267MG	N022535	001	Oct 15, 2014	Feb CAHN

PODOFILOX

GEL;TOPICAL

CONDYLOX

>A>		+	ACTAVIS LABS UT INC	0.5%	N020529	001	Mar 13, 1997	Feb CAHN
>D>		+	WATSON PHARMS	0.5%	N020529	001	Mar 13, 1997	Feb CAHN

SOLUTION;TOPICAL

CONDYLOX

	AT	+	ACTAVIS LABS UT INC	0.5%	N019795	001	Dec 13, 1990	Jan CAHN

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

SOLUTION/DROPS;OPHTHALMIC

TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE

	AT		ALCON RES LTD	10,000 UNITS/ML;EQ 1MG BASE/ML	A064211	001	Apr 13, 1998	Jan CAHN

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE;ORAL

POTASSIUM CHLORIDE

>D>	AB2		MYLAN PHARMS INC	8.0MEQ	A204662	001	Aug 21, 2014	Feb CPOT
>A>	AB2			8MEQ	A204662	001	Aug 21, 2014	Feb CPOT
>D>	AB2			10.0MEQ	A204662	002	Aug 21, 2014	Feb CPOT
>A>	AB2			10MEQ	A204662	002	Aug 21, 2014	Feb CPOT

PROCHLORPERAZINE EDISYLATE

INJECTABLE;INJECTION

PROCHLORPERAZINE EDISYLATE

>A>	AP	+	EUROHLTH INTL SARL	EQ 5MG BASE/ML	A089903	001	Aug 29, 1989	Feb CAHN
>D>	AP	+	HIKMA MAPLE	EQ 5MG BASE/ML	A089903	001	Aug 29, 1989	Feb CAHN

PROGESTERONE

CAPSULE;ORAL

PROGESTERONE

	AB		BANNER LIFE SCIENCES	100MG	A200900	001	Aug 16, 2013	Jan CAHN
	AB			200MG	A200900	002	Aug 16, 2013	Jan CAHN

GEL;VAGINAL

CRINONE

>A>			ACTAVIS LABS UT INC	4%	N020701	001	Jul 31, 1997	Feb CAHN
>A>		+		8%	N020701	002	Jul 31, 1997	Feb CAHN
>D>			WATSON LABS	4%	N020701	001	Jul 31, 1997	Feb CAHN
>D>		+		8%	N020701	002	Jul 31, 1997	Feb CAHN

RALOXIFENE HYDROCHLORIDE

TABLET;ORAL

RALOXIFENE HYDROCHLORIDE

AB		WATSON LABS INC	60MG	A200825	001	Jan 21, 2015	Jan	NEWA

SCOPOLAMINE

FILM, EXTENDED RELEASE;TRANSDERMAL

SCOPOLAMINE

AB		PERRIGO R AND D	1MG/72HR	A078830	001	Jan 30, 2015	Jan	NEWA

TRANSDERM SCOP

AB	+	NOVARTIS	1MG/72HR	N017874	001		Jan	CFTG

SODIUM CHLORIDE

INJECTABLE;INJECTION

SODIUM CHLORIDE 0.9%

>A> AP		EUROHLTH INTL SARL	9MG/ML	A201850	001	Jan 20, 2012	Feb	CAHN
>D> AP		HIKMA (MAPLE)	9MG/ML	A201850	001	Jan 20, 2012	Feb	CAHN

SODIUM CHLORIDE 0.9%

>A>		EUROHLTH INTL SARL	9MG/ML	A201833	001	Sep 24, 2013	Feb	CAHN
>D>		HIKMA MAPLE	9MG/ML	A201833	001	Sep 24, 2013	Feb	CAHN

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

>A>	+	LIEBEL-FLARSHEIM	45MG/50ML (9MG/ML)	N021569	001	Jul 27, 2006	Feb	CAHN
>A>			112.5MG/125ML (9MG/ML)	N021569	002	Jul 27, 2006	Feb	CAHN
>A>	+		405MG/50ML (9MG/ML)	N021569	001	Jul 27, 2006	Feb	CPOT
>A>			1012.5MG/125ML (9MG/ML)	N021569	002	Jul 27, 2006	Feb	CPOT
>D>	+	MALLINCKRODT	45MG/50ML (9MG/ML)	N021569	001	Jul 27, 2006	Feb	CAHN
>D>			112.5MG/125ML (9MG/ML)	N021569	002	Jul 27, 2006	Feb	CAHN

SODIUM FLUORIDE F-18

INJECTABLE;INTRAVENOUS

SODIUM FLUORIDE F-18

>A> AP		PRECISION NUCLEAR	10-200mCi/ML	A204542	001	Feb 27, 2015	Feb	NEWA

SOMATROPIN RECOMBINANT

INJECTABLE;INJECTION

NORDITROPIN FLEXPRO

		NOVO NORDISK INC	30MG/3ML	N021148	011	Jan 23, 2015	Jan	NEWA

NORDITROPIN NORDIFLEX

	@	NOVO NORDISK INC	30MG/3ML	N021148	007	Mar 10, 2009	Jan	DISC

TELAPREVIR

TABLET;ORAL

INCIVEK

	@	VERTEX PHARMS	375MG	N201917	001	May 23, 2011	Jan	DISC

TERBINAFINE HYDROCHLORIDE

TABLET;ORAL

TERBINAFINE HYDROCHLORIDE

>D> AB		WOCKHARDT	EQ 250MG BASE	A078229	001	Jul 02, 2007	Feb	DISC
>A>	@		EQ 250MG BASE	A078229	001	Jul 02, 2007	Feb	DISC

TESTOSTERONE

GEL;TRANSDERMAL

ANDROGEL

AB1		ABBVIE	25MG/2.5GM PACKET	N021015	001	Feb 28, 2000	Jan	CTEC
AB1	+		50MG/5GM PACKET	N021015	002	Feb 28, 2000	Jan	CTEC

TESTIM

AB2	+	AUXILIUM PHARMS	50MG/5GM PACKET	N021454	001	Oct 31, 2002	Jan	CTEC

TESTOSTERONE

AB1		PERRIGO ISRAEL	25MG/2.5GM PACKET	N203098	002	Jan 31, 2013	Jan	CTEC
AB1			50MG/5GM PACKET	N203098	003	Jan 31, 2013	Jan	CTEC

VOGELXO

AB2		UPSHER SMITH	50MG/5GM PACKET	N204399	002	Jun 04, 2014	Jan	CTEC

TETRABENAZINE

TABLET;ORAL

XENAZINE

>D>		VALEANT BERMUDA	12.5MG	N021894	001	Aug 15, 2008	Feb	CAHN
>D>	+		25MG	N021894	002	Aug 15, 2008	Feb	CAHN
>A>		VALEANT PHARMS NORTH	12.5MG	N021894	001	Aug 15, 2008	Feb	CAHN
>A>	+		25MG	N021894	002	Aug 15, 2008	Feb	CAHN

TOBRAMYCIN

SOLUTION;INHALATION

KITABIS PAK

>D>		+	PULMOFLOW INC	300MG/5ML	N205433	001	Dec 02, 2014	Feb CTEC
>A>	AN			300MG/5ML	N205433	001	Dec 02, 2014	Feb CTEC

TOLTERODINE TARTRATE

TABLET;ORAL

TOLTERODINE TARTRATE

>A>	AB		IVAX SUB TEVA PHARMS	1MG	A077006	001	Feb 23, 2015	Feb NEWA
>A>	AB			2MG	A077006	002	Feb 23, 2015	Feb NEWA

TORSEMIDE

INJECTABLE;INJECTION

TORSEMIDE

		@	EUROHLTH INTL SARL	20MG/2ML (10MG/ML)	A078007	001	Jun 11, 2008	Jan DISC
		@		50MG/5ML (10MG/ML)	A078007	002	Jun 11, 2008	Jan DISC
		@	LUITPOLD	20MG/2ML (10MG/ML)	A090656	001	Apr 21, 2010	Jan DISC
		@		50MG/5ML (10MG/ML)	A090656	002	Apr 21, 2010	Jan DISC

TRIPTORELIN PAMOATE

INJECTABLE;INTRAMUSCULAR

TRELSTAR

		+	ACTAVIS LABS UT INC	EQ 3.75MG BASE/VIAL	N020715	001	Jun 15, 2000	Jan CAHN
		+		EQ 11.25MG BASE/VIAL	N021288	001	Jun 29, 2001	Jan CAHN
		+		EQ 22.5MG BASE/VIAL	N022437	001	Mar 10, 2010	Jan CAHN

UNOPROSTONE ISOPROPYL

SOLUTION/DROPS;OPHTHALMIC

RESCULA

		+	SUCAMPO PHARMA LLC	0.15%	N021214	001	Aug 03, 2000	Jan CAHN

VALPROIC ACID

CAPSULE;ORAL

VALPROIC ACID

	AB		BANNER LIFE SCIENCES	250MG	A073484	001	Jun 29, 1993	Jan CAHN

CAPSULE, DELAYED RELEASE;ORAL

STAVZOR

		@	BANNER LIFE SCIENCES	125MG	N022152	001	Jul 29, 2008	Jan CAHN
		@		250MG	N022152	002	Jul 29, 2008	Jan CAHN
		@		500MG	N022152	003	Jul 29, 2008	Jan CAHN

VANCOMYCIN HYDROCHLORIDE

CAPSULE;ORAL

VANCOMYCIN HYDROCHLORIDE

	AB		LUPIN LTD	EQ 125MG BASE	A090439	001	Jan 28, 2015	Jan NEWA
	AB			EQ 250MG BASE	A090439	002	Jan 28, 2015	Jan NEWA

VENLAFAXINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

VENLAFAXINE HYDROCHLORIDE

>D>	AB		VALEANT BERMUDA	EQ 37.5MG BASE	A090071	001	Apr 15, 2011	Feb CAHN
>D>	AB			EQ 75MG BASE	A090071	002	Apr 15, 2011	Feb CAHN
>D>	AB			EQ 150MG BASE	A090071	003	Apr 15, 2011	Feb CAHN
>A>	AB		VALEANT PHARMS NORTH	EQ 37.5MG BASE	A090071	001	Apr 15, 2011	Feb CAHN
>A>	AB			EQ 75MG BASE	A090071	002	Apr 15, 2011	Feb CAHN
>A>	AB			EQ 150MG BASE	A090071	003	Apr 15, 2011	Feb CAHN

ZAFIRLUKAST

TABLET;ORAL

ACCOLATE

>D>	AB		ASTRAZENECA	10MG	N020547	003	Sep 17, 1999	Feb CAHN
>D>	AB	+		20MG	N020547	001	Sep 26, 1996	Feb CAHN
>A>	AB		PAR PHARM INC	10MG	N020547	003	Sep 17, 1999	Feb CAHN
>A>	AB	+		20MG	N020547	001	Sep 26, 1996	Feb CAHN

ZONISAMIDE

CAPSULE;ORAL

ZONISAMIDE

AB	BANNER LIFE SCIENCES	25MG	A077813	001	Aug 16, 2006	Jan CAHN
AB		50MG	A077813	002	Aug 16, 2006	Jan CAHN
AB		100MG	A077813	003	Aug 16, 2006	Jan CAHN

CETIRIZINE HYDROCHLORIDE

CAPSULE;ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

	BANNER LIFE SCIENCES	5MG	N022429	001	Jul 23, 2009	Jan	CAHN
+		10MG	N022429	004	Jul 23, 2009	Jan	CAHN

CETIRIZINE HYDROCHLORIDE HIVES RELIEF

	BANNER LIFE SCIENCES	5MG	N022429	003	Jul 23, 2009	Jan	CAHN
+		10MG	N022429	002	Jul 23, 2009	Jan	CAHN

TABLET, CHEWABLE;ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

>D>	SANDOZ	5MG	A078692	001	Feb 14, 2008	Feb	CTNA
>D> +		10MG	A078692	002	Feb 14, 2008	Feb	CTNA

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

>A>	JUBILANT GENERICS	5MG	A091116	001	Feb 19, 2015	Feb	NEWA
>A>		10MG	A091116	002	Feb 19, 2015	Feb	NEWA
>A>	SANDOZ	5MG	A078692	001	Feb 14, 2008	Feb	CTNA
>A> +		10MG	A078692	002	Feb 14, 2008	Feb	CTNA

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

>A>	JUBILANT GENERICS	5MG	A091116	003	Feb 19, 2015	Feb	NEWA
>A>		10MG	A091116	004	Feb 19, 2015	Feb	NEWA

DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN

CAPSULE;ORAL

IBUPROFEN AND DIPHENHYDRAMINE HYDROCHLORIDE

	BANNER LIFE SCIENCES	25MG;EQ 200MG FREE ACID AND POTASSIUM SALT	A090397	001	Nov 22, 2010	Jan	CAHN

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

	SUN PHARMA GLOBAL	60MG;120MG	A090818	001	Jan 29, 2015	Jan	NEWA

IBUPROFEN

CAPSULE;ORAL

IBUPROFEN

	BANNER LIFE SCIENCES	EQ 200MG FREE ACID AND POTASSIUM SALT	A078682	001	Mar 24, 2009	Jan	CAHN

MIDOL LIQUID GELS

+	BANNER LIFE SCIENCES	200MG	N021472	001	Oct 18, 2002	Jan	CAHN

KETOTIFEN FUMARATE

SOLUTION/DROPS;OPHTHALMIC

ALAWAY

>A>	BAUSCH AND LOMB	EQ 0.035% BASE	N021996	002	Feb 11, 2015	Feb	NEWA

LOPERAMIDE HYDROCHLORIDE

CAPSULE;ORAL

LOPERAMIDE HYDROCHLORIDE

	BANNER LIFE SCIENCES	1MG	N021855	001	Aug 04, 2005	Jan	CAHN
+		2MG	N021855	002	Aug 04, 2005	Jan	CAHN

NAPROXEN SODIUM

CAPSULE;ORAL

NAPROXEN SODIUM

+	BANNER LIFE SCIENCES	EQ 200MG BASE	N021920	001	Feb 17, 2006	Jan	CAHN
>A>	CATALENT	EQ 200MG BASE	A202807	001	Feb 13, 2015	Feb	NEWA

POLYETHYLENE GLYCOL 3350

FOR SOLUTION;ORAL

POLYETHYLENE GLYCOL 3350

	RARITAN PHARMS INC	17GM/SCOOPFUL	A202071	001	Dec 28, 2012	Jan	CAHN

RANITIDINE HYDROCHLORIDE

TABLET;ORAL

RANITIDINE HYDROCHLORIDE

	@ WOCKHARDT	EQ 75MG BASE	A078884	001	Jul 31, 2008	Jan	DISC

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

CUMULATIVE SUPPLEMENT NUMBER 1 FEBRUARY 2015

NO FEBRUARY 2015 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 2015 ADDITIONS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2015

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
ABACAVIR SULFATE; DOLUTEGRAVIR SODIUM; LAMIVUDINE - TRIUMEQ								
N 205551	001	>A>	6417191	Mar 28, 2016	DP U-1572			
		>A>	6417191*PED	Sep 28, 2016				
ABACAVIR SULFATE; LAMIVUDINE - EPZICOM								
N 021652	001	>A>	6417191	Mar 28, 2016	DP U-257			
		>A>	6417191*PED	Sep 28, 2016				
ALVIMOPAN - ENTEREG								
N 021775	001	>A>	8946262	Feb 12, 2030	U-1655			
ARIPIPRAZOLE - ABILIFY								
N 021436	001						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY								
N 021436	002						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY								
N 021436	003						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY								
N 021436	004						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY								
N 021436	005						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY								
N 021436	006						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY								
N 021713	001		6977257	Apr 24, 2022	DP		>A> ODE	Dec 12, 2021
			6977257*PED	Oct 24, 2022				
ARIPIPRAZOLE - ABILIFY								
N 021729	002						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY								
N 021729	003						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY								
N 021729	004						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY								
N 021729	005						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY								
N 021866	001						>A> ODE	Dec 12, 2021
ARIPIPRAZOLE - ABILIFY MAINTENA KIT								
N 202971	001		5006528	Apr 20, 2015	DS DP U-543			
			5006528	Apr 20, 2015	DS DP U-1632			
			8030313	Oct 19, 2024	U-543			
			8030313	Oct 19, 2024	U-1632			
			8338427	Mar 15, 2025	DP U-543			
			8338427	Mar 15, 2025	DP U-1633			
			8338428	Aug 06, 2023	DP U-543			
			8338428	Aug 06, 2023	DP U-1633			
			8759351	Aug 06, 2023	DP U-1530			
			8759351	Aug 06, 2023	DP U-1633			
ARIPIPRAZOLE - ABILIFY MAINTENA KIT								
N 202971	002		5006528	Apr 20, 2015	DS DP U-543			
			5006528	Apr 20, 2015	DS DP U-1632			
			8030313	Oct 19, 2024	U-543			
			8030313	Oct 19, 2024	U-1632			
			8338427	Mar 15, 2025	DP U-543			
			8338427	Mar 15, 2025	DP U-1633			
			8338428	Aug 06, 2023	DP U-543			
			8338428	Aug 06, 2023	DP U-1633			
			8759351	Aug 06, 2023	DP U-1530			
			8759351	Aug 06, 2023	DP U-1633			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2015

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
ARIPIPRAZOLE - ABILIFY MAINTENA KIT								
N 202971	003		5006528	Apr 20, 2015	DS DP U-543			
			5006528	Apr 20, 2015	DS DP U-1632			
			8030313	Oct 19, 2024	U-543			
			8030313	Oct 19, 2024	U-1632			
			8338427	Mar 15, 2025	DP U-543			
			8338427	Mar 15, 2025	DP U-1633			
			8338428	Aug 06, 2023	DP U-543			
			8338428	Aug 06, 2023	DP U-1633			
			8759351	Aug 06, 2023	DP U-1530			
			8759351	Aug 06, 2023	DP U-1633			
ARIPIPRAZOLE - ABILIFY MAINTENA KIT								
N 202971	004		5006528	Apr 20, 2015	DS DP U-543			
			5006528	Apr 20, 2015	DS DP U-1632			
			8030313	Oct 19, 2024	U-543			
			8030313	Oct 19, 2024	U-1632			
			8338427	Mar 15, 2025	DP U-543			
			8338427	Mar 15, 2025	DP U-1633			
			8338428	Aug 06, 2023	DP U-543			
			8338428	Aug 06, 2023	DP U-1633			
			8759351	Aug 06, 2023	DP U-1530			
			8759351	Aug 06, 2023	DP U-1633			
ASENAPINE MALEATE - SAPHRIS								
N 022117	001	>A>	5763476	Jun 09, 2020	DP U-326			
		>A>	5763476*PED	Dec 09, 2020				
		>A>	7741358	Apr 06, 2026	DS DP U-1064			
		>A>	7741358*PED	Oct 06, 2026				
		>A>	8022228	Apr 06, 2026	DS DP			
		>A>	8022228*PED	Oct 06, 2026				
ASENAPINE MALEATE - SAPHRIS								
N 022117	002	>A>	5763476	Jun 09, 2020	DP U-326			
		>A>	5763476*PED	Dec 09, 2020				
		>A>	7741358	Apr 06, 2026	DS DP U-1064			
		>A>	7741358*PED	Oct 06, 2026				
		>A>	8022228	Apr 06, 2026	DS DP			
		>A>	8022228*PED	Oct 06, 2026				
ATAZANAVIR SULFATE; COBICISTAT - EVOTAZ								
N 206353	001	>A>	5849911	Jun 20, 2017	DS DP U-167			
		>A>	6087383	Dec 21, 2018	DS DP			
		>A>	8148374	Sep 03, 2029	DS DP U-1279			
AZELASTINE HYDROCHLORIDE - ASTEPRO								
N 022203	001						>A> NPP	Feb 20, 2018
							>A> NPP	Feb 20, 2018
AZELASTINE HYDROCHLORIDE; FLUTICASONE PROPIONATE - DYMISTA								
N 202236	001						>A> NPP	Feb 20, 2018
BESIFLOXACIN HYDROCHLORIDE - BESIVANCE								
N 022308	001		8937062	Nov 13, 2029	U-80			
BIMATOPROST - LUMIGAN								
N 022184	001		8933120	Mar 16, 2025	DP			
			8933127	Mar 16, 2025	DP			
BIMATOPROST - LATISSE								
N 022369	001		7351404	May 25, 2024	U-939	Y		
			7388029	Jan 21, 2022	U-938	Y		
BUDESONIDE - UCERIS								
N 205613	001	>A>	5914122	Dec 19, 2015	DP			
BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - ZUBSOLV								
N 204242	001		8940330	Sep 18, 2032	DP			
BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - ZUBSOLV								
N 204242	002		8940330	Sep 18, 2032	DP			
BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - ZUBSOLV								
N 204242	003		8940330	Sep 18, 2032	DP			

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BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - ZUBSOLV							
N 204242 004		8940330	Sep 18, 2032	DP			
BUPROPION HYDROCHLORIDE; NALTREXONE HYDROCHLORIDE - CONTRAVE							
N 200063 001		8916195	Feb 02, 2030	U-1639			
CARBIDOPA; LEVODOPA - RYTARY							
N 203312 001		7094427	May 29, 2022	DP U-1645		NDF	Jan 07, 2018
	>A>	8377474	Dec 26, 2028	DP U-219			
	>A>	8377474	Dec 26, 2028	DP U-1645			
	>A>	8454998	Dec 26, 2028	DP U-219			
	>A>	8454998	Dec 26, 2028	DP U-1645			
	>A>	8454998	Dec 26, 2028	DP U-1646			
	>A>	8454998	Dec 26, 2028	DP U-1647			
	>A>	8454998	Dec 26, 2028	DP U-1649			
		8557283	Dec 26, 2028	DP U-219			
		8557283	Dec 26, 2028	DP U-1645			
CARBIDOPA; LEVODOPA - RYTARY							
N 203312 002		7094427	May 29, 2022	DP U-1645		NDF	Jan 07, 2018
	>A>	8377474	Dec 26, 2028	DP U-219			
	>A>	8377474	Dec 26, 2028	DP U-1645			
	>A>	8454998	Dec 26, 2028	DP U-219			
	>A>	8454998	Dec 26, 2028	DP U-1645			
	>A>	8454998	Dec 26, 2028	DP U-1646			
	>A>	8454998	Dec 26, 2028	DP U-1647			
	>A>	8454998	Dec 26, 2028	DP U-1649			
		8557283	Dec 26, 2028	DP U-219			
		8557283	Dec 26, 2028	DP U-1645			
CARBIDOPA; LEVODOPA - RYTARY							
N 203312 003		7094427	May 29, 2022	DP U-1645		NDF	Jan 07, 2018
	>A>	8377474	Dec 26, 2028	DP U-219			
	>A>	8377474	Dec 26, 2028	DP U-1645			
	>A>	8454998	Dec 26, 2028	DP U-219			
	>A>	8454998	Dec 26, 2028	DP U-1645			
	>A>	8454998	Dec 26, 2028	DP U-1646			
	>A>	8454998	Dec 26, 2028	DP U-1647			
	>A>	8454998	Dec 26, 2028	DP U-1649			
		8557283	Dec 26, 2028	DP U-219			
		8557283	Dec 26, 2028	DP U-1645			
CARBIDOPA; LEVODOPA - RYTARY							
N 203312 004		7094427	May 29, 2022	DP U-1645		NDF	Jan 07, 2018
	>A>	8377474	Dec 26, 2028	DP U-219			
	>A>	8377474	Dec 26, 2028	DP U-1645			
	>A>	8454998	Dec 26, 2028	DP U-219			
	>A>	8454998	Dec 26, 2028	DP U-1645			
	>A>	8454998	Dec 26, 2028	DP U-1646			
	>A>	8454998	Dec 26, 2028	DP U-1647			
	>A>	8454998	Dec 26, 2028	DP U-1649			
		8557283	Dec 26, 2028	DP U-219			
		8557283	Dec 26, 2028	DP U-1645			
CARBIDOPA; LEVODOPA - DUOPA							
N 203952 001						NP	Jan 09, 2018
						>A> ODE	Jan 09, 2022
CELECOXIB - CELECOXIB							
A 076898 002						PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 076898 003						PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 076898 004						PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 078857 002						PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 078857 003						PC	Jun 02, 2015

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CELECOXIB - CELECOXIB						
A 078857 004					PC	Jun 02, 2015
CELECOXIB - CELECOXIB						
A 200562 002					PC	Jun 02, 2015
CELECOXIB - CELECOXIB						
A 200562 003					PC	Jun 02, 2015
CELECOXIB - CELECOXIB						
A 200562 004					PC	Jun 02, 2015
CICLESONIDE - ALVESCO						
N 021658 002	>A> 8371292	Feb 01, 2028	U-1355			
CICLESONIDE - ALVESCO						
N 021658 003	>A> 8371292	Feb 01, 2028	U-1355			
CICLESONIDE - OMNARIS						
N 022004 001	>A> 8371292	Feb 01, 2028	U-1356			
CICLESONIDE - ZETONNA						
N 202129 001	>A> 8371292	Feb 01, 2028	U-1357			
COBICISTAT; DARUNAVIR ETHANOLATE - PREZCOBIX						
N 205395 001	>A> 5843946	Dec 01, 2015	DP U-1660			
	>A> 5843946*PED	Jun 01, 2016				
	>A> 7470506	Jun 23, 2019	U-1660			
	>A> 7470506*PED	Dec 23, 2019				
	>A> 7700645	Dec 26, 2026	DS DP			
	>A> 7700645*PED	Jun 26, 2027				
	>A> 8148374	Sep 03, 2029	DS DP U-1660			
	>A> 8518987	Feb 16, 2024	DS DP			
	>A> 8518987*PED	Aug 16, 2024				
	>A> 8597876	Jun 23, 2019	U-1660			
	>A> 8597876*PED	Dec 23, 2019				
	>A> RE42889	Oct 19, 2016	DP			
	>A> RE42889*PED	Apr 19, 2017				
	>A> RE43596	May 09, 2017	DS DP			
	>A> RE43596*PED	Nov 09, 2017				
	>A> RE43802	Oct 19, 2016	U-1660			
	>A> RE43802*PED	Apr 19, 2017				
COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - STRIBILD						
N 203100 001					I-704	Dec 17, 2017
COLCHICINE - MITIGARE						
N 204820 001	8927607	Aug 22, 2033	U-1020			
CRIZOTINIB - XALKORI						
N 202570 001	>A> 7230098	Aug 26, 2025	DS			
CRIZOTINIB - XALKORI						
N 202570 002	>A> 7230098	Aug 26, 2025	DS			
CROFELEMER - FULYZAQ						
N 202292 001	>A> 8962680	Oct 31, 2031	U-1319			
CYANOCOBALAMIN - NASCOBAL						
N 021642 001	7229636	Aug 01, 2024	DP U-817			
	7879349	Aug 01, 2024	DP U-1152			
	8003353	Aug 01, 2024	U-817			
	8940714	Feb 26, 2024	U-1152			
DANTROLENE SODIUM - RYANODEX						
N 205579 001					>A> ODE	Jul 22, 2021

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DASABUVIR SODIUM ; OMBITASVIR; PARITAPREVIR; RITONAVIR - VIEKIRA PAK (COPACKAGED)								
N 206619	001		6037157	Jun 26, 2016			U-1635	
			6703403	Jun 26, 2016			U-1635	
			7148359	Jul 19, 2019	DP			
			7364752	Nov 10, 2020	DP			
			8188104	May 17, 2029	DS DP		U-1636	
			8268349	Aug 25, 2024	DP			
			8399015	Aug 25, 2024	DP			
			8420596	Apr 10, 2031	DS DP			
			8466159	Sep 04, 2032			U-1637	
			8492386	Sep 04, 2032			U-1637	
			8501238	Sep 17, 2028	DS DP		U-1636	
			8642538	Sep 10, 2029	DS DP		U-1638	
			8680106	Sep 04, 2032			U-1637	
			8685984	Sep 04, 2032			U-1637	
			8686026	Jun 09, 2031	DP			
			8691938	Apr 13, 2032	DS DP			
DESMOPRESSIN ACETATE - DESMOPRESSIN ACETATE								
A 200653	001						PC	May 16, 2015
DESMOPRESSIN ACETATE - DESMOPRESSIN ACETATE								
A 200653	002						PC	May 16, 2015
DESVENLAFAXINE SUCCINATE - PRISTIQ								
N 021992	003		6673838	Mar 01, 2022	DS		U-860	
			6673838	Mar 01, 2022	DS		U-1364	
			8269040	Jul 05, 2027	DS			
DEXAMETHASONE - OZURDEX								
N 022315	001	>A>	8043628	Oct 20, 2020			U-1205	
		>A>	8088407	Oct 20, 2020			U-1205	
DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX								
N 021038	004		6716867	Mar 31, 2019			U-1472	
			6716867*PED	Oct 01, 2019				
			8242158	Jan 04, 2032	DP			
			8242158*PED	Jul 04, 2032				
			8338470	Jan 04, 2032	DP			
			8338470*PED	Jul 04, 2032				
			8455527	Jan 04, 2032			U-421	
			8455527*PED	Jul 04, 2032				
			8648106	Jan 04, 2032	DP			
			8648106*PED	Jul 04, 2032				
DICLOFENAC POTASSIUM - CAMBIA								
N 022165	001		8927604	Jun 16, 2026			U-436	
DICLOFENAC SODIUM - DYLOJECT								
N 022396	001		6407079	Jun 18, 2019	DP			
		>A>	8946292	Mar 22, 2027			U-1659	
DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - NAMZARIC								
N 206439	001		5061703	Oct 11, 2015			U-1641	
			5061703*PED	Apr 11, 2016				
			8058291	Dec 05, 2029			U-1641	
			8168209	May 22, 2026	DP			
			8168209*PED	Nov 22, 2026				
			8173708	May 22, 2026			U-1641	
			8173708*PED	Nov 22, 2026				
			8283379	May 22, 2026			U-1641	
			8283379*PED	Nov 22, 2026				
			8293794	Nov 22, 2025	DP			

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DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - NAMZARIC							
N 206439	002	5061703	Oct 11, 2015	U-1641			
		5061703*PED	Apr 11, 2016				
		8039009	Sep 24, 2029	U-1641			
		8039009*PED	Mar 24, 2030				
		8058291	Dec 05, 2029	U-1641			
		8168209	May 22, 2026	DP			
		8168209*PED	Nov 22, 2026				
		8173708	May 22, 2026	U-1641			
		8173708*PED	Nov 22, 2026				
		8283379	May 22, 2026	U-1641			
		8283379*PED	Nov 22, 2026				
		8293794	Nov 22, 2025	DP			
		8329752	May 22, 2026	DP			
		8329752*PED	Nov 22, 2026				
		8338485	Nov 22, 2025	DP			
		8338486	Nov 22, 2025	U-1641			
		8362085	May 22, 2026	U-1641			
		8362085*PED	Nov 22, 2026				
		8580858	Nov 22, 2025	U-1641			
		8598233	May 22, 2026	DP			
		8598233*PED	Nov 22, 2026				
DOXYCYCLINE HYCLATE - DOXTERIC							
N 050795	006	6958161	Dec 15, 2022	DP U-918			
		8715724	Feb 03, 2028	DP			
EDOXABAN TOSYLATE - SAVAYSA							
N 206316	001	7365205	Jun 12, 2023	DS		NCE	Jan 08, 2020
EDOXABAN TOSYLATE - SAVAYSA							
N 206316	002	7365205	Jun 12, 2023	DS		NCE	Jan 08, 2020
EDOXABAN TOSYLATE - SAVAYSA							
N 206316	003	7365205	Jun 12, 2023	DS		NCE	Jan 08, 2020
EMPAGLIFLOZIN; LINAGLIPTIN - GLYXAMBI							
N 206073	001	>A> 6303661	Apr 24, 2017	U-1651		NC	Jan 30, 2018
		>A> 6890898	Feb 02, 2019	U-1652		NCE	May 02, 2016
		>A> 7078381	Feb 02, 2019	U-1651		NCE	Aug 01, 2019
		>A> 7407955	Aug 12, 2023	DS DP			
		>A> 7459428	Feb 02, 2019	U-1651			
		>A> 7579449	Nov 05, 2025	DS			
		>A> 7713938	Apr 15, 2027	DS DP			
		>A> 8119648	Aug 12, 2023	U-1651			
		>A> 8178541	Aug 12, 2023	DP U-1653			
		>A> 8178541	Aug 12, 2023	DP U-1654			
		>A> 8551957	Oct 19, 2029	DP U-1651			
		>A> 8673927	May 04, 2027	DP U-1652			
		>A> 8846695	Jun 04, 2030	U-1652			
		>A> 8883805	Nov 26, 2025	DP			
EMPAGLIFLOZIN; LINAGLIPTIN - GLYXAMBI							
N 206073	002	>A> 6303661	Apr 24, 2017	U-1651		NC	Jan 30, 2018
		>A> 6890898	Feb 02, 2019	U-1652		NCE	May 02, 2016
		>A> 7078381	Feb 02, 2019	U-1651		NCE	Aug 01, 2019
		>A> 7407955	Aug 12, 2023	DS DP			
		>A> 7459428	Feb 02, 2019	U-1651			
		>A> 7579449	Nov 05, 2025	DS			
		>A> 7713938	Apr 15, 2027	DS DP			
		>A> 8119648	Aug 12, 2023	U-1651			
		>A> 8178541	Aug 12, 2023	DP U-1653			
		>A> 8178541	Aug 12, 2023	DP U-1654			
		>A> 8551957	Oct 19, 2029	DP U-1651			
		>A> 8673927	May 04, 2024	DP U-1652			
		>A> 8846695	Jun 04, 2030	U-1652			
		>A> 8883805	Nov 26, 2025	DP			
EPINEPHRINE - AUVI-Q							
N 201739	001	8920377	Nov 23, 2024	DP			
		8926594	Mar 31, 2026	DP			

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EPINEPHRINE - AUVI-Q								
N 201739	002		8920377	Nov 23, 2024	DP			
			8926594	Mar 31, 2026	DP			
ERIBULIN MESYLATE - HALAVEN								
N 201532	001	>A>	6214865	Jul 20, 2023	DS			
ESOMEPRAZOLE MAGNESIUM - NEXIUM 24HR								
N 204655	001	>A>	5690960	Nov 25, 2014	DP U-1509			
		>A>	5690960*PED	May 25, 2015				
		>A>	5714504	Feb 03, 2015	DP U-1509			
		>A>	5714504*PED	Aug 03, 2015				
		>A>	5877192*PED	Nov 27, 2014				
		>A>	5900424	May 04, 2016	DS U-1509			
		>A>	5900424*PED	Nov 04, 2016				
		>A>	6369085	May 25, 2018	DS DP U-1509			
		>A>	6369085*PED	Nov 25, 2018				
		>A>	6428810	Nov 03, 2019	DP U-1509			
		>A>	6428810*PED	May 03, 2020				
		>A>	6875872*PED	Nov 27, 2014				
		>A>	7411070	May 25, 2018	DS			
		>A>	7411070*PED	Nov 25, 2018				
ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO								
N 022511	001	>A>	8945621	Oct 17, 2031	U-1661			
ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO								
N 022511	002	>A>	8945621	Oct 17, 2031	U-1661			
FERRIC PYROPHOSPHATE CITRATE - TRIFERIC								
N 206317	001	>A>	6689275	Dec 31, 2016	U-1656			
		>A>	6779468	Dec 31, 2016	U-1656			
		>A>	7816404	Apr 17, 2029	DP U-1656			
FEXOFENADINE HYDROCHLORIDE - CHILDREN'S ALLEGRA ALLERGY								
N 201373	001	>A>	8933097	Aug 16, 2032	DP			
FEXOFENADINE HYDROCHLORIDE - CHILDREN'S ALLEGRA HIVES								
N 201373	002	>A>	8933097	Aug 16, 2032	DP			
FLUTEMETAMOL F-18 - VIZAMYL								
N 203137	001	>A>	8916131	Sep 16, 2028	DP			
FLUTEMETAMOL F-18 - VIZAMYL								
N 203137	002	>A>	8916131	Sep 16, 2028	DP			
FLUTICASONE PROPIONATE - CUTIVATE								
N 021152	001						NPP	Jan 16, 2018
GLATIRAMER ACETATE - COPAXONE								
N 020622	003	>A>	8969302	Aug 19, 2030	U-441			
GUANFACINE HYDROCHLORIDE - GUANFACINE HYDROCHLORIDE								
A 200881	001						>A> PC	May 30, 2015
GUANFACINE HYDROCHLORIDE - GUANFACINE HYDROCHLORIDE								
A 200881	002						>A> PC	May 30, 2015
GUANFACINE HYDROCHLORIDE - GUANFACINE HYDROCHLORIDE								
A 200881	003						>A> PC	May 30, 2015
GUANFACINE HYDROCHLORIDE - GUANFACINE HYDROCHLORIDE								
A 200881	004						>A> PC	May 30, 2015
IBRUTINIB - IMBRUVICA								
N 205552	001		8497277	Dec 28, 2026	U-1456		I-702	Jan 29, 2018
			8497277	Dec 28, 2026	U-1491		>A> ODE	Jan 29, 2022
			8497277	Dec 28, 2026	U-1650			
INSULIN ASPART RECOMBINANT - NOVOLOG FLEXTOUCH								
N 020986	005		8920383	Jul 17, 2026	DP			
INSULIN DETEMIR RECOMBINANT - LEVEMIR FLEXTOUCH								
N 021536	005	>A>	8920383	Jul 17, 2026	DP			
INSULIN GLARGINE RECOMBINANT - TOUJEO SOLOSTAR								
N 206538	001						>A> NP	Feb 25, 2018

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IOFLUPANE I-123 - DATSCAN							
N 022454 001	>A>	5310912	Feb 25, 2016	DS			
ISOTRETINOIN - ABSORICA							
N 021951 001	>A>	8952064	Sep 21, 2021	DP			
ISOTRETINOIN - ABSORICA							
N 021951 002	>A>	8952064	Sep 21, 2021	DP			
ISOTRETINOIN - ABSORICA							
N 021951 003	>A>	8952064	Sep 21, 2021	DP			
ISOTRETINOIN - ABSORICA							
N 021951 004	>A>	8952064	Sep 21, 2021	DP			
ISOTRETINOIN - ABSORICA							
N 021951 005	>A>	8952064	Sep 21, 2021	DP			
ISOTRETINOIN - ABSORICA							
N 021951 006	>A>	8952064	Sep 21, 2021	DP			
IVACAFTOR - KALYDECO							
N 203188 001		8354427	Jul 06, 2026	U-1311		I-705	Dec 30, 2017
IVERMECTIN - SOOLANTRA							
N 206255 001		5952372	Sep 18, 2018	U-1631			
		6133310	Apr 26, 2019	U-1631			
		7550440	Apr 22, 2024	DP U-1631			
		8080530	Apr 22, 2024	DP U-1631			
		8093219	Apr 22, 2024	DP U-1631			
		8415311	Apr 22, 2024	DP U-1631			
		8470788	Apr 22, 2024	DP U-1631			
		8815816	Apr 22, 2024	DP U-1631			
KETOROLAC TROMETHAMINE - ACULAR LS							
N 021528 001	>A>	8946281	May 28, 2024	U-1662			
LAMIVUDINE; RALTEGRAVIR POTASSIUM - DUTREBIS							
N 206510 001	>A>	7169780	Oct 03, 2023	DS DP			
	>A>	7217713	Oct 21, 2022	U-1663			
	>A>	7435734	Oct 21, 2022	U-1663			
	>A>	7754731	Mar 11, 2029	DS DP U-1663			
	>A>	7820660	Apr 25, 2023	DS			
LENALIDOMIDE - REVLIMID							
N 021880 001						>A> I-706	Feb 17, 2018
LENALIDOMIDE - REVLIMID							
N 021880 002						>A> I-706	Feb 17, 2018
LENALIDOMIDE - REVLIMID							
N 021880 003						>A> I-706	Feb 17, 2018
LENALIDOMIDE - REVLIMID							
N 021880 004						>A> I-706	Feb 17, 2018
LENALIDOMIDE - REVLIMID							
N 021880 005						>A> I-706	Feb 17, 2018
LENALIDOMIDE - REVLIMID							
N 021880 006						>A> I-706	Feb 17, 2018
LENVATINIB MESYLATE - LENVIMA							
N 206947 001	>A>	7253286	Oct 19, 2021	DS DP		>A> NCE	Feb 13, 2020
	>A>	7612208	Sep 19, 2026	DS DP		>A> ODE	Feb 13, 2022
LENVATINIB MESYLATE - LENVIMA							
N 206947 002	>A>	7253286	Oct 19, 2021	DS DP		>A> NCE	Feb 13, 2020
	>A>	7612208	Sep 19, 2026	DS DP		>A> ODE	Feb 13, 2022
LEVALBUTEROL HYDROCHLORIDE - XOPENEX							
N 020837 001						M-151	Jan 22, 2018
LEVALBUTEROL HYDROCHLORIDE - XOPENEX							
N 020837 002						M-151	Jan 22, 2018
LEVALBUTEROL HYDROCHLORIDE - XOPENEX							
N 020837 003						M-151	Jan 22, 2018

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
LEVALBUTEROL HYDROCHLORIDE - XOPENEX						
N 020837 004					M-151	Jan 22, 2018
LEVONORGESTREL - LILETTA						
N 206229 001					>A> NP	Feb 26, 2018
LINACLOTIDE - LINZESS						
N 202811 001	8933030	Feb 17, 2031	DP			
LINACLOTIDE - LINZESS						
N 202811 002	8933030	Feb 17, 2031	DP			
LINAGLIPTIN - TRADJENTA						
N 201280 001	8853156	Mar 05, 2031	U-1642			
LIRAGLUTIDE RECOMBINANT - SAXENDA						
N 206321 001	6268343	Aug 22, 2022	DS DP U-1255			
	6458924	Aug 22, 2017	DS DP U-1255			
	6899699	Jan 01, 2022	DP			
	7235627	Aug 22, 2017	DS DP			
	7686786	Aug 03, 3026	DP			
	8114833	Aug 13, 2025	DP			
	8672898	Jan 02, 2022	DP			
	8684969	Oct 20, 2025	DP			
	8920383	Jul 17, 2026	DP			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 001					I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 002					I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 003					I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 004					I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 005					I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 006					I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 007					I-703	Jan 30, 2018
LOMITAPIDE MESYLATE - JUXTAPID						
N 203858 001 >A>	5712279	Feb 21, 2016	DS U-1317			
LOMITAPIDE MESYLATE - JUXTAPID						
N 203858 002 >A>	5712279	Feb 21, 2016	DS U-1317			
LOMITAPIDE MESYLATE - JUXTAPID						
N 203858 003 >A>	5712279	Feb 21, 2016	DS U-1317			
LORCASERIN HYDROCHLORIDE - BELVIQ						
N 022529 001 >A>	8946207	Jun 16, 2024	DP			
MESALAMINE - APRISO						
N 022301 001	8940328	Apr 20, 2018	DP			
>A>	8956647	Apr 20, 2018	DP			
METHOTREXATE - OTREXUP						
N 204824 001 >A>	8945063	Mar 19, 2030	DP U-1442			
METHOTREXATE - OTREXUP						
N 204824 002 >A>	8945063	Mar 19, 2030	DP U-1442			
METHOTREXATE - OTREXUP						
N 204824 003 >A>	8945063	Mar 19, 2030	DP U-1442			
METHOTREXATE - OTREXUP						
N 204824 004 >A>	8945063	Mar 19, 2030	DP U-1442			
METHOTREXATE - OTREXUP						
N 204824 005 >A>	8945063	Mar 19, 2030	DP U-1442			
METRONIDAZOLE - NUVESSA						
N 205223 001 >A>	8946276	Jun 28, 2032	U-1664			

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MIFEPRISTONE - KORLYM									
N 202107	001		8921348	Aug 27, 2028		U-1643			
MINOXIDIL - WOMEN'S ROGAINE									
N 021812	002		6946120	Apr 20, 2019		DP U-702			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA									
N 022321	001		8623418	Nov 07, 2029		U-1640			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA									
N 022321	002		8623418	Nov 07, 2029		U-1640			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA									
N 022321	003		8623418	Nov 07, 2029		U-1640			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA									
N 022321	004		8623418	Nov 07, 2029		U-1640			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA									
N 022321	005		8623418	Nov 07, 2029		U-1640			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA									
N 022321	006		8623418	Nov 07, 2029		U-1640			
NALOXONE HYDROCHLORIDE - EVZIO									
N 205787	001		8926594	Mar 31, 2026		DP			
NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE - TARGINIQ									
N 205777	001	>A>	8969369	May 10, 2022		DP U-1556			
NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE - TARGINIQ									
N 205777	002	>A>	8969369	May 10, 2022		DP U-1556			
NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE - TARGINIQ									
N 205777	003	>A>	8969369	May 10, 2022		DP U-1556			
NETUPITANT; PALONOSETRON HYDROCHLORIDE - AKYNZEO									
N 205718	001	>A>	8951969	Nov 18, 2030		DP			
NICOTINE POLACRILEX - NICORETTE									
N 022360	001	>A>	8940772	Apr 30, 2029		DP			
NICOTINE POLACRILEX - NICORETTE									
N 022360	002	>A>	8940772	Apr 30, 2029		DP			
OLAPARIB - LYNPARZA									
N 206162	001		7151102	Apr 29, 2022	DS	DP		>A> ODE	Dec 19, 2021
			7449464	Oct 11, 2024	DS	DP			
			7981889	Oct 11, 2024	DS	DP			
			8143241	Aug 12, 2027		U-1634			
			8247416	Sep 24, 2028	DS				
			8859562	Aug 04, 2031		U-1634			
			8912187	Mar 12, 2024		U-1634			
OLOPATADINE HYDROCHLORIDE - PAZEO									
N 206276	001							NP	Jan 30, 2018
								PED	Jul 30, 2018
OXYBUTYNIN CHLORIDE - GELNIQUE									
N 022204	001		8920392	Mar 26, 2031		U-1644			
OXYCODONE HYDROCHLORIDE - OXYCONTIN									
N 022272	001							>A> M-153	Apr 16, 2016
OXYCODONE HYDROCHLORIDE - OXYCONTIN									
N 022272	002							>A> M-153	Apr 16, 2016
OXYCODONE HYDROCHLORIDE - OXYCONTIN									
N 022272	003							>A> M-153	Apr 16, 2016
OXYCODONE HYDROCHLORIDE - OXYCONTIN									
N 022272	004							>A> M-153	Apr 16, 2016
OXYCODONE HYDROCHLORIDE - OXYCONTIN									
N 022272	005							>A> M-153	Apr 16, 2016
OXYCODONE HYDROCHLORIDE - OXYCONTIN									
N 022272	006							>A> M-153	Apr 16, 2016
OXYCODONE HYDROCHLORIDE - OXYCONTIN									
N 022272	007							>A> M-153	Apr 16, 2016

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PALBOCICLIB - IBRANCE							
N 207103 001	>A>	6936612	Jan 22, 2023	DS DP		>A> NCE	Feb 03, 2020
	>A>	7208489	Jan 16, 2023	DS DP			
	>A>	7456168	Jan 16, 2023	U-1658			
PALBOCICLIB - IBRANCE							
N 207103 002	>A>	6936612	Jan 22, 2023	DS DP		>A> NCE	Feb 03, 2020
	>A>	7208489	Jan 16, 2023	DS DP			
	>A>	7456168	Jan 16, 2023	U-1658			
PALBOCICLIB - IBRANCE							
N 207103 003	>A>	6936612	Jan 22, 2023	DS DP		>A> NCE	Feb 03, 2020
	>A>	7208489	Jan 16, 2023	DS DP			
	>A>	7456168	Jan 16, 2023	U-1658			
PANOBINOSTAT - FARYDAK							
N 205353 001						>A> NCE	Feb 23, 2020
PANOBINOSTAT - FARYDAK							
N 205353 002						>A> NCE	Feb 23, 2020
PANOBINOSTAT - FARYDAK							
N 205353 003						>A> NCE	Feb 23, 2020
PAROXETINE MESYLATE - BRISDELLE							
N 204516 001		8946251	Aug 04, 2026	DS DP U-904			
RIFAXIMIN - XIFAXAN							
N 022554 001		8946252	Jul 24, 2029	U-1481			
	>A>	8969398	Oct 02, 2029	U-1481			
ROFLUMILAST - DALIRESP							
N 022522 001		5712298	Jan 27, 2016	DS DP U-1115			
SODIUM OXYBATE - XYREM							
N 021196 001	>A>	8952062	Dec 22, 2019	U-1101			
	>A>	8952062	Dec 22, 2019	U-1102			
SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO							
N 021148 008		8920383	Jul 17, 2026	DP			
SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO							
N 021148 009		8920383	Jul 17, 2026	DP			
SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO							
N 021148 010		8920383	Jul 17, 2026	DP			
SPINOSAD - NATROBA							
N 022408 001						M-152	Nov 30, 2017
TIGECYCLINE - TYGACIL							
N 021821 001	>A>	8975242	Oct 24, 2028	DP			
TRANEXAMIC ACID - LYSTEDA							
N 022430 001	>A>	8957113	Mar 04, 2025	DP U-1182			
ULIPRISTAL ACETATE - ELLA							
N 022474 001	>A>	8962603	Jun 12, 2030	U-1657			

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