APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

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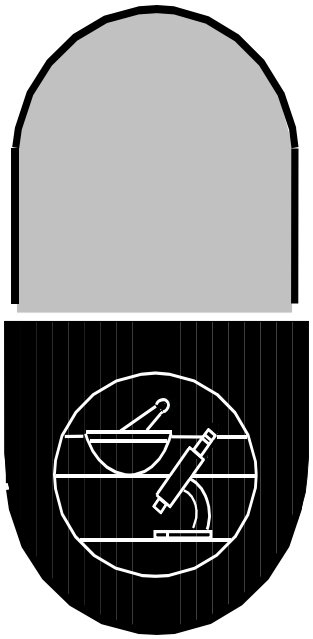
CUMULATIVE SUPPLEMENT 1
JANUARY 2015



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
Food and Drug Administration

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35th EDITION

Cumulative Supplement 1

January 2015

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35th EDITION

CUMULATIVE SUPPLEMENT 1
January 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

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 will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

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

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

1.4 LEVOTHYROXINE SODIUM

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

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

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

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

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

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

1.5 AVAILABILITY OF THE EDITION

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

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Publications. The PDF annual and cumulative supplements duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

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

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

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

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

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

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

DEFINITIONS

Drug Product

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

New Molecular Entity

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

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

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; CODEINE PHOSPHATE

CAPSULE;ORAL

FIORICET W/ CODEINE

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

AMANTADINE HYDROCHLORIDE

CAPSULE;ORAL

AMANTADINE HYDROCHLORIDE

>A>	AB		BANNER LIFE SCIENCES	100MG	A078720	001	May 29, 2008	Jan CAHN
>D>	AB		BANNER PHARMACAPS	100MG	A078720	001	May 29, 2008	Jan CAHN

>A> AMLODIPINE BESYLATE; PERINDOPRIL ARGININE

>A> TABLET;ORAL

>A> PRESTALIA

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

AMMONIA N-13

INJECTABLE;INTRAVENOUS

AMMONIA N 13

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

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE;ORAL

FIORINAL

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

TABLET;ORAL

FIORINAL

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

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE;ORAL

FIORINAL W/CODEINE

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

>A> ATAZANAVIR SULFATE; COBICISTAT

>A> TABLET;ORAL

>A> EVOTAZ

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

BENAZEPRIL HYDROCHLORIDE

TABLET;ORAL

BENAZEPRIL HYDROCHLORIDE

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

BENZONATATE

CAPSULE;ORAL

BENZONATATE

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

BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE

GEL;TOPICAL

ONEXTON

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

BETHANECHOL CHLORIDE

TABLET;ORAL

DUVOID

>D>		@ WELLSPRING PHARM	10MG	A086262	001		Jan	CMFD
>A>	AA		10MG	A086262	001		Jan	CMFD

BEXAROTENE

CAPSULE;ORAL

BEXAROTENE

>A>		@ BANNER LIFE SCIENCES	75MG	A203174	001	Aug 12, 2014	Jan	CAHN
>D>		@ BANNER PHARMACAPS	75MG	A203174	001	Aug 12, 2014	Jan	CAHN

BROMFENAC SODIUM

SOLUTION/DROPS;OPHTHALMIC

BROMFENAC SODIUM

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

CALCITRIOL

CAPSULE;ORAL

CALCITRIOL

>A>	AB	BANNER LIFE SCIENCES	0.25MCG	A091174	001	May 24, 2013	Jan	CAHN
>A>	AB		0.5MCG	A091174	002	May 24, 2013	Jan	CAHN
>D>	AB	BANNER PHARMACAPS	0.25MCG	A091174	001	May 24, 2013	Jan	CAHN
>D>	AB		0.5MCG	A091174	002	May 24, 2013	Jan	CAHN
>D>	AB	STRIDES ARCOLAB LTD	0.25MCG	A091356	001	Dec 12, 2014	Jan	CAHN
>D>	AB		0.5MCG	A091356	002	Dec 12, 2014	Jan	CAHN
>A>	AB	STRIDES PHARMA	0.25MCG	A091356	001	Dec 12, 2014	Jan	CAHN
>A>	AB		0.5MCG	A091356	002	Dec 12, 2014	Jan	CAHN

CALCIUM ACETATE

TABLET;ORAL

CALCIUM ACETATE

>A>	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

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

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

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

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

		INJECTABLE;INJECTION						
		PRISMASOL B22GK 4/2.5 IN PLASTIC CONTAINER						
			GM/1000ML					
>A>	+		3.68GM/1000ML;20GM/1000ML;5.4GM/10 00ML;3.05GM/1000ML;0.314GM/1000ML; 2.21GM/1000ML;7.07GM/1000ML (5000ML)	N021703	013	Oct 10, 2008	Jan CPOT	
		PRISMASOL BGK 0/2.5 IN PLASTIC CONTAINER						
>D>	+	GAMBRO RENAL PRODS	3.68GM/1000ML;20GM/1000ML;5.4GM/10 00ML;3.05GM/1000ML;N/A/1000ML;3.09 GM/1000ML;6.46GM/1000ML	N021703	006	Oct 25, 2006	Jan CPOT	
>A>	+		3.68GM/1000ML;20GM/1000ML;5.4GM/10 00ML;3.05GM/1000ML;N/A/1000ML;3.09 GM/1000ML;6.46GM/1000ML (5000ML)	N021703	006	Oct 25, 2006	Jan CPOT	
		PRISMASOL BGK 2/0 IN PLASTIC CONTAINER						
>D>	+	GAMBRO RENAL PRODS	N/A/1000ML;20GM/1000ML;5.4GM/1000M L;2.03GM/1000ML;0.157GM/1000ML;3.0 9GM/1000ML;6.46GM/1000ML	N021703	002	Oct 25, 2006	Jan CPOT	
>A>	+		N/A/1000ML;20GM/1000ML;5.4GM/1000M L;2.03GM/1000ML;0.157GM/1000ML;3.0 9GM/1000ML;6.46GM/1000ML (5000ML)	N021703	002	Oct 25, 2006	Jan CPOT	
		PRISMASOL BGK 2/3.5 IN PLASTIC CONTAINER						
>D>	+	GAMBRO RENAL PRODS	5.15GM/1000ML;20GM/1000ML;5.4GM/10 00ML;2.03GM/1000ML;0.157GM/1000ML; 3.09GM/1000ML;6.46GM/1000ML	N021703	003	Oct 25, 2006	Jan CPOT	
>A>	+		5.15GM/1000ML;20GM/1000ML;5.4GM/10 00ML;2.03GM/1000ML;0.157GM/1000ML; 3.09GM/1000ML;6.46GM/1000ML (5000ML)	N021703	003	Oct 25, 2006	Jan CPOT	
		PRISMASOL BGK 4/0 IN PLASTIC CONTAINER						
>D>	@	GAMBRO RENAL PRODS	N/A/1000ML;20GM/1000ML;5.4GM/1000M L;3.05GM/1000ML;0.314GM/1000ML;3.0 9GM/1000ML;6.46GM/1000ML	N021703	005	Oct 25, 2006	Jan CPOT	
>A>	@		N/A/1000ML;20GM/1000ML;5.4GM/1000M L;3.05GM/1000ML;0.314GM/1000ML;3.0 9GM/1000ML;6.46GM/1000ML (5000ML)	N021703	005	Oct 25, 2006	Jan CPOT	
		PRISMASOL BGK 4/0/1.2 IN PLASTIC CONTAINER						
>D>	+	GAMBRO RENAL PRODS	N/A/1000ML;20GM/1000ML;5.4GM/1000M L;2.44GM/1000ML;0.314GM/1000ML;3.0 9GM/1000ML;6.46GM/1000ML	N021703	015	Oct 10, 2008	Jan CPOT	
>A>	+		N/A/1000ML;20GM/1000ML;5.4GM/1000M L;2.44GM/1000ML;0.314GM/1000ML;3.0 9GM/1000ML;6.46GM/1000ML (5000ML)	N021703	015	Oct 10, 2008	Jan CPOT	
		PRISMASOL BGK 4/2.5 IN PLASTIC CONTAINER						
>D>	+	GAMBRO RENAL PRODS	3.68GM/1000ML;20GM/1000ML;5.4GM/10 00ML;3.05GM/1000ML;0.314GM/1000ML; 3.09GM/1000ML;6.46GM/1000ML	N021703	004	Oct 25, 2006	Jan CPOT	
>A>	+		3.68GM/1000ML;20GM/1000ML;5.4GM/10 00ML;3.05GM/1000ML;0.314GM/1000ML; 3.09GM/1000ML;6.46GM/1000ML (5000ML)	N021703	004	Oct 25, 2006	Jan CPOT	
		PRISMASOL BGK 4/3.5 IN PLASTIC CONTAINER						
>D>	@	GAMBRO RENAL PRODS	5.15GM/1000ML;20GM/1000ML;5.4GM/10 00ML;2.03GM/1000ML;0.314GM/1000ML; 3.09GM/1000ML;6.46GM/1000ML	N021703	008	Oct 25, 2006	Jan CPOT	
>A>	@		5.15GM/1000ML;20GM/1000ML;5.4GM/10 00ML;2.03GM/1000ML;0.314GM/1000ML; 3.09GM/1000ML;6.46GM/1000ML (5000ML)	N021703	008	Oct 25, 2006	Jan CPOT	
		PRISMASOL BK 0/0 IN PLASTIC CONTAINER						
>D>	@	GAMBRO RENAL PRODS	N/A/1000ML;N/A/1000ML;5.4GM/1000ML ;3.05GM/1000ML;N/A/1000ML;3.09GM/1 000ML;6.46GM/1000ML	N021703	007	Oct 25, 2006	Jan CPOT	
>A>	@		N/A/1000ML;N/A/1000ML;5.4GM/1000ML ;3.05GM/1000ML;N/A/1000ML;3.09GM/1 000ML;6.46GM/1000ML (5000ML)	N021703	007	Oct 25, 2006	Jan CPOT	

		INJECTABLE;INJECTION						
		PRISMASOL BK 0/0/1.2 IN PLASTIC CONTAINER						
>D>	+	GAMBRO RENAL PRODS	N/A/1000ML;N/A/1000ML;5.4GM/1000ML;2.44GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML	N021703	014	Oct 10, 2008	Jan CPOT	
>A>	+		N/A/1000ML;N/A/1000ML;5.4GM/1000ML;2.44GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N021703	014	Oct 10, 2008	Jan CPOT	
		PRISMASOL BK 0/3.5 IN PLASTIC CONTAINER						
>D>	+	GAMBRO RENAL PRODS	5.15GM/1000ML;N/A/1000ML;5.4GM/1000ML;2.03GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML	N021703	001	Oct 25, 2006	Jan CPOT	
>A>	+		5.15GM/1000ML;N/A/1000ML;5.4GM/1000ML;2.03GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N021703	001	Oct 25, 2006	Jan CPOT	
		PRISMASOL BK 4/2.5 IN PLASTIC CONTAINER						
>D>	@	GAMBRO RENAL PRODS	3.68GM/1000ML;N/A/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML	N021703	009	Oct 25, 2006	Jan CPOT	
>A>	@		3.68GM/1000ML;N/A/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)	N021703	009	Oct 25, 2006	Jan CPOT	
		CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE						
		INJECTABLE;INJECTION						
>A>		PHOXILLUM B22K 4/0 IN PLASTIC CONTAINER						
>A>	+	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)	N207026	002	Jan 13, 2015	Jan NEWA	
>A>		PHOXILLUM BK 4/2.5 IN PLASTIC CONTAINER						
>A>	+	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)	N207026	001	Jan 13, 2015	Jan NEWA	
		CARBIDOPA; LEVODOPA						
>A>		CAPSULE, EXTENDED RELEASE;ORAL						
>A>		RYTARY						
>A>		IMPAX LABS INC	23.75MG;95MG	N203312	001	Jan 07, 2015	Jan NEWA	
>A>			36.25MG;145MG	N203312	002	Jan 07, 2015	Jan NEWA	
>A>			48.75MG;195MG	N203312	003	Jan 07, 2015	Jan NEWA	
>A>	+		61.25MG;245MG	N203312	004	Jan 07, 2015	Jan NEWA	
>A>		SUSPENSION;ENTERAL						
>A>		DUOPA						
>A>	+	ABBVIE INC	4.63MG/ML;20MG/ML	N203952	001	Jan 09, 2015	Jan NEWA	
		CEFAZOLIN SODIUM						
		INJECTABLE;INJECTION						
		CEFAZOLIN SODIUM						
>A>	AP	FACTA FARMA	EQ 1GM BASE/VIAL	A063207	001	Dec 27, 1991	Jan CAHN	
>A>	AP		EQ 10GM BASE/VIAL	A063209	001	Dec 27, 1991	Jan CAHN	
>A>	AP +		EQ 20GM BASE/VIAL	A063209	002	Apr 30, 1999	Jan CAHN	
>A>	AP		EQ 500MG BASE/VIAL	A063214	001	Dec 27, 1991	Jan CAHN	
>D>	AP	STERI PHARMA	EQ 1GM BASE/VIAL	A063207	001	Dec 27, 1991	Jan CAHN	
>D>	AP		EQ 10GM BASE/VIAL	A063209	001	Dec 27, 1991	Jan CAHN	
>D>	AP +		EQ 20GM BASE/VIAL	A063209	002	Apr 30, 1999	Jan CAHN	
>D>	AP		EQ 500MG BASE/VIAL	A063214	001	Dec 27, 1991	Jan CAHN	
		CEFTRIAXONE SODIUM						
		INJECTABLE;INJECTION						
		CEFTRIAXONE						
>A>	AP	FACTA FARMA	EQ 10GM BASE/VIAL	A065269	001	Feb 28, 2007	Jan CAHN	
>D>	AP	STERI PHARMA	EQ 10GM BASE/VIAL	A065269	001	Feb 28, 2007	Jan CAHN	
		INJECTABLE;INTRAMUSCULAR, INTRAVENOUS						
		CEFTRIAXONE						
>A>		@ FACTA FARMA	EQ 1GM BASE/VIAL	A065268	001	Feb 28, 2007	Jan CAHN	
>A>		@	EQ 2GM BASE/VIAL	A065268	002	Feb 28, 2007	Jan CAHN	
>D>		@ STERI PHARMA	EQ 1GM BASE/VIAL	A065268	001	Feb 28, 2007	Jan CAHN	

		INJECTABLE;INTRAMUSCULAR, INTRAVENOUS						
		CEFTRIAXONE						
>D>		@	EQ 2GM BASE/VIAL	A065268	002	Feb 28, 2007	Jan CAHN
		CEFUROXIME SODIUM						
		INJECTABLE;INJECTION						
		CEFUROXIME SODIUM						
>A>	AP	FACTA FARMA	EQ 1.5GM BASE/VIAL	A064125	002	May 30, 1997	Jan CAHN
>A>	AP		EQ 7.5GM BASE/VIAL	A064124	001	May 30, 1997	Jan CAHN
>D>	AP	STERI PHARMA	EQ 1.5GM BASE/VIAL	A064125	002	May 30, 1997	Jan CAHN
>D>	AP		EQ 7.5GM BASE/VIAL	A064124	001	May 30, 1997	Jan CAHN
		INJECTABLE;INTRAMUSCULAR, INTRAVENOUS						
		CEFUROXIME SODIUM						
>A>	AB	FACTA FARMA	EQ 750MG BASE/VIAL	A064125	001	May 30, 1997	Jan CAHN
>D>	AB	STERI PHARMA	EQ 750MG BASE/VIAL	A064125	001	May 30, 1997	Jan CAHN
		CELECOXIB						
		CAPSULE;ORAL						
		CELECOXIB						
>A>	AB	MYLAN PHARMS INC	100MG	A078857	002	Feb 11, 2015	Jan NEWA
>A>	AB		200MG	A078857	003	Feb 11, 2015	Jan NEWA
>A>	AB		400MG	A078857	004	Feb 11, 2015	Jan NEWA
>A>	AB	WATSON LABS INC	50MG	A200562	001	Feb 11, 2015	Jan NEWA
>A>	AB		100MG	A200562	002	Feb 11, 2015	Jan NEWA
>A>	AB		200MG	A200562	003	Feb 11, 2015	Jan NEWA
>A>	AB		400MG	A200562	004	Feb 11, 2015	Jan NEWA
		CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE						
		SOLUTION;ORAL						
>A>		HYDROCODONE BITARTRATE AND CHLORPHENIRAMINE MALEATE						
>A>	AA	TRIS PHARMA INC	4MG/5ML;5MG/5ML	A206438	001	Jan 27, 2015	Jan NEWA
		VITUZ						
>D>	+	CYPRESS PHARM	4MG/5ML;5MG/5ML	N204307	001	Feb 20, 2013	Jan CFTG
>A>	AA +		4MG/5ML;5MG/5ML	N204307	001	Feb 20, 2013	Jan CFTG
		CLARITHROMYCIN						
		TABLET, EXTENDED RELEASE;ORAL						
>D>		BIAXIN XL						
>D>	AB +	ABBVIE	500MG	N050775	001	Mar 03, 2000	Jan DISC
>A>		@	500MG	N050775	001	Mar 03, 2000	Jan DISC
		CLARITHROMYCIN						
>D>	AB	TEVA	500MG	A065154	001	May 18, 2005	Jan CRLD
>A>	AB +		500MG	A065154	001	May 18, 2005	Jan CRLD
		CLINDAMYCIN PHOSPHATE						
		SOLUTION;TOPICAL						
		CLINDAMYCIN PHOSPHATE						
>A>		@ BOCA PHARMA LLC	EQ 1% BASE	A062944	001	Jan 11, 1989	Jan CAHN
>D>		@ COPLEY PHARM	EQ 1% BASE	A062944	001	Jan 11, 1989	Jan CAHN
>A>		COBICISTAT; DARUNAVIR ETHANOLATE						
>A>		TABLET;ORAL						
>A>		PREZCOBIX						
>A>	+	JANSSEN PRODS	150MG;EQ 800MG BASE	N205395	001	Jan 29, 2015	Jan NEWA
		CODEINE SULFATE						
>D>		SOLUTION;ORAL						
>D>		CODEINE SULFATE						
>D>	+	ROXANE	30MG/5ML	N202245	001	Jun 30, 2011	Jan DISC
>A>		@	30MG/5ML	N202245	001	Jun 30, 2011	Jan DISC
		COLCHICINE						
		CAPSULE;ORAL						
		MITIGARE						
>A>		HIKMA INTL PHARMS	0.6MG	N204820	001	Sep 26, 2014	Jan CAHN
>D>		HIKMA PHARMS LLC	0.6MG	N204820	001	Sep 26, 2014	Jan CAHN

DECITABINE

INJECTABLE;INTRAVENOUS

DACOGEN

>D>	AP	+	EISAI INC	50MG/VIAL	N021790	001	May 02, 2006	Jan CAHN
>A>	AP	+	OTSUKA PHARM CO LTD	50MG/VIAL	N021790	001	May 02, 2006	Jan CAHN

DESMOPRESSIN ACETATE

TABLET;ORAL

DDAVP

>A>	AB		FERRING PHARMS INC	0.1MG	N019955	001	Sep 06, 1995	Jan CAHN
>A>	AB	+		0.2MG	N019955	002	Sep 06, 1995	Jan CAHN
>D>	AB		SANOFI AVENTIS US	0.1MG	N019955	001	Sep 06, 1995	Jan CAHN
>D>	AB	+		0.2MG	N019955	002	Sep 06, 1995	Jan CAHN

DEXMEDETOMIDINE HYDROCHLORIDE

INJECTABLE;INJECTION

PRECEDEX

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

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

SOLUTION;ORAL, RECTAL

MD-GASTROVIEW

>A>	AA		LIEBEL-FLARSHEIM	66%;10%	A087388	001		Jan CAHN
>D>	AA		MALLINCKRODT	66%;10%	A087388	001		Jan CAHN

DIGOXIN

TABLET;ORAL

DIGOXIN

>D>			MYLAN PHARMS INC	0.125MG	A040282	001	Dec 23, 1999	Jan CTEC
>A>	AB			0.125MG	A040282	001	Dec 23, 1999	Jan CTEC
>D>				0.25MG	A040282	002	Dec 23, 1999	Jan CTEC
>A>	AB			0.25MG	A040282	002	Dec 23, 1999	Jan CTEC

DONEPEZIL HYDROCHLORIDE

TABLET;ORAL

DONEPEZIL HYDROCHLORIDE

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

DOXEPIN HYDROCHLORIDE

CAPSULE;ORAL

DOXEPIN HYDROCHLORIDE

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

>A> EDOXABAN TOSYLATE

>A> TABLET;ORAL

>A> SAVAYSA

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

>A> EMPAGLIFLOZIN; LINAGLIPTIN

>A> TABLET;ORAL

>A> GLYXAMBI

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

ERGOCALCIFEROL

CAPSULE;ORAL

VITAMIN D

>A>	AA		BANNER LIFE SCIENCES	50,000 IU	A080704	001		Jan CAHN
>D>	AA		BANNER PHARMACAPS	50,000 IU	A080704	001		Jan CAHN

ESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED REL PELLETS;ORAL

ESOMEPRAZOLE MAGNESIUM

>A>			IVAX SUB TEVA PHARMS	EQ 20MG BASE	A	078003	001	Jan 26, 2015 Jan NEWA
>A>	AB			EQ 40MG BASE	A	078003	002	Jan 26, 2015 Jan NEWA

NEXIUM

>D>			ASTRAZENECA PHARMS	EQ 20MG BASE	N	021153	001	Feb 20, 2001 Jan CFTG
>A>	AB			EQ 20MG BASE	N	021153	001	Feb 20, 2001 Jan CFTG
>D>		+		EQ 40MG BASE	N	021153	002	Feb 20, 2001 Jan CFTG
>A>	AB	+		EQ 40MG BASE	N	021153	002	Feb 20, 2001 Jan CFTG

ESTRADIOL

FILM, EXTENDED RELEASE;TRANSDERMAL

MINIVELLE

>A>			NOVEN	0.025MG/24HR	N	203752	005	Sep 23, 2014 Jan NEWA

ESZOPICLONE

TABLET;ORAL

ESZOPICLONE

>A>	AB		MACLEODS PHARMS LTD	1MG	A	202929	001	Jan 30, 2015 Jan NEWA
>A>	AB			2MG	A	202929	002	Jan 30, 2015 Jan NEWA
>A>	AB			3MG	A	202929	003	Jan 30, 2015 Jan NEWA

ETHAMBUTOL HYDROCHLORIDE

TABLET;ORAL

ETHAMBUTOL HYDROCHLORIDE

>D>		@	VERSAPHARM INC	100MG	A	075095	001	Nov 30, 1999 Jan CMFD
>A>	AB			100MG	A	075095	001	Nov 30, 1999 Jan CMFD
>D>		@		400MG	A	075095	002	Nov 30, 1999 Jan CMFD
>A>	AB			400MG	A	075095	002	Nov 30, 1999 Jan CMFD

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET;ORAL

LOESTRIN 24 FE

>D>	AB	+	WARNER CHILCOTT	0.02MG;1MG	N	021871	001	Feb 17, 2006 Jan DISC
>A>		@		0.02MG;1MG	N	021871	001	Feb 17, 2006 Jan DISC

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

>D>	AB		AMNEAL PHARMS	0.02MG;1MG	A	078267	001	Sep 01, 2009 Jan CRLD
>A>	AB	+		0.02MG;1MG	A	078267	001	Sep 01, 2009 Jan CRLD

ETHOSUXIMIDE

CAPSULE;ORAL

ETHOSUXIMIDE

>A>	AB		BANNER LIFE SCIENCES	250MG	A	040430	001	Oct 28, 2002 Jan CAHN
>D>	AB		BANNER PHARMACAPS	250MG	A	040430	001	Oct 28, 2002 Jan CAHN

FERRIC CITRATE

TABLET;ORAL

AURYXIA

>A>		+	KERYX BIOPHARMS	EQ 210MG IRON	N	205874	001	Sep 05, 2014 Jan CTNA

FERRIC CITRATE

>D>		+	KERYX BIOPHARMS	EQ 210MG IRON	N	205874	001	Sep 05, 2014 Jan CTNA

>A> FERRIC PYROPHOSPHATE CITRATE

SOLUTION;IV (INFUSION)

TRIFERIC

>A>		+	ROCKWELL MEDICAL INC	27.2MG IRON/5ML (5.44MG IRON/ML)	N	206317	001	Jan 23, 2015 Jan NEWA

FLUDEOXYGLUCOSE F-18

INJECTABLE;INTRAVENOUS

FLUDEOXYGLUCOSE F 18

>A>			UNIV NORTH DAKOTA	4-500mCi/ML	A	203994	001	Feb 04, 2015 Jan NEWA

GRANISETRON HYDROCHLORIDE

INJECTABLE;INJECTION

GRANISETRON HYDROCHLORIDE

>A>	AP		BANNER LIFE SCIENCES	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A	078863	001	Jun 30, 2008 Jan CAHN
>A>	AP			EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A	078880	001	Jun 30, 2008 Jan CAHN
>D>	AP		BANNER PHARMACAPS	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A	078863	001	Jun 30, 2008 Jan CAHN

		INJECTABLE;INJECTION						
		GRANISETRON HYDROCHLORIDE						
>D>	AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A078880	001	Jun 30, 2008	Jan	CAHN
		GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE						
>A>	AP	BANNER LIFE SCIENCES	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A078863	002	Jun 30, 2008	Jan	CAHN
>D>	AP	BANNER PHARMACAPS	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A078863	002	Jun 30, 2008	Jan	CAHN
		ILOPERIDONE						
		TABLET;ORAL						
		FANAPT						
>D>	+	NOVARTIS	1MG	N022192	001	May 06, 2009	Jan	CAHN
>D>			2MG	N022192	002	May 06, 2009	Jan	CAHN
>D>			4MG	N022192	003	May 06, 2009	Jan	CAHN
>D>			6MG	N022192	004	May 06, 2009	Jan	CAHN
>D>			8MG	N022192	005	May 06, 2009	Jan	CAHN
>D>			10MG	N022192	006	May 06, 2009	Jan	CAHN
>D>			12MG	N022192	007	May 06, 2009	Jan	CAHN
>A>	+	VANDA PHARMS INC	1MG	N022192	001	May 06, 2009	Jan	CAHN
>A>			2MG	N022192	002	May 06, 2009	Jan	CAHN
>A>			4MG	N022192	003	May 06, 2009	Jan	CAHN
>A>			6MG	N022192	004	May 06, 2009	Jan	CAHN
>A>			8MG	N022192	005	May 06, 2009	Jan	CAHN
>A>			10MG	N022192	006	May 06, 2009	Jan	CAHN
>A>			12MG	N022192	007	May 06, 2009	Jan	CAHN
		IOPAMIDOL						
		INJECTABLE;INJECTION						
		IOPAMIDOL-250						
>D>	AP	FRESENIUS KABI USA	51%	A074679	001	Apr 02, 1997	Jan	DISC
>A>		@	51%	A074679	001	Apr 02, 1997	Jan	DISC
		IOPAMIDOL-300						
>D>	AP	FRESENIUS KABI USA	61%	A074679	002	Apr 02, 1997	Jan	DISC
>A>		@	61%	A074679	002	Apr 02, 1997	Jan	DISC
		IOPAMIDOL-370						
>D>	AP	FRESENIUS KABI USA	76%	A074679	003	Apr 02, 1997	Jan	DISC
>A>		@	76%	A074679	003	Apr 02, 1997	Jan	DISC
		KETOROLAC TROMETHAMINE						
		SPRAY, METERED;NASAL						
		SPRIX						
>A>	+	EGALET US INC	15.75MG/SPRAY	N022382	001	May 14, 2010	Jan	CAHN
>D>	+	LUITPOLD	15.75MG/SPRAY	N022382	001	May 14, 2010	Jan	CAHN
		LABETALOL HYDROCHLORIDE						
		TABLET;ORAL						
		LABETALOL HYDROCHLORIDE						
>D>		@ MUTUAL PHARM	100MG	A075215	001	Jul 29, 1999	Jan	CMFD
>A>	AB		100MG	A075215	001	Jul 29, 1999	Jan	CMFD
>D>		@	200MG	A075215	002	Jul 29, 1999	Jan	CMFD
>A>	AB		200MG	A075215	002	Jul 29, 1999	Jan	CMFD
>D>		@	300MG	A075215	003	Jul 29, 1999	Jan	CMFD
>A>	AB		300MG	A075215	003	Jul 29, 1999	Jan	CMFD
		LIDOCAINE HYDROCHLORIDE						
		JELLY;TOPICAL						
		ANESTACON						
>A>		@ BANNER LIFE SCIENCES	2%	A080429	001		Jan	CAHN
>D>		@ BANNER PHARMACAPS	2%	A080429	001		Jan	CAHN
		LOMUSTINE						
		CAPSULE;ORAL						
		GLEOSTINE						
>A>		CORDEN PHARMA	5MG	N017588	004	Dec 19, 2014	Jan	NEWA
		MEMANTINE HYDROCHLORIDE						
		TABLET;ORAL						
		MEMANTINE HYDROCHLORIDE						
>A>	AB	MYLAN PHARMS INC	5MG	A079225	001	Jan 30, 2015	Jan	NEWA
>A>	AB		10MG	A079225	002	Jan 30, 2015	Jan	NEWA

MILRINONE LACTATE

INJECTABLE;INJECTION

MILRINONE LACTATE

>D> AP	+	BEDFORD	EQ 1MG BASE/ML	A075660	001	May 28, 2002	Jan	CRLD
>A> AP			EQ 1MG BASE/ML	A075660	001	May 28, 2002	Jan	CRLD
>D> AP		HIKMA FARMACEUTICA	EQ 1MG BASE/ML	A077966	001	Dec 03, 2010	Jan	CRLD
>A> AP	+		EQ 1MG BASE/ML	A077966	001	Dec 03, 2010	Jan	CRLD

MIVACURIUM CHLORIDE

SOLUTION;INTRAVENOUS

MIVACRON

>A>		ABBVIE	EQ 10MG BASE/5ML (EQ 2MG BASE/ML)	N020098	004	Jan 22, 1992	Jan	NEWA
>A>	+		EQ 20MG BASE/10ML (EQ 2MG BASE/ML)	N020098	005	Jan 22, 1992	Jan	NEWA

NEOSTIGMINE METHYLSULFATE

SOLUTION;INTRAVENOUS

>A> NEOSTIGMINE METHYLSULFATE

>A>		FRESENIUS KABI USA	5MG/10ML (0.5MG/ML)	N203629	001	Jan 08, 2015	Jan	NEWA
>A>			10MG/10ML (1MG/ML)	N203629	002	Jan 08, 2015	Jan	NEWA

NIMODIPINE

CAPSULE;ORAL

NIMODIPINE

>A> AB	+	BANNER LIFE SCIENCES	30MG	A076740	001	Jan 17, 2008	Jan	CAHN
>D> AB	+	BANNER PHARMACAPS	30MG	A076740	001	Jan 17, 2008	Jan	CAHN

OLAPARIB

CAPSULE;ORAL

>A> LYNPARZA

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

>D> OLAPARIB

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

OLOPATADINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

>A> PAZEO

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

ONDANSETRON HYDROCHLORIDE

INJECTABLE;INJECTION

ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE

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

PARICALCITOL

CAPSULE;ORAL

PARICALCITOL

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

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE;ORAL

>D> BONTRIL

>D> BC		VALEANT	105MG	A088021	001	Sep 21, 1982	Jan	DISC
>A>	@		105MG	A088021	001	Sep 21, 1982	Jan	DISC

PHENDIMETRAZINE TARTRATE

>D> BC	+	SANDOZ	105MG	N018074	001		Jan	CTEC
>A>	+		105MG	N018074	001		Jan	CTEC

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

PHENYLEPHRINE HYDROCHLORIDE

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

PIRBUTEROL ACETATE
AEROSOL, METERED;INHALATION
MAXAIR

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

PODOFILOX
SOLUTION;TOPICAL
CONDYLOX

>A>	AT	+	ACTAVIS LABS UT INC	0.5%	N019795	001	Dec 13, 1990	Jan CAHN
>D>	AT	+	WATSON PHARMS	0.5%	N019795	001	Dec 13, 1990	Jan CAHN

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE
SOLUTION/DROPS;OPHTHALMIC
TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE

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

PROGESTERONE
CAPSULE;ORAL
PROGESTERONE

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

RALOXIFENE HYDROCHLORIDE
TABLET;ORAL
RALOXIFENE HYDROCHLORIDE

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

SCOPOLAMINE
FILM, EXTENDED RELEASE;TRANSDERMAL
SCOPOLAMINE

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

TRANSDERM SCOP

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

SOMATROPIN RECOMBINANT
INJECTABLE;INJECTION
NORDITROPIN FLEXPRO

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

NORDITROPIN NORDIFLEX

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

TELAPREVIR
TABLET;ORAL
INCIVEK

>D>		+	VERTEX PHARMS	375MG	N201917	001	May 23, 2011	Jan DISC
>A>		@		375MG	N201917	001	May 23, 2011	Jan DISC

TESTOSTERONE
GEL;TRANSDERMAL
ANDROGEL

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

TESTIM

>D>	BX	+	AUXILIUM PHARMS	1% (50MG/5GM PACKET)	N021454	001	Oct 31, 2002	Jan CTEC
>A>	AB2	+		50MG/5GM PACKET	N021454	001	Oct 31, 2002	Jan CTEC

TESTOSTERONE

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

VOGELXO

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

TORSEMIDE

INJECTABLE;INJECTION

TORSEMIDE

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

TRIPTORELIN PAMOATE

INJECTABLE;INTRAMUSCULAR

TRELSTAR

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

UNOPROSTONE ISOPROPYL

SOLUTION/DROPS;OPHTHALMIC

RESCULA

>A>	+	SUCAMPO PHARMA LLC	0.15%	N021214	001	Aug 03, 2000	Jan CAHN
>D>	+	SUCAMPO PHARMS	0.15%	N021214	001	Aug 03, 2000	Jan CAHN

VALPROIC ACID

CAPSULE;ORAL

VALPROIC ACID

>A> AB		BANNER LIFE SCIENCES	250MG	A073484	001	Jun 29, 1993	Jan CAHN
>D> AB		BANNER PHARMACAPS	250MG	A073484	001	Jun 29, 1993	Jan CAHN

CAPSULE, DELAYED RELEASE;ORAL

STAVZOR

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

VANCOMYCIN HYDROCHLORIDE

CAPSULE;ORAL

VANCOMYCIN HYDROCHLORIDE

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

ZONISAMIDE

CAPSULE;ORAL

ZONISAMIDE

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

CETIRIZINE HYDROCHLORIDE

CAPSULE;ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

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

CETIRIZINE HYDROCHLORIDE HIVES RELIEF

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

DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN

CAPSULE;ORAL

IBUPROFEN AND DIPHENHYDRAMINE HYDROCHLORIDE

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

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

IBUPROFEN

CAPSULE;ORAL

IBUPROFEN

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

MIDOL LIQUID GELS

>A>	+	BANNER LIFE SCIENCES	200MG	N021472	001	Oct 18, 2002	Jan CAHN
>D>	+	BANNER PHARMACAPS	200MG	N021472	001	Oct 18, 2002	Jan CAHN

LOPERAMIDE HYDROCHLORIDE

CAPSULE;ORAL

LOPERAMIDE HYDROCHLORIDE

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

NAPROXEN SODIUM

CAPSULE;ORAL

NAPROXEN SODIUM

>A>	+	BANNER LIFE SCIENCES	EQ 200MG BASE	N021920	001	Feb 17, 2006	Jan CAHN
>D>	+	BANNER PHARMACAPS	EQ 200MG BASE	N021920	001	Feb 17, 2006	Jan CAHN

POLYETHYLENE GLYCOL 3350

FOR SOLUTION;ORAL

POLYETHYLENE GLYCOL 3350

>D>		EMCURE PHARMS USA	17GM/SCOOPFUL	A202071	001	Dec 28, 2012	Jan CAHN
>A>		RARITAN PHARMS INC	17GM/SCOOPFUL	A202071	001	Dec 28, 2012	Jan CAHN

RANITIDINE HYDROCHLORIDE

TABLET;ORAL

RANITIDINE HYDROCHLORIDE

>D>		WOCKHARDT	EQ 75MG BASE	A078884	001	Jul 31, 2008	Jan DISC
>A>	@		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 JANUARY 2015

NO JANUARY 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 JANUARY 2015 ADDITIONS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 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							
N 021713	001	>A> 6977257	Apr 24, 2022	DP			
		>A> 6977257*PED	Oct 24, 2022				
ARIPIPRAZOLE - ABILIFY MAINTENA KIT							
N 202971	001	>A> 5006528	Apr 20, 2015	DS DP		U-543	
		>A> 5006528	Apr 20, 2015	DS DP		U-1632	
		>A> 8030313	Oct 19, 2024			U-543	
		>A> 8030313	Oct 19, 2024			U-1632	
		>A> 8338427	Mar 15, 2025	DP		U-543	
		>A> 8338427	Mar 15, 2025	DP		U-1633	
		>A> 8338428	Aug 06, 2023	DP		U-543	
		>A> 8338428	Aug 06, 2023	DP		U-1633	
		>A> 8759351	Aug 06, 2023	DP		U-1530	
		>A> 8759351	Aug 06, 2023	DP		U-1633	
ARIPIPRAZOLE - ABILIFY MAINTENA KIT							
N 202971	002	>A> 5006528	Apr 20, 2015	DS DP		U-543	
		>A> 5006528	Apr 20, 2015	DS DP		U-1632	
		>A> 8030313	Oct 19, 2024			U-543	
		>A> 8030313	Oct 19, 2024			U-1632	
		>A> 8338427	Mar 15, 2025	DP		U-543	
		>A> 8338427	Mar 15, 2025	DP		U-1633	
		>A> 8338428	Aug 06, 2023	DP		U-543	
		>A> 8338428	Aug 06, 2023	DP		U-1633	
		>A> 8759351	Aug 06, 2023	DP		U-1530	
		>A> 8759351	Aug 06, 2023	DP		U-1633	
ARIPIPRAZOLE - ABILIFY MAINTENA KIT							
N 202971	003	>A> 5006528	Apr 20, 2015	DS DP		U-543	
		>A> 5006528	Apr 20, 2015	DS DP		U-1632	
		>A> 8030313	Oct 19, 2024			U-543	
		>A> 8030313	Oct 19, 2024			U-1632	
		>A> 8338427	Mar 15, 2025	DP		U-543	
		>A> 8338427	Mar 15, 2025	DP		U-1633	
		>A> 8338428	Aug 06, 2023	DP		U-543	
		>A> 8338428	Aug 06, 2023	DP		U-1633	
		>A> 8759351	Aug 06, 2023	DP		U-1530	
		>A> 8759351	Aug 06, 2023	DP		U-1633	
ARIPIPRAZOLE - ABILIFY MAINTENA KIT							
N 202971	004	>A> 5006528	Apr 20, 2015	DS DP		U-543	
		>A> 5006528	Apr 20, 2015	DS DP		U-1632	
		>A> 8030313	Oct 19, 2024			U-543	
		>A> 8030313	Oct 19, 2024			U-1632	
		>A> 8338427	Mar 15, 2025	DP		U-543	
		>A> 8338427	Mar 15, 2025	DP		U-1633	
		>A> 8338428	Aug 06, 2023	DP		U-543	
		>A> 8338428	Aug 06, 2023	DP		U-1633	
		>A> 8759351	Aug 06, 2023	DP		U-1530	
		>A> 8759351	Aug 06, 2023	DP		U-1633	
BESIFLOXACIN HYDROCHLORIDE - BESIVANCE							
N 022308	001	>A> 8937062	Nov 13, 2029			U-80	
BIMATOPROST - LUMIGAN							
N 022184	001	>A> 8933120	Mar 16, 2025	DP			
		>A> 8933127	Mar 16, 2025	DP			
BIMATOPROST - LATISSE							
N 022369	001	>A> 7351404	May 25, 2024			U-939	Y
		>A> 7388029	Jan 21, 2022			U-938	Y
BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - ZUBSOLV							
N 204242	001	>A> 8940330	Sep 18, 2032	DP			
BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - ZUBSOLV							
N 204242	002	>A> 8940330	Sep 18, 2032	DP			
BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - ZUBSOLV							
N 204242	003	>A> 8940330	Sep 18, 2032	DP			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 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
BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - ZUBSOLV							
N 204242	004	>A> 8940330	Sep 18, 2032	DP			
BUPROPION HYDROCHLORIDE; NALTREXONE HYDROCHLORIDE - CONTRAVE							
N 200063	001	>A> 8916195	Feb 02, 2030	U-1639			
CARBIDOPA; LEVODOPA - RYTARY							
N 203312	001	>A> 7094427	May 29, 2022	DP U-1645		>A> NDF	Jan 07, 2018
		>A> 8377474	Dec 26, 2022	DP U-219			
		>A> 8377474	Dec 26, 2022	DP U-1645			
		>A> 8454998	Dec 26, 2028	DP U-219			
		>A> 8454998	Dec 26, 2028	DP U-1646			
		>A> 8454998	Dec 26, 2028	DP U-1647			
		>A> 8454998	Dec 26, 2028	DP U-1648			
		>A> 8454998	Dec 26, 2028	DP U-1649			
		>A> 8557283	Dec 26, 2028	DP U-219			
		>A> 8557283	Dec 26, 2028	DP U-1645			
CARBIDOPA; LEVODOPA - RYTARY							
N 203312	002	>A> 7094427	May 29, 2022	DP U-1645		>A> NDF	Jan 07, 2018
		>A> 8377474	Dec 26, 2022	DP U-219			
		>A> 8377474	Dec 26, 2022	DP U-1645			
		>A> 8454998	Dec 26, 2028	DP U-219			
		>A> 8454998	Dec 26, 2028	DP U-1646			
		>A> 8454998	Dec 26, 2028	DP U-1647			
		>A> 8454998	Dec 26, 2028	DP U-1648			
		>A> 8454998	Dec 26, 2028	DP U-1649			
		>A> 8557283	Dec 26, 2028	DP U-219			
		>A> 8557283	Dec 26, 2028	DP U-1645			
CARBIDOPA; LEVODOPA - RYTARY							
N 203312	003	>A> 7094427	May 29, 2022	DP U-1645		>A> NDF	Jan 07, 2018
		>A> 8377474	Dec 26, 2022	DP U-219			
		>A> 8377474	Dec 26, 2022	DP U-1645			
		>A> 8454998	Dec 26, 2028	DP U-219			
		>A> 8454998	Dec 26, 2028	DP U-1646			
		>A> 8454998	Dec 26, 2028	DP U-1647			
		>A> 8454998	Dec 26, 2028	DP U-1648			
		>A> 8454998	Dec 26, 2028	DP U-1649			
		>A> 8557283	Dec 26, 2028	DP U-219			
		>A> 8557283	Dec 26, 2028	DP U-1645			
CARBIDOPA; LEVODOPA - RYTARY							
N 203312	004	>A> 7094427	May 29, 2022	DP U-1645		>A> NDF	Jan 07, 2018
		>A> 8377474	Dec 26, 2022	DP U-219			
		>A> 8377474	Dec 26, 2022	DP U-1645			
		>A> 8454998	Dec 26, 2028	DP U-219			
		>A> 8454998	Dec 26, 2028	DP U-1646			
		>A> 8454998	Dec 26, 2028	DP U-1647			
		>A> 8454998	Dec 26, 2028	DP U-1648			
		>A> 8454998	Dec 26, 2028	DP U-1649			
		>A> 8557283	Dec 26, 2028	DP U-219			
		>A> 8557283	Dec 26, 2028	DP U-1645			
CARBIDOPA; LEVODOPA - DUOPA							
N 203952	001					>A> NP	Jan 09, 2018
CELECOXIB - CELECOXIB							
A 076898	002					>A> PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 076898	003					>A> PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 076898	004					>A> PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 078857	002					>A> PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 078857	003					>A> PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 078857	004					>A> PC	Jun 02, 2015

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CELECOXIB - CELECOXIB							
A 200562	002					>A> PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 200562	003					>A> PC	Jun 02, 2015
CELECOXIB - CELECOXIB							
A 200562	004					>A> PC	Jun 02, 2015
COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - STRIBILD							
N 203100	001					>A> I-704	Dec 17, 2017
COLCHICINE - MITIGARE							
N 204820	001	>A> 8927607	Aug 22, 2033		U-1020		
CYANOCOBALAMIN - NASCOBAL							
N 021642	001	>A> 7229636	Aug 01, 2024	DP	U-817		
		>A> 7879349	Aug 01, 2024	DP	U-1152		
		>A> 8003353	Aug 01, 2024		U-817		
		>A> 8940714	Aug 26, 2024		U-1152		
DASABUVIR SODIUM ; OMBITASVIR; PARITAPREVIR; RITONAVIR - VIEKIRA PAK (COPACKAGED)							
N 206619	001	>A> 6037157	Jun 26, 2016		U-1635		
		>A> 6703403	Jun 26, 2016		U-1635		
		>A> 7148359	Jul 19, 2019	DP			
		>A> 7364752	Nov 10, 2020	DP			
		>A> 8188104	May 17, 2029	DS DP	U-1636		
		>A> 8268349	Aug 25, 2024	DP			
		>A> 8399015	Aug 25, 2024	DP			
		>A> 8420596	Apr 10, 2031	DS DP			
		>A> 8466159	Sep 04, 2032		U-1637		
		>A> 8492386	Sep 04, 2032		U-1637		
		>A> 8501238	Sep 17, 2028	DS DP	U-1636		
		>A> 8642538	Sep 10, 2029	DS DP	U-1638		
		>A> 8680106	Sep 04, 2032		U-1637		
		>A> 8685984	Sep 04, 2032		U-1637		
		>A> 8686026	Jun 09, 2031	DP			
		>A> 8691938	Apr 13, 2032	DS DP			
DESMOPRESSIN ACETATE - DESMOPRESSIN ACETATE							
A 200653	001					>A> PC	May 16, 2015
DESMOPRESSIN ACETATE - DESMOPRESSIN ACETATE							
A 200653	002					>A> PC	May 16, 2015
DESVENLAFAXINE SUCCINATE - PRISTIQ							
N 021992	003	>A> 6673838	Mar 01, 2022	DS	U-860		
		>A> 6673838	Mar 01, 2022	DS	U-1364		
		>A> 8269040	Jul 05, 2027	DS			
DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX							
N 021038	004	>A> 6716867	Mar 31, 2019		U-1472		
		>A> 6716867*PED	Oct 01, 2019				
		>A> 8242158	Jan 04, 2032	DP			
		>A> 8242158*PED	Jul 04, 2032				
		>A> 8338470	Jan 04, 2032	DP			
		>A> 8338470*PED	Jul 04, 2032				
		>A> 8455527	Jan 04, 2032		U-421		
		>A> 8455527*PED	Jul 04, 2032				
		>A> 8648106	Jan 04, 2032	DP			
		>A> 8648106*PED	Jul 04, 2032				
DICLOFENAC POTASSIUM - CAMBIA							
N 022165	001	>A> 8927604	Jun 16, 2026		U-436		
DICLOFENAC SODIUM - DYLOJECT							
N 022396	001	>A> 6407079	Jun 18, 2019	DP			

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DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - NAMZARIC								
N 206439	001	>A>	5061703	Oct 11, 2015	U-1641			
		>A>	5061703*PED	Apr 11, 2016				
		>A>	8058291	Dec 05, 2029	U-1641			
		>A>	8168209	May 22, 2026	DP			
		>A>	8168209*PED	Nov 22, 2026				
		>A>	8173708	May 22, 2026	U-1641			
		>A>	8173708*PED	Nov 22, 2026				
		>A>	8283379	May 22, 2026	U-1641			
		>A>	8283379*PED	Nov 22, 2026				
		>A>	8293794	Nov 22, 2025	DP			
DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - NAMZARIC								
N 206439	002	>A>	5061703	Oct 11, 2015	U-1641			
		>A>	5061703*PED	Apr 11, 2016				
		>A>	8039009	Sep 24, 2029	U-1641			
		>A>	8039009*PED	Mar 24, 2030				
		>A>	8058291	Dec 05, 2029	U-1641			
		>A>	8168209	May 22, 2026	DP			
		>A>	8168209*PED	Nov 22, 2026				
		>A>	8173708	May 22, 2026	U-1641			
		>A>	8173708*PED	Nov 22, 2026				
		>A>	8283379	May 22, 2026	U-1641			
		>A>	8283379*PED	Nov 22, 2026				
		>A>	8293794	Nov 22, 2025	DP			
		>A>	8329752	May 22, 2026	DP			
		>A>	8329752*PED	Nov 22, 2026				
		>A>	8338485	Nov 22, 2025	DP			
		>A>	8338486	Nov 22, 2025	U-1641			
		>A>	8362085	May 22, 2026	U-1641			
		>A>	8362085*PED	Nov 22, 2026				
		>A>	8580858	Nov 22, 2025	U-1641			
		>A>	8598233	May 22, 2026	DP			
		>A>	8598233*PED	Nov 22, 2026				
DOXYCYCLINE HYCLATE - DOXTERIC								
N 050795	006	>A>	6958161	Dec 15, 2022	DP U-918			
		>A>	8715724	Feb 03, 2028	DP			
EDOXABAN TOSYLATE - SAVAYSA								
N 206316	001	>A>	7365205	Jun 12, 2023	DS		>A> NCE	Jan 08, 2020
EDOXABAN TOSYLATE - SAVAYSA								
N 206316	002	>A>	7365205	Jun 12, 2023	DS		>A> NCE	Jan 08, 2020
EDOXABAN TOSYLATE - SAVAYSA								
N 206316	003	>A>	7365205	Jun 12, 2023	DS		>A> NCE	Jan 08, 2020
EMPAGLIFLOZIN; LINAGLIPTIN - GLYXAMBI								
N 206073	001						>A> NC	Jan 30, 2018
							>A> NCE	May 02, 2016
							>A> NCE	Aug 01, 2019
EMPAGLIFLOZIN; LINAGLIPTIN - GLYXAMBI								
N 206073	002						>A> NC	Jan 30, 2018
							>A> NCE	May 02, 2016
							>A> NCE	Aug 01, 2019
EPINEPHRINE - AUVI-Q								
N 201739	001	>A>	8920377	Nov 23, 2024	DP			
		>A>	8926594	Mar 31, 2026	DP			
EPINEPHRINE - AUVI-Q								
N 201739	002	>A>	8920377	Nov 23, 2024	DP			
		>A>	8926594	Mar 31, 2026	DP			
FLUTICASONE PROPIONATE - CUTIVATE								
N 021152	001						>A> NPP	Jan 16, 2018
IBRUTINIB - IMBRUVICA								
N 205552	001	>A>	8497277	Dec 28, 2026	U-1456		>A> I-702	Jan 29, 2018
		>A>	8497277	Dec 28, 2026	U-1491			
		>A>	8497277	Dec 28, 2026	U-1650			

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INSULIN ASPART RECOMBINANT - NOVOLOG FLEXTOUCH						
N 020986 005	>A> 8920383	Jul 17, 2026	DP			
IVACAFTOR - KALYDECO						
N 203188 001	>A> 8354427	Jul 06, 2026	U-1311		>A> I-705	Dec 30, 2017
IVERMECTIN - SOOLANTRA						
N 206255 001	>A> 5952372	Sep 18, 2018	U-1631			
	>A> 6133310	Apr 26, 2019	U-1631			
	>A> 7550440	Apr 22, 2024	DP U-1631			
	>A> 8080530	Apr 22, 2024	DP U-1631			
	>A> 8093219	Apr 22, 2024	DP U-1631			
	>A> 8415311	Apr 22, 2024	DP U-1631			
	>A> 8470788	Apr 22, 2024	DP U-1631			
	>A> 8815816	Apr 22, 2024	DP U-1631			
LEVALBUTEROL HYDROCHLORIDE - XOPENEX						
N 020837 001					>A> M-151	Jan 22, 2018
LEVALBUTEROL HYDROCHLORIDE - XOPENEX						
N 020837 002					>A> M-151	Jan 22, 2018
LEVALBUTEROL HYDROCHLORIDE - XOPENEX						
N 020837 003					>A> M-151	Jan 22, 2018
LEVALBUTEROL HYDROCHLORIDE - XOPENEX						
N 020837 004					>A> M-151	Jan 22, 2018
LINACLOTIDE - LINZESS						
N 202811 001	>A> 8933030	Feb 17, 2031	DP			
LINACLOTIDE - LINZESS						
N 202811 002	>A> 8933030	Feb 17, 2031	DP			
LINAGLIPTIN - TRADJENTA						
N 201280 001	>A> 8853156	Mar 05, 2031	U-1642			
LIRAGLUTIDE RECOMBINANT - SAXENDA						
N 206321 001	>A> 6268343	Aug 22, 2022	DS DP U-1255			
	>A> 6458924	Aug 22, 2017	DS DP U-1255			
	>A> 6899699	Jan 01, 2022	DP			
	>A> 7235627	Aug 22, 2017	DS DP			
	>A> 7686786	Aug 03, 3026	DP			
	>A> 8114833	Aug 13, 2025	DP			
	>A> 8672898	Jan 02, 2022	DP			
	>A> 8684969	Oct 20, 2025	DP			
	>A> 8920383	Jul 17, 2026	DP			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 001					>A> I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 002					>A> I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 003					>A> I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 004					>A> I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 005					>A> I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 006					>A> I-703	Jan 30, 2018
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N 021977 007					>A> I-703	Jan 30, 2018
MESALAMINE - APRISO						
N 022301 001	>A> 8940328	Apr 20, 2018	DP			
MIFEPRISTONE - KORLYM						
N 202107 001	>A> 8921348	Aug 27, 2028	U-1643			
MINOXIDIL - WOMEN'S ROGAINE						
N 021812 002	>A> 6946120	Apr 20, 2019	DP U-702			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA						
N 022321 001	>A> 8623418	Nov 07, 2029	U-1640			

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MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA						
N 022321 002	>A> 8623418	Nov 07, 2029	U-1640			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA						
N 022321 003	>A> 8623418	Nov 07, 2029	U-1640			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA						
N 022321 004	>A> 8623418	Nov 07, 2029	U-1640			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA						
N 022321 005	>A> 8623418	Nov 07, 2029	U-1640			
MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA						
N 022321 006	>A> 8623418	Nov 07, 2029	U-1640			
NALOXONE HYDROCHLORIDE - EVZIO						
N 205787 001	>A> 8926594	Mar 31, 2026	DP			
OLAPARIB - LYNPARZA						
N 206162 001	>A> 7151102	Apr 29, 2022	DS DP			
	>A> 7449464	Oct 11, 2024	DS DP			
	>A> 7981889	Oct 11, 2024	DS DP			
	>A> 8143241	Aug 12, 2027	U-1634			
	>A> 8247416	Sep 24, 2028	DS			
	>A> 8859562	Aug 04, 2031	U-1634			
	>A> 8912187	Mar 12, 2024	U-1634			
OLOPATADINE HYDROCHLORIDE - PAZEO						
N 206276 001					>A> NP	Jan 30, 2018
					>A> PED	Jul 30, 2018
OXYBUTYNIN CHLORIDE - GELNIQUE						
N 022204 001	>A> 8920392	Mar 26, 2031	U-1644			
PAROXETINE MESYLATE - BRISDELLE						
N 204516 001	>A> 8946251	Aug 04, 2026	DS DP U-904			
RIFAXIMIN - XIFAXAN						
N 022554 001	>A> 8946252	Jul 24, 2029	U-1481			
ROFLUMILAST - DALIRESP						
N 022522 001	>A> 5712298	Jan 27, 2016	DS DP U-1115			
SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO						
N 021148 008	>A> 8920383	Jul 17, 2026	DP			
SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO						
N 021148 009	>A> 8920383	Jul 17, 2026	DP			
SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO						
N 021148 010	>A> 8920383	Jul 17, 2026	DP			
SPINOSAD - NATROBA						
N 022408 001					>A> M-152	Nov 30, 2017

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