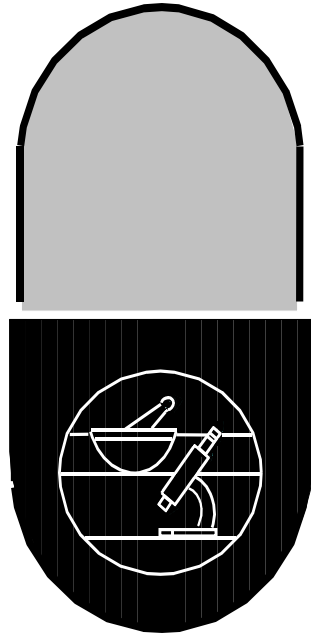


**CUMULATIVE  
SUPPLEMENT 1  
JANUARY 2016**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**36th EDITION**

**Department of Health and Human Services**

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

**2016**

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

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**36<sup>th</sup> EDITION**

**Cumulative Supplement 1**

**January 2016**

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**APPROVED DRUG PRODUCTS**  
**with**  
**THERAPEUTIC EQUIVALENCE EVALUATIONS**

**36<sup>th</sup> EDITION**

**CUMULATIVE SUPPLEMENT 01**  
**January 2016**

**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, 35th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 [orangebook@fda.hhs.gov](mailto:orangebook@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	NEW APPLICANT NAME
<u>          (FORMER ABBREVIATED NAME)          </u>	<u>          (NEW ABBREVIATED NAME)          </u>

### 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

<u>CATEGORIES COUNTED</u>	<u>DEC 2015</u>	<u>MAR 2016</u>	<u>JUN 2016</u>	<u>SEPT 2016</u>	<u>DEC 2016</u>
DRUG PRODUCTS LISTED	17151				
SINGLE SOURCE	2664 (15.5%)				
MULTISOURCE	14487 (84.5%)				
THERAPEUTICALLY EQUIVALENT	14366 (83.8%)				
NOT THERAPEUTICALLY EQUIVALENT	121 (0.7%)				
EXCEPTIONS <sup>1</sup>	73 (0.4%)				
NEW MOLECULAR ENTITIES APPROVED	28				
NUMBER OF APPLICANTS	1011				

<sup>1</sup>Amino acid-containing products of varying composition (see Introduction, page xx of the List).

## 1.7 CUMULATIVE SUPPLEMENT LEGEND

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

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

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

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

The change code and description:

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET;ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

>A>	@	INGENUS PHARMS NJ	325MG;50MG;40MG	A 040864	001	Dec 01, 2008	Jan CAHN
>D>	@	MIRROR PHARMS	325MG;50MG;40MG	A 040864	001	Dec 01, 2008	Jan CAHN
>D>	@	MUTUAL PHARM	325MG;50MG;40MG	A 040601	001	Jul 29, 2005	Jan CAHN
>A>	@	SUN PHARM INDS	325MG;50MG;40MG	A 040601	001	Jul 29, 2005	Jan CAHN

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET;ORAL

OXYCODONE AND ACETAMINOPHEN

>D>	AA	ALVOGEN INC	325MG;7.5MG	A 202677	001	Jul 26, 2012	Jan CAHN
>D>	AA		325MG;10MG	A 202677	002	Jul 26, 2012	Jan CAHN
>A>	AA	ALVOGEN MALTA	325MG;7.5MG	A 202677	001	Jul 26, 2012	Jan CAHN
>A>	AA		325MG;10MG	A 202677	002	Jul 26, 2012	Jan CAHN

ACETYLCYSTEINE

>A> TABLET, EFFERVESCENT;ORAL

>A> CETYLEV

>A>		ARBOR PHARMS LLC	500MG	N 207916	001	Jan 29, 2016	Jan NEWA
>A>	+		2.5MG	N 207916	002	Jan 29, 2016	Jan NEWA

ACYCLOVIR

TABLET;BUCCAL

SITAVIG

>A>	+	CIPHER PHARMS US	50MG	N 203791	001	Apr 12, 2013	Jan CAHN
>D>	+	INNOCUTIS HOLDINGS	50MG	N 203791	001	Apr 12, 2013	Jan CAHN

ALFUZOSIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

ALFUZOSIN HYDROCHLORIDE

>A>	AB	UNICHEM LABS LTD	10MG	A 203192	001	Jan 28, 2016	Jan NEWA
-----	----	------------------	------	----------	-----	--------------	----------

ALLOPURINOL

TABLET;ORAL

ZYLOPRIM

>D>	AB	PROMETHEUS LABS	100MG	N 016084	001		Jan CAHN
>D>	AB	+	300MG	N 016084	002		Jan CAHN
>A>	AB	SEBELA IRELAND LTD	100MG	N 016084	001		Jan CAHN
>A>	AB	+	300MG	N 016084	002		Jan CAHN

ALPRAZOLAM

TABLET, EXTENDED RELEASE;ORAL

ALPRAZOLAM

>D>	AB	ACTAVIS LABS FL INC	0.5MG	A 077198	001	May 13, 2010	Jan DISC
>A>		@	0.5MG	A 077198	001	May 13, 2010	Jan DISC
>D>	AB		1MG	A 077198	002	May 13, 2010	Jan DISC
>A>		@	1MG	A 077198	002	May 13, 2010	Jan DISC
>D>	AB		2MG	A 077198	003	May 13, 2010	Jan DISC
>A>		@	2MG	A 077198	003	May 13, 2010	Jan DISC
>D>	AB		3MG	A 077198	004	May 13, 2010	Jan DISC
>A>		@	3MG	A 077198	004	May 13, 2010	Jan DISC
>D>	AB	IMPAX LABS	0.5MG	A 077968	004	May 24, 2007	Jan DISC
>A>		@	0.5MG	A 077968	004	May 24, 2007	Jan DISC
>D>	AB		1MG	A 077968	003	May 24, 2007	Jan DISC
>A>		@	1MG	A 077968	003	May 24, 2007	Jan DISC
>D>	AB		2MG	A 077968	002	May 24, 2007	Jan DISC
>A>		@	2MG	A 077968	002	May 24, 2007	Jan DISC
>D>	AB		3MG	A 077968	001	May 24, 2007	Jan DISC
>A>		@	3MG	A 077968	001	May 24, 2007	Jan DISC

ALPROSTADIL

SUPPOSITORY;URETHRAL

MUSE

>D>		MEDA PHARMS	0.125MG	N 020700	001	Nov 19, 1996	Jan CRLD
>A>	+		0.125MG	N 020700	001	Nov 19, 1996	Jan CRLD
>D>			0.25MG	N 020700	002	Nov 19, 1996	Jan CRLD
>A>	+		0.25MG	N 020700	002	Nov 19, 1996	Jan CRLD
>D>			0.5MG	N 020700	003	Nov 19, 1996	Jan CRLD
>A>	+		0.5MG	N 020700	003	Nov 19, 1996	Jan CRLD

AMANTADINE HYDROCHLORIDE

CAPSULE;ORAL

AMANTADINE HYDROCHLORIDE

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

AMMONIA N-13

INJECTABLE;INTRAVENOUS

AMMONIA N 13

>A>	AP	MA GENERAL HOSP	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A207025	001	Feb 03, 2016	Jan NEWA
>A>	AP	MIDWEST MEDCL	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204457	001	Nov 18, 2015	Jan NEWA

AMOXICILLIN

TABLET, EXTENDED RELEASE;ORAL

MOXATAG

>D>	+	PRAGMA PHARMS LLC	775MG	N050813	001	Jan 23, 2008	Jan CAHN
>A>	+	VERNALIS R AND D LTD	775MG	N050813	001	Jan 23, 2008	Jan CAHN

AMPHETAMINE

&gt;A&gt; TABLET, ORALLY DISINTEGRATING, EXTENDED RELEASE;ORAL

&gt;A&gt; ADZENYS XR-ODT

>A>		NEOS THERAPS	EQ 3.1MG BASE	N204326	001	Jan 27, 2016	Jan NEWA
>A>			EQ 6.3MG BASE	N204326	002	Jan 27, 2016	Jan NEWA
>A>			EQ 9.4MG BASE	N204326	003	Jan 27, 2016	Jan NEWA
>A>			EQ 12.5MG BASE	N204326	004	Jan 27, 2016	Jan NEWA
>A>			EQ 15.7MG BASE	N204326	005	Jan 27, 2016	Jan NEWA
>A>			EQ 18.8MG BASE	N204326	006	Jan 27, 2016	Jan NEWA

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET;ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>A>	AB	ACTAVIS ELIZABETH	1.25MG;1.25MG;1.25MG;1.25MG	A206340	001	Feb 05, 2016	Jan NEWA
>A>	AB		1.875MG;1.875MG;1.875MG;1.875MG	A206340	002	Feb 05, 2016	Jan NEWA
>A>	AB		2.5MG;2.5MG;2.5MG;2.5MG	A206340	003	Feb 05, 2016	Jan NEWA
>A>	AB		3.125MG;3.125MG;3.125MG;3.125MG	A206340	004	Feb 05, 2016	Jan NEWA
>A>	AB		3.75MG;3.75MG;3.75MG;3.75MG	A206340	005	Feb 05, 2016	Jan NEWA
>A>	AB		5MG;5MG;5MG;5MG	A206340	006	Feb 05, 2016	Jan NEWA
>A>	AB		7.5MG;7.5MG;7.5MG;7.5MG	A206340	007	Feb 05, 2016	Jan NEWA

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE; VITAMIN A; VITAMIN E

INJECTABLE;INJECTION

M.V.I.-12 LYOPHILIZED

>D>		@ IGI LABS INC	100MG/VIAL;0.06MG/VIAL;0.005MG/VIAL;15MG/VIAL;5MCG/VIAL;0.4MG/VIAL;40MG/VIAL;4MG/VIAL;3.6MG/VIAL;3MG/VIAL;1MG/VIAL;10MG/VIAL	N018933	002	Aug 08, 1985	Jan CAHN
>A>		@ TELIGENT PHARMA INC	100MG/VIAL;0.06MG/VIAL;0.005MG/VIAL;15MG/VIAL;5MCG/VIAL;0.4MG/VIAL;40MG/VIAL;4MG/VIAL;3.6MG/VIAL;3MG/VIAL;1MG/VIAL;10MG/VIAL	N018933	002	Aug 08, 1985	Jan CAHN

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE;ORAL

BUTALBITAL, ASPIRIN AND CAFFEINE

>D>		@ MUTUAL PHARM	325MG;50MG;40MG	A078149	001	Jun 13, 2007	Jan CAHN
>A>		@ NOSTRUM LABS INC	325MG;50MG;40MG	A078149	001	Jun 13, 2007	Jan CAHN

ASPIRIN; CARISOPRODOL

TABLET;ORAL

CARISOPRODOL AND ASPIRIN

>A>	AB	INGENUS PHARMS NJ	325MG;200MG	A040832	001	Jan 07, 2010	Jan CAHN
>D>	AB	MIRROR PHARMS	325MG;200MG	A040832	001	Jan 07, 2010	Jan CAHN

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE

TABLET;ORAL

CARISOPRODOL, ASPIRIN AND CODEINE PHOSPHATE

>A>		@ INGENUS PHARMS NJ	325MG;200MG;16MG	A040860	001	Jan 07, 2010	Jan CAHN
>D>		@ MIRROR PHARMS	325MG;200MG;16MG	A040860	001	Jan 07, 2010	Jan CAHN
>D>	AB	SANDOZ	325MG;200MG;16MG	A040118	001	Apr 16, 1996	Jan CRLD

TABLET;ORAL

CARISOPRODOL, ASPIRIN AND CODEINE PHOSPHATE

>A>	+		325MG;200MG;16MG	A040118	001	Apr 16, 1996	Jan	CRLD
>D>		SOMA COMPOUND W/ CODEINE						
>D>	AB	+	MEDA PHARMS 325MG;200MG;16MG	N012366	002	Jul 11, 1983	Jan	DISC
>A>		@	325MG;200MG;16MG	N012366	002	Jul 11, 1983	Jan	DISC

ATENOLOL

TABLET;ORAL

ATENOLOL

>D>	AB		ALVOGEN IPCO SARL 25MG	A073646	001	Jul 31, 1992	Jan	CAHN
>D>	AB		50MG	A072303	001	Jul 15, 1988	Jan	CAHN
>D>	AB		100MG	A072304	001	Jul 15, 1988	Jan	CAHN
>A>	AB		ALVOGEN MALTA 25MG	A073646	001	Jul 31, 1992	Jan	CAHN
>A>	AB		50MG	A072303	001	Jul 15, 1988	Jan	CAHN
>A>	AB		100MG	A072304	001	Jul 15, 1988	Jan	CAHN

TENORMIN

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

ATENOLOL; CHLORTHALIDONE

TABLET;ORAL

ATENOLOL AND CHLORTHALIDONE

>D>	AB		ALVOGEN IPCO SARL 50MG;25MG	A072301	001	May 31, 1990	Jan	CAHN
>D>	AB		100MG;25MG	A072302	001	May 31, 1990	Jan	CAHN
>A>	AB		ALVOGEN MALTA 50MG;25MG	A072301	001	May 31, 1990	Jan	CAHN
>A>	AB		100MG;25MG	A072302	001	May 31, 1990	Jan	CAHN

TENORETIC 100

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

TENORETIC 50

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

AURANOFIN

CAPSULE;ORAL

RIDAURA

>D>		+	PROMETHEUS LABS 3MG	N018689	001	May 24, 1985	Jan	CAHN
>A>		+	SEBELA IRELAND LTD 3MG	N018689	001	May 24, 1985	Jan	CAHN

AZATHIOPRINE

TABLET;ORAL

IMURAN

>D>		@	PROMETHEUS LABS 25MG	N016324	002		Jan	CAHN
>D>	AB	+	50MG	N016324	001		Jan	CAHN
>A>		@	SEBELA IRELAND LTD 25MG	N016324	002		Jan	CAHN
>A>	AB	+	50MG	N016324	001		Jan	CAHN

AZATHIOPRINE SODIUM

INJECTABLE;INJECTION

IMURAN

>D>		@	PROMETHEUS LABS EQ 100MG BASE/VIAL	N017391	001		Jan	CAHN
>A>		@	SEBELA IRELAND LTD EQ 100MG BASE/VIAL	N017391	001		Jan	CAHN

AZILSARTAN KAMEDOXOMIL

TABLET;ORAL

EDARBI

>D>			ARBOR PHARMS IRELAND EQ 40MG MEDOXOMIL	N200796	001	Feb 25, 2011	Jan	CAHN
>D>		+	EQ 80MG MEDOXOMIL	N200796	002	Feb 25, 2011	Jan	CAHN
>A>			ARBOR PHARMS LLC EQ 40MG MEDOXOMIL	N200796	001	Feb 25, 2011	Jan	CAHN
>A>		+	EQ 80MG MEDOXOMIL	N200796	002	Feb 25, 2011	Jan	CAHN

AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE

TABLET;ORAL

EDARBYCLOL

>D>			ARBOR PHARMS IRELAND EQ 40MG MEDOXOMIL;12.5MG	N202331	001	Dec 20, 2011	Jan	CAHN
>D>		+	EQ 40MG MEDOXOMIL;25MG	N202331	002	Dec 20, 2011	Jan	CAHN
>A>			ARBOR PHARMS LLC EQ 40MG MEDOXOMIL;12.5MG	N202331	001	Dec 20, 2011	Jan	CAHN

TABLET;ORAL  
EDARBYCLOR  
>A> + EQ 40MG MEDOXOMIL;25MG N202331 002 Dec 20, 2011 Jan CAHN

BACLOFEN

TABLET;ORAL  
BACLOFEN  
>A> AB NORTHSTAR HLTHCARE 10MG A078401 002 Sep 18, 2009 Jan NEWA

BARIUM SULFATE

FOR SUSPENSION;ORAL  
E-Z-HD  
>A> + BRACCO 334GM/BOTTLE N208036 001 Jan 11, 2016 Jan NEWA  
SUSPENSION;ORAL  
READI-CAT 2  
>A> + BRACCO 2% (9GM/450ML) N208143 001 Jan 15, 2016 Jan NEWA  
>A> READI-CAT 2 SMOOTHIES  
>A> BRACCO 2% (9GM/450ML) N208143 002 Jan 15, 2016 Jan NEWA

BENZAEPRIIL HYDROCHLORIDE

TABLET;ORAL  
BENZAEPRIIL HYDROCHLORIDE  
>D> AB ACTAVIS LABS FL INC 5MG A076267 001 Feb 11, 2004 Jan DISC  
>A> @ 5MG A076267 001 Feb 11, 2004 Jan DISC  
>D> AB 10MG A076267 002 Feb 11, 2004 Jan DISC  
>A> @ 10MG A076267 002 Feb 11, 2004 Jan DISC  
>D> AB 20MG A076267 003 Feb 11, 2004 Jan DISC  
>A> @ 20MG A076267 003 Feb 11, 2004 Jan DISC  
>D> AB 40MG A076267 004 Feb 11, 2004 Jan DISC  
>A> @ 40MG A076267 004 Feb 11, 2004 Jan DISC

BENZAEPRIIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET;ORAL  
BENZAEPRIIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE  
>D> AB ACTAVIS LABS FL INC 5MG;6.25MG A076342 001 Feb 11, 2004 Jan DISC  
>A> @ 5MG;6.25MG A076342 001 Feb 11, 2004 Jan DISC  
>D> AB 10MG;12.5MG A076342 002 Feb 11, 2004 Jan DISC  
>A> @ 10MG;12.5MG A076342 002 Feb 11, 2004 Jan DISC  
>D> AB 20MG;12.5MG A076342 003 Feb 11, 2004 Jan DISC  
>A> @ 20MG;12.5MG A076342 003 Feb 11, 2004 Jan DISC  
>D> AB 20MG;25MG A076342 004 Feb 11, 2004 Jan DISC  
>A> @ 20MG;25MG A076342 004 Feb 11, 2004 Jan DISC

BENZONATATE

CAPSULE;ORAL  
BENZONATATE  
>D> AA BANNER LIFE SCIENCES 100MG A081297 001 Jan 29, 1993 Jan CAHN  
>D> AA 200MG A081297 002 Oct 30, 2007 Jan CAHN  
>A> AA BIONPHARMA INC 100MG A081297 001 Jan 29, 1993 Jan CAHN  
>A> AA 200MG A081297 002 Oct 30, 2007 Jan CAHN

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC  
BETAXOLOL HYDROCHLORIDE  
>D> AT IGI LABS INC EQ 0.5% BASE A075630 001 Apr 12, 2001 Jan CAHN  
>A> AT TELIGENT PHARMA INC EQ 0.5% BASE A075630 001 Apr 12, 2001 Jan CAHN

BISMUTH SUBSALICYLATE; METRONIDAZOLE; TETRACYCLINE HYDROCHLORIDE

TABLET, CHEWABLE, TABLET, CAPSULE;ORAL  
HELIDAC  
>D> @ PROMETHEUS LABS 262.4MG,N/A,N/A;N/A,250MG,N/A;N/A, N050719 001 Aug 15, 1996 Jan CAHN  
>A> @ SEBELA IRELAND LTD 262.4MG,N/A,N/A;N/A,250MG,N/A;N/A, N050719 001 Aug 15, 1996 Jan CAHN  
N/A,500MG

BROMOCRIPTINE MESYLATE

CAPSULE;ORAL  
BROMOCRIPTINE MESYLATE  
>D> AB MYLAN EQ 5MG BASE A077226 001 Apr 04, 2005 Jan CRLD  
>A> AB + EQ 5MG BASE A077226 001 Apr 04, 2005 Jan CRLD  
>D> PARLODEL  
>D> AB + US PHARMS HOLDINGS I EQ 5MG BASE N017962 002 Mar 01, 1982 Jan DISC

CAPSULE;ORAL  
 PARLODEL  
 >A> @ EQ 5MG BASE N017962 002 Mar 01, 1982 Jan DISC  
 TABLET;ORAL  
 BROMOCRIPTINE MESYLATE  
 >D> AB PADDOCK LLC EQ 2.5MG BASE A077646 001 Oct 01, 2008 Jan CRLD  
 >A> AB + EQ 2.5MG BASE A077646 001 Oct 01, 2008 Jan CRLD  
 >D> PARLODEL  
 >D> AB + US PHARMS HOLDINGS I EQ 2.5MG BASE N017962 001 Jan DISC  
 >A> @ EQ 2.5MG BASE N017962 001 Jan DISC

BUDESONIDE

CAPSULE;ORAL  
 ENTOCORT EC  
 >D> AB + ASTRAZENECA 3MG N021324 001 Oct 02, 2001 Jan CAHN  
 >A> AB + ELAN PHARMA INTL LTD 3MG N021324 001 Oct 02, 2001 Jan CAHN

BUPRENORPHINE HYDROCHLORIDE

TABLET;SUBLINGUAL  
 BUPRENORPHINE HYDROCHLORIDE  
 >A> AB SUN PHARM INDS LTD EQ 2MG BASE A201760 001 Jan 29, 2016 Jan NEWA  
 >A> AB EQ 8MG BASE A201760 002 Jan 29, 2016 Jan NEWA

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL  
 BUPROPION HYDROCHLORIDE  
 >A> AB1 INVAGEN PHARMS 100MG A206674 001 Feb 09, 2016 Jan NEWA  
 >A> AB1 150MG A206674 002 Feb 09, 2016 Jan NEWA  
 >A> AB1 200MG A206674 003 Feb 09, 2016 Jan NEWA

BUTORPHANOL TARTRATE

INJECTABLE;INJECTION  
 BUTORPHANOL TARTRATE  
 >D> @ APOTEX INC 2MG/ML A075697 001 Oct 23, 2001 Jan CAHN  
 >A> @ CLARIS 2MG/ML A075697 001 Oct 23, 2001 Jan CAHN

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY;RECTAL  
 MIGERGOT  
 >D> + CREALTA PHARMS LLC 100MG;2MG A086557 001 Oct 04, 1983 Jan CAHN  
 >A> + HORIZON PHARMA 100MG;2MG A086557 001 Oct 04, 1983 Jan CAHN

CALCITRIOL

CAPSULE;ORAL  
 CALCITRIOL  
 >D> AB BANNER LIFE SCIENCES 0.25MCG A091174 001 May 24, 2013 Jan CAHN  
 >D> AB 0.5MCG A091174 002 May 24, 2013 Jan CAHN  
 >A> AB BIONPHARMA INC 0.25MCG A091174 001 May 24, 2013 Jan CAHN  
 >A> AB 0.5MCG A091174 002 May 24, 2013 Jan CAHN

CAPTOPRIL

TABLET;ORAL  
 CAPTOPRIL  
 >D> AB SANDOZ 12.5MG A074363 001 Nov 09, 1995 Jan DISC  
 >A> @ 12.5MG A074363 001 Nov 09, 1995 Jan DISC  
 >D> AB 25MG A074363 002 Nov 09, 1995 Jan DISC  
 >A> @ 25MG A074363 002 Nov 09, 1995 Jan DISC  
 >D> AB 50MG A074363 003 Nov 09, 1995 Jan DISC  
 >A> @ 50MG A074363 003 Nov 09, 1995 Jan DISC  
 >D> AB 100MG A074363 004 Nov 09, 1995 Jan DISC  
 >A> @ 100MG A074363 004 Nov 09, 1995 Jan DISC

CARBAMAZEPINE

CAPSULE, EXTENDED RELEASE;ORAL  
 CARBAMAZEPINE  
 >A> AB MYLAN IRELAND LTD 100MG A076697 001 May 20, 2011 Jan CAHN  
 >A> AB 200MG A076697 002 May 20, 2011 Jan CAHN  
 >A> AB 300MG A076697 003 May 20, 2011 Jan CAHN  
 >D> AB MYLAN PHARMS INC 100MG A076697 001 May 20, 2011 Jan CAHN  
 >D> AB 200MG A076697 002 May 20, 2011 Jan CAHN  
 >D> AB 300MG A076697 003 May 20, 2011 Jan CAHN

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

>A>	AA	INGENUS PHARMS NJ	350MG	A040823	001	Oct 22, 2008	Jan	CAHN
>D>	AA	MIRROR PHARMS	350MG	A040823	001	Oct 22, 2008	Jan	CAHN

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

>A>	AP	HOSPIRA INC	EQ 1GM BASE/VIAL	A201654	001	Feb 03, 2016	Jan	NEWA
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CEFEPIME HYDROCHLORIDE

INJECTABLE; INJECTION

CEFEPIME HYDROCHLORIDE

>A>	AP	QILU PHARM CO LTD	EQ 500MG BASE/VIAL	A203704	001	Feb 01, 2016	Jan	NEWA
>A>	AP		EQ 1GM BASE/VIAL	A203704	002	Feb 01, 2016	Jan	NEWA
>A>	AP		EQ 2GM BASE/VIAL	A203704	003	Feb 01, 2016	Jan	NEWA

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CLAFORAN

>D>	AP	+ SANOFI AVENTIS US	EQ 500MG BASE/VIAL	N050547	001		Jan	CAHN
>D>	AP	+	EQ 1GM BASE/VIAL	N050547	002		Jan	CAHN
>D>	AP	+	EQ 2GM BASE/VIAL	N050547	003		Jan	CAHN
>D>	AP	+	EQ 10GM BASE/VIAL	N050547	004	Dec 29, 1983	Jan	CAHN
>A>	AP	+ US PHARM HOLDINGS	EQ 500MG BASE/VIAL	N050547	001		Jan	CAHN
>A>	AP	+	EQ 1GM BASE/VIAL	N050547	002		Jan	CAHN
>A>	AP	+	EQ 2GM BASE/VIAL	N050547	003		Jan	CAHN
>A>	AP	+	EQ 10GM BASE/VIAL	N050547	004	Dec 29, 1983	Jan	CAHN
		CLAFORAN IN DEXTROSE 5% IN PLASTIC CONTAINER						
>D>		+ SANOFI AVENTIS US	EQ 20MG BASE/ML	N050596	002	May 20, 1985	Jan	CAHN
>D>		+	EQ 40MG BASE/ML	N050596	004	May 20, 1985	Jan	CAHN
>A>		+ US PHARM HOLDINGS	EQ 20MG BASE/ML	N050596	002	May 20, 1985	Jan	CAHN
>A>		+	EQ 40MG BASE/ML	N050596	004	May 20, 1985	Jan	CAHN
		CLAFORAN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER						
>D>		@ SANOFI AVENTIS US	EQ 20MG BASE/ML	N050596	001	May 20, 1985	Jan	CAHN
>D>		@	EQ 40MG BASE/ML	N050596	003	May 20, 1985	Jan	CAHN
>A>		@ US PHARM HOLDINGS	EQ 20MG BASE/ML	N050596	001	May 20, 1985	Jan	CAHN
>A>		@	EQ 40MG BASE/ML	N050596	003	May 20, 1985	Jan	CAHN

CEFOTETAN DISODIUM

INJECTABLE; INJECTION

CEFOTAN

>D>		@ IGI LABS INC	EQ 1GM BASE/VIAL	A063293	001	Apr 29, 1993	Jan	CAHN
>D>		@	EQ 1GM BASE/VIAL	N050588	001	Dec 27, 1985	Jan	CAHN
>D>		@	EQ 2GM BASE/VIAL	A063293	002	Apr 29, 1993	Jan	CAHN
>D>		@	EQ 2GM BASE/VIAL	N050588	002	Dec 27, 1985	Jan	CAHN
>D>		@	EQ 10GM BASE/VIAL	N050588	003	Apr 25, 1988	Jan	CAHN
>A>		@ TELIGENT PHARMA INC	EQ 1GM BASE/VIAL	A063293	001	Apr 29, 1993	Jan	CAHN
>A>		@	EQ 1GM BASE/VIAL	N050588	001	Dec 27, 1985	Jan	CAHN
>A>		@	EQ 2GM BASE/VIAL	A063293	002	Apr 29, 1993	Jan	CAHN
>A>		@	EQ 2GM BASE/VIAL	N050588	002	Dec 27, 1985	Jan	CAHN
>A>		@	EQ 10GM BASE/VIAL	N050588	003	Apr 25, 1988	Jan	CAHN

CEFUROXIME SODIUM

INJECTABLE; INJECTION

ZINACEF

>D>	AP	+ CONCORDIA PHARMS INC	EQ 1.5GM BASE/VIAL	N050558	003	Oct 19, 1983	Jan	CAHN
>D>	AP	+	EQ 7.5GM BASE/VIAL	N050558	004	Oct 23, 1986	Jan	CAHN
>A>	AP	+ IGI LABS INC	EQ 1.5GM BASE/VIAL	N050558	003	Oct 19, 1983	Jan	CAHN
>A>	AP	+	EQ 7.5GM BASE/VIAL	N050558	004	Oct 23, 1986	Jan	CAHN
		ZINACEF IN PLASTIC CONTAINER						
>D>		@ CONCORDIA PHARMS INC	EQ 15MG BASE/ML	N050643	001	Apr 28, 1989	Jan	CAHN
>D>		+	EQ 30MG BASE/ML	N050643	002	Apr 28, 1989	Jan	CAHN
>A>		@ IGI LABS INC	EQ 15MG BASE/ML	N050643	001	Apr 28, 1989	Jan	CAHN
>A>		+	EQ 30MG BASE/ML	N050643	002	Apr 28, 1989	Jan	CAHN
		INJECTABLE; INTRAMUSCULAR, INTRAVENOUS						
		ZINACEF						
>D>	AB	+ CONCORDIA PHARMS INC	EQ 750MG BASE/VIAL	N050558	002	Oct 19, 1983	Jan	CAHN
>A>	AB	+ IGI LABS INC	EQ 750MG BASE/VIAL	N050558	002	Oct 19, 1983	Jan	CAHN



CELECOXIB

CAPSULE;ORAL  
CELECOXIB

>A>	AB	AUROBINDO PHARMA LTD	50MG	A206827	001	Feb 01, 2016	Jan NEWA
>A>	AB		100MG	A206827	002	Feb 01, 2016	Jan NEWA
>A>	AB		200MG	A206827	003	Feb 01, 2016	Jan NEWA
>A>	AB		400MG	A206827	004	Feb 01, 2016	Jan NEWA

CHLORHEXIDINE GLUCONATE

SOLUTION;DENTAL  
PERIOGARD

>A>	AT	COLGATE-PALMOLIVE CO	0.12%	A203212	001	Jan 28, 2016	Jan NEWA
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CHLORTHALIDONE

TABLET;ORAL  
CHLORTHALIDONE

>D>		MYLAN	25MG	A086831	002		Jan CTEC
>A>	AB		25MG	A086831	002		Jan CTEC
>A>	AB	SUN PHARM INDS	25MG	A089286	002	Jul 21, 1986	Jan NEWA

CICLESONIDE

AEROSOL, METERED;INHALATION  
ALVESCO

>D>		TAKEDA GMBH	0.08MG/INH	N021658	002	Jan 10, 2008	Jan CRLD
>A>	+		0.08MG/INH	N021658	002	Jan 10, 2008	Jan CRLD

CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL  
CIPROFLOXACIN EXTENDED RELEASE

>D>	AB	ACTAVIS LABS FL INC	212.6MG;EQ 287.5MG BASE	A077417	001	Nov 30, 2010	Jan DISC
>A>		@	212.6MG;EQ 287.5MG BASE	A077417	001	Nov 30, 2010	Jan DISC
>D>	AB		425.2MG;EQ 574.9MG BASE	A077809	001	Nov 30, 2010	Jan DISC
>A>		@	425.2MG;EQ 574.9MG BASE	A077809	001	Nov 30, 2010	Jan DISC

CLINDAMYCIN PHOSPHATE; TRETINOIN

GEL;TOPICAL  
VELTIN

>A>	BX	+ AQUA PHARMS LLC	1.2%;0.025%	N050803	001	Jul 16, 2010	Jan CAHN
>D>	BX	+ STIEFEL GSK	1.2%;0.025%	N050803	001	Jul 16, 2010	Jan CAHN

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE;ORAL  
ANAFRANIL

>D>	AB	MALLINCKRODT LLC	25MG	N019906	001	Dec 29, 1989	Jan CRLD
>A>	AB	+	25MG	N019906	001	Dec 29, 1989	Jan CRLD
>D>	AB	+	50MG	N019906	002	Dec 29, 1989	Jan CRLD
>A>	AB		50MG	N019906	002	Dec 29, 1989	Jan CRLD

COLCHICINE; PROBENECID

TABLET;ORAL  
PROBENECID AND COLCHICINE

>A>	AB	INGENUS PHARMS NJ	0.5MG;500MG	A040618	001	May 13, 2008	Jan CAHN
>D>	AB	MIRROR PHARMS	0.5MG;500MG	A040618	001	May 13, 2008	Jan CAHN

CYPROHEPTADINE HYDROCHLORIDE

TABLET;ORAL  
CYPROHEPTADINE HYDROCHLORIDE

>A>	AA	INGENUS PHARMS NJ	4MG	A205087	001	Sep 23, 2015	Jan CAHN
>D>	AA	MIRROR PHARMS LLC	4MG	A205087	001	Sep 23, 2015	Jan CAHN

DALBAVANCIN HYDROCHLORIDE

>D>		INJECTABLE;IV (INFUSION)					
>D>		DALVANCE					
>D>	+	DURATA THERAPS INTL	EQ 500MG BASE/VIAL	N021883	001	May 23, 2014	Jan CDFR
>A>		POWDER;IV (INFUSION)					
>A>		DALVANCE					
>A>	+	DURATA THERAPS INTL	EQ 500MG BASE/VIAL	N021883	001	May 23, 2014	Jan CDFR

DAPTOMYCIN

>D>	INJECTABLE;IV (INFUSION)						
>D>	CUBICIN						
>D>	@ CUBIST	250MG/VIAL		N021572	001	Sep 12, 2003	Jan CDFR
>D> AP	+	500MG/VIAL		N021572	002	Sep 12, 2003	Jan CDFR
>D>	DAPTOMYCIN						
>D> AP	HOSPIRA INC	500MG/VIAL		A202857	001	Sep 12, 2014	Jan CDFR
>A>	POWDER;INTRAVENOUS						
>A>	CUBICIN						
>A> AP	+	500MG/VIAL		N021572	002	Sep 12, 2003	Jan CDFR
>A>	DAPTOMYCIN						
>A> AP	HOSPIRA INC	500MG/VIAL		A202857	001	Sep 12, 2014	Jan CDFR
>A>	POWDER;IV (INFUSION)						
>A>	CUBICIN						
>A>	@ CUBIST	250MG/VIAL		N021572	001	Sep 12, 2003	Jan CDFR

DARIFENACIN HYDROBROMIDE

TABLET, EXTENDED RELEASE;ORAL  
ENABLEX

>A> AB	ALLERGAN PHARMS INTL	EQ 7.5MG BASE		N021513	001	Dec 22, 2004	Jan CAHN
>A> AB	+	EQ 15MG BASE		N021513	002	Dec 22, 2004	Jan CAHN
>D> AB	WARNER CHILCOTT LLC	EQ 7.5MG BASE		N021513	001	Dec 22, 2004	Jan CAHN
>D> AB	+	EQ 15MG BASE		N021513	002	Dec 22, 2004	Jan CAHN

DEFERASIROX

TABLET, FOR SUSPENSION;ORAL

>A>	DEFERASIROX						
>A> AB	ACTAVIS ELIZABETH	125MG		A203560	001	Jan 26, 2016	Jan NEWA
>A> AB		250MG		A203560	002	Jan 26, 2016	Jan NEWA
>A> AB		500MG		A203560	003	Jan 26, 2016	Jan NEWA
>A>	EXJADE						
>D>	NOVARTIS	125MG		N021882	001	Nov 02, 2005	Jan CFTG
>A> AB		125MG		N021882	001	Nov 02, 2005	Jan CFTG
>D>		250MG		N021882	002	Nov 02, 2005	Jan CFTG
>A> AB		250MG		N021882	002	Nov 02, 2005	Jan CFTG
>D>	+	500MG		N021882	003	Nov 02, 2005	Jan CFTG
>A> AB	+	500MG		N021882	003	Nov 02, 2005	Jan CFTG

DESIPRAMINE HYDROCHLORIDE

TABLET;ORAL  
NORPRAMIN

>D> AB	SANOFI AVENTIS US	10MG		N014399	007	Feb 11, 1982	Jan CAHN
>D> AB		25MG		N014399	001		Jan CAHN
>D> AB		50MG		N014399	003		Jan CAHN
>D> AB		75MG		N014399	004		Jan CAHN
>D> AB	+	100MG		N014399	005		Jan CAHN
>D> AB		150MG		N014399	006		Jan CAHN
>A> AB	US PHARM HOLDINGS	10MG		N014399	007	Feb 11, 1982	Jan CAHN
>A> AB		25MG		N014399	001		Jan CAHN
>A> AB		50MG		N014399	003		Jan CAHN
>A> AB		75MG		N014399	004		Jan CAHN
>A> AB	+	100MG		N014399	005		Jan CAHN
>A> AB		150MG		N014399	006		Jan CAHN

DESONIDE

CREAM;TOPICAL  
DESONIDE

>A> AB	G AND W LABS INC	0.05%		A074027	001	Sep 28, 1992	Jan CAHN
>D> AB	TEVA PHARMS	0.05%		A074027	001	Sep 28, 1992	Jan CAHN

DEXLANSOPRAZOLE

>A>	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL						
>A>	DEXILANT SOLUTAB						
>A>	+	30MG		N208056	001	Jan 26, 2016	Jan NEWA

DEXMEDETOMIDINE HYDROCHLORIDE

INJECTABLE;INJECTION  
DEXMEDETOMIDINE HYDROCHLORIDE

>A> AP	ACCORD HLTHCARE INC	EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML)		A204023	001	Feb 09, 2016	Jan NEWA
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DEXTROAMPHETAMINE SULFATECAPSULE, EXTENDED RELEASE;ORAL  
DEXTROAMPHETAMINE SULFATE

>A>	AB	MYLAN PHARMS INC	5MG	A206735	001	Jan 27, 2016	Jan NEWA
>A>	AB		10MG	A206735	002	Jan 27, 2016	Jan NEWA
>A>	AB		15MG	A206735	003	Jan 27, 2016	Jan NEWA

DIAZEPAMINJECTABLE;INJECTION  
DIAZEPAM

>A>		@ EUROHLTH INTL SARL	5MG/ML	A070313	001	Dec 16, 1985	Jan CAHN
>D>		@ HIKMA MAPLE	5MG/ML	A070313	001	Dec 16, 1985	Jan CAHN

TABLET;ORAL

DIAZEPAM

>A>		DAVA PHARMS INC	2MG	A070228	002	Sep 26, 1985	Jan NEWA
>A>			5MG	A070228	003	Sep 26, 1985	Jan NEWA

DICLOFENAC SODIUMSOLUTION/DROPS;OPHTHALMIC  
DICLOFENAC SODIUM

>D>	AT	NEXUS PHARMS	0.1%	A078553	001	Dec 28, 2007	Jan CAHN
>A>	AT	RISING PHARMS INC	0.1%	A078553	001	Dec 28, 2007	Jan CAHN

DICYCLOMINE HYDROCHLORIDE

SYRUP;ORAL

BENTYL

>D>	AA	+ APTALIS PHARMA US	10MG/5ML	N007961	002	Oct 15, 1984	Jan DISC
>A>		@	10MG/5ML	N007961	002	Oct 15, 1984	Jan DISC

DICYCLOMINE HYDROCHLORIDE

>D>	AA	MIKART	10MG/5ML	A040169	001	Mar 24, 2005	Jan CRLD
>A>		+	10MG/5ML	A040169	001	Mar 24, 2005	Jan CRLD

DILTIAZEM HYDROCHLORIDECAPSULE, EXTENDED RELEASE;ORAL  
DILTIAZEM HYDROCHLORIDE

>D>	AB2	ACTAVIS LABS FL INC	120MG	A074852	001	Oct 10, 1997	Jan DISC
>A>		@	120MG	A074852	001	Oct 10, 1997	Jan DISC
>D>	AB2		180MG	A074852	002	Oct 10, 1997	Jan DISC
>A>		@	180MG	A074852	002	Oct 10, 1997	Jan DISC
>D>	AB2		240MG	A074852	003	Oct 10, 1997	Jan DISC
>A>		@	240MG	A074852	003	Oct 10, 1997	Jan DISC
>D>	AB3	VALEANT INTL	120MG	A075116	001	Dec 23, 1999	Jan CAHN
>D>	AB3		180MG	A075116	002	Dec 23, 1999	Jan CAHN
>D>	AB3		240MG	A075116	003	Dec 23, 1999	Jan CAHN
>D>	AB3		300MG	A075116	004	Dec 23, 1999	Jan CAHN
>A>	AB3	VALEANT PHARMS NORTH	120MG	A075116	001	Dec 23, 1999	Jan CAHN
>A>	AB3		180MG	A075116	002	Dec 23, 1999	Jan CAHN
>A>	AB3		240MG	A075116	003	Dec 23, 1999	Jan CAHN
>A>	AB3		300MG	A075116	004	Dec 23, 1999	Jan CAHN

DINOPROSTONEINSERT, EXTENDED RELEASE;VAGINAL  
CERVIDIL

>D>		+ FERRING CONTROLLED	10MG	N020411	001	Mar 30, 1995	Jan CAHN
>A>		+ FERRING PHARMS INC	10MG	N020411	001	Mar 30, 1995	Jan CAHN

DISULFIRAMTABLET;ORAL  
DISULFIRAM

>A>	AB	ALVOGEN MALTA	250MG	A091681	001	Aug 08, 2013	Jan CAHN
>D>	AB	ALVOGEN PINE BROOK	250MG	A091681	001	Aug 08, 2013	Jan CAHN

DOBUTAMINE HYDROCHLORIDEINJECTABLE;INJECTION  
DOBUTAMINE HYDROCHLORIDE

>D>		@ IGI LABS INC	EQ 12.5MG BASE/ML	A074098	001	Feb 21, 1995	Jan CAHN
>A>		@ TELIGENT PHARMA INC	EQ 12.5MG BASE/ML	A074098	001	Feb 21, 1995	Jan CAHN

DOCETAXEL

SOLUTION;IV (INFUSION)  
DOCETAXEL

>A>	EAGLE PHARMS	20MG/ML (20MG/ML)	N205934	001	Dec 22, 2015	Jan CAHN
>A>		80MG/4ML (20MG/ML)	N205934	002	Dec 22, 2015	Jan CAHN
>A>		160MG/8ML (20MG/ML)	N205934	003	Dec 22, 2015	Jan CAHN
>D>	TEIKOKU PHARMA	20MG/ML (20MG/ML)	N205934	001	Dec 22, 2015	Jan CAHN
>D>		80MG/4ML (20MG/ML)	N205934	002	Dec 22, 2015	Jan CAHN
>D>		160MG/8ML (20MG/ML)	N205934	003	Dec 22, 2015	Jan CAHN

DOLASETRON MESYLATE

INJECTABLE;INJECTION  
ANZEMET

>D>	+ SANOFI AVENTIS US	12.5MG/0.625ML (20MG/ML)	N020624	002	Sep 11, 1997	Jan CAHN
>D>	+	100MG/5ML (20MG/ML)	N020624	001	Sep 11, 1997	Jan CAHN
>D>	+	500MG/25ML (20MG/ML)	N020624	003	Dec 11, 2001	Jan CAHN
>A>	+ US PHARM HOLDINGS	12.5MG/0.625ML (20MG/ML)	N020624	002	Sep 11, 1997	Jan CAHN
>A>	+	100MG/5ML (20MG/ML)	N020624	001	Sep 11, 1997	Jan CAHN
>A>	+	500MG/25ML (20MG/ML)	N020624	003	Dec 11, 2001	Jan CAHN

TABLET;ORAL

ANZEMET

>D>	SANOFI AVENTIS US	50MG	N020623	001	Sep 11, 1997	Jan CAHN
>D>	+	100MG	N020623	002	Sep 11, 1997	Jan CAHN
>A>	US PHARM HOLDINGS	50MG	N020623	001	Sep 11, 1997	Jan CAHN
>A>	+	100MG	N020623	002	Sep 11, 1997	Jan CAHN

DONEPEZIL HYDROCHLORIDE

TABLET;ORAL

DONEPEZIL HYDROCHLORIDE

>A> AB	OSMOTICA PHARM CORP	23MG	A203114	001	Jan 26, 2016	Jan NEWA
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DOXEPIIN HYDROCHLORIDE

TABLET;ORAL

DOXEPIIN HYDROCHLORIDE

>A> AB	MYLAN PHARMS INC	EQ 3MG BASE	A202337	001	Jan 20, 2016	Jan NEWA
>A> AB		EQ 6MG BASE	A202337	002	Jan 20, 2016	Jan NEWA

DROSPIRENONE; ETHINYL ESTRADIOL

TABLET;ORAL

MELAMISA

>A> AB	NOVAST LABS LTD	3MG;0.02MG	A202016	001	Jan 26, 2016	Jan NEWA
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DUTASTERIDE

CAPSULE;ORAL

DUTASTERIDE

>D> AB	BANNER PHARMACAPS	0.5MG	A200899	001	Nov 20, 2015	Jan CAHN
>A> AB	BIONPHARMA INC	0.5MG	A200899	001	Nov 20, 2015	Jan CAHN

EDROPHONIUM CHLORIDE

INJECTABLE;INJECTION

TENSILON

>D>	@ IGI LABS INC	10MG/ML	N007959	001		Jan CAHN
>A>	@ TELIGENT PHARMA INC	10MG/ML	N007959	001		Jan CAHN
	TENSILON PRESERVATIVE FREE					
>D>	@ IGI LABS INC	10MG/ML	N007959	002		Jan CAHN
>A>	@ TELIGENT PHARMA INC	10MG/ML	N007959	002		Jan CAHN

ELBASVIR; GRAZOPREVIK

TABLET;ORAL

ZEPATIER

>A>	+ MERCK SHARP DOHME	50MG;100MG	N208261	001	Jan 28, 2016	Jan NEWA
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ERGOALCIFEROL

CAPSULE;ORAL

DRISDOL

>D> AA	+ SANOFI AVENTIS US	50,000 IU	N003444	001		Jan CAHN
>A> AA	+ US PHARM HOLDINGS	50,000 IU	N003444	001		Jan CAHN
	VITAMIN D					
>D> AA	BANNER LIFE SCIENCES	50,000 IU	A080704	001		Jan CAHN
>A> AA	BIONPHARMA INC	50,000 IU	A080704	001		Jan CAHN

ERYTHROMYCINSOLUTION;TOPICAL  
ERYTHROMYCIN

>D>	AT	FOUGERA PHARMS	2%	A064187	001	Sep 30, 1997	Jan	CRLD	
>A>	AT	+	2%	A064187	001	Sep 30, 1997	Jan	CRLD	
>D>	AT	+	PERRIGO NEW YORK	2%	A063038	001	Jan 11, 1991	Jan	CRLD
>A>	AT		2%	A063038	001	Jan 11, 1991	Jan	CRLD	

ESTRADIOL ACETATEINSERT, EXTENDED RELEASE;VAGINAL  
FEMRING

>A>		ALLERGAN PHARMS INTL	EQ 0.05MG BASE/24HR	N021367	001	Mar 20, 2003	Jan	CAHN
>A>		+	EQ 0.1MG BASE/24HR	N021367	002	Mar 20, 2003	Jan	CAHN
>D>		WARNER IRELAND	EQ 0.05MG BASE/24HR	N021367	001	Mar 20, 2003	Jan	CAHN
>D>		+	EQ 0.1MG BASE/24HR	N021367	002	Mar 20, 2003	Jan	CAHN

TABLET;ORAL  
FEMTRACE

>A>		ALLERGAN PHARMS INTL	0.45MG	N021633	001	Aug 20, 2004	Jan	CAHN
>A>			0.9MG	N021633	002	Aug 20, 2004	Jan	CAHN
>A>		+	1.8MG	N021633	003	Aug 20, 2004	Jan	CAHN
>D>		WARNER CHILCOTT LLC	0.45MG	N021633	001	Aug 20, 2004	Jan	CAHN
>D>			0.9MG	N021633	002	Aug 20, 2004	Jan	CAHN
>D>		+	1.8MG	N021633	003	Aug 20, 2004	Jan	CAHN

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE

TABLET;ORAL-28

>A>		ETHYNODIOL DIACETATE AND ETHINYL ESTRADIOL						
>A>	AB	JAI PHARMA LTD	0.05MG;1MG	A204704	001	Feb 09, 2016	Jan	NEWA
		ZOVIA 1/50E-28						
>D>		+	WATSON LABS	A072723	001	Dec 30, 1991	Jan	CTEC
>A>	AB	+	0.05MG;1MG	A072723	001	Dec 30, 1991	Jan	CTEC

ETHINYL ESTRADIOL; NORETHINDRONETABLET, CHEWABLE;ORAL  
FEMCON FE

>A>	AB	+	ALLERGAN PHARMS INTL	0.035MG;0.4MG	N021490	001	Nov 14, 2003	Jan	CAHN
>D>	AB	+	WARNER CHILCOTT LLC	0.035MG;0.4MG	N021490	001	Nov 14, 2003	Jan	CAHN
			NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE						
>A>	AB	+	ALLERGAN PHARMS INTL	0.025MG;0.8MG	N022573	001	Dec 22, 2010	Jan	CAHN
>D>	AB	+	WARNER CHILCOTT	0.025MG;0.8MG	N022573	001	Dec 22, 2010	Jan	CAHN

ETHINYL ESTRADIOL; NORETHINDRONE ACETATETABLET;ORAL  
FEMHRT

>A>	AB		ALLERGAN PHARMS INTL	0.0025MG;0.5MG	N021065	001	Jan 14, 2005	Jan	CAHN
>A>		@		0.005MG;1MG	N021065	002	Oct 15, 1999	Jan	CAHN
>D>	AB		WARNER CHILCOTT LLC	0.0025MG;0.5MG	N021065	001	Jan 14, 2005	Jan	CAHN
>D>		@		0.005MG;1MG	N021065	002	Oct 15, 1999	Jan	CAHN
			LO LOESTRIN FE						
>A>		+	ALLERGAN PHARMS INTL	0.01MG,0.01MG;1MG,N/A	N022501	001	Oct 21, 2010	Jan	CAHN
>D>		+	WARNER CHILCOTT LLC	0.01MG,0.01MG;1MG,N/A	N022501	001	Oct 21, 2010	Jan	CAHN

TABLET;ORAL-21

ESTROSTEP 21

>A>		@	ALLERGAN PHARMS INTL	0.02MG,0.03MG,0.035MG;1MG,1MG,1MG	N020130	001	Oct 09, 1996	Jan	CAHN
>D>		@	WARNER CHILCOTT LLC	0.02MG,0.03MG,0.035MG;1MG,1MG,1MG	N020130	001	Oct 09, 1996	Jan	CAHN

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL

>A>	AB		GLENMARK PHARMS LTD	0.02MG;1MG	A206969	001	Jan 20, 2016	Jan	NEWA
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TABLET;ORAL-28

ESTROSTEP FE

>A>	AB	+	ALLERGAN PHARMS INTL	0.02MG,0.03MG,0.035MG;1MG,1MG,1MG	N020130	002	Oct 09, 1996	Jan	CAHN
>D>	AB	+	WARNER CHILCOTT LLC	0.02MG,0.03MG,0.035MG;1MG,1MG,1MG	N020130	002	Oct 09, 1996	Jan	CAHN

TABLET, CHEWABLE;ORAL

MINASTRIN 24 FE

>A>		+	ALLERGAN PHARMS INTL	0.02MG;1MG	N203667	001	May 08, 2013	Jan	CAHN
>D>		+	WARNER CHILCOTT LLC	0.02MG;1MG	N203667	001	May 08, 2013	Jan	CAHN

TABLET, CHEWABLE, TABLET;ORAL

LO MINASTRIN FE

>A>		+	ALLERGAN PHARMS INTL	0.01MG,0.01MG,N/A;1MG,N/A,N/A	N204654	001	Jul 24, 2013	Jan	CAHN
>D>		+	WARNER CHILCOTT	0.01MG,0.01MG,N/A;1MG,N/A,N/A	N204654	001	Jul 24, 2013	Jan	CAHN

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET;ORAL-28

NORGESTIMATE AND ETHINYL ESTRADIOL

>A>	AB	JAI PHARMA LTD	0.035MG, 0.035MG, 0.035MG;0.18MG, 0.215MG, 0.25MG	A201897	001	Jan 27, 2016	Jan NEWA
>A>	AB		0.035MG;0.25MG	A201896	001	Jan 27, 2016	Jan NEWA

ETHOSUXIMIDE

CAPSULE;ORAL

ETHOSUXIMIDE

>D>	AB	BANNER LIFE SCIENCES	250MG	A040430	001	Oct 28, 2002	Jan CAHN
>A>	AB	BIONPHARMA INC	250MG	A040430	001	Oct 28, 2002	Jan CAHN

EXEMESTANE

TABLET;ORAL

EXEMESTANE

>D>	AB	ALVOGEN INC	25MG	A200898	001	Jul 28, 2014	Jan CAHN
>A>	AB	ALVOGEN MALTA	25MG	A200898	001	Jul 28, 2014	Jan CAHN

FENTANYL

FILM, EXTENDED RELEASE;TRANSDERMAL

FENTANYL-12

>A>	AB	AVEVA	12.5MCG/HR	A077449	005	Sep 11, 2015	Jan NEWA
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FESOTERODINE FUMARATE

TABLET, EXTENDED RELEASE;ORAL

FESOTERODINE FUMARATE

>D>	AB	ALKEM LABS LTD	4MG	A204827	001	Dec 10, 2015	Jan DISC
>A>		@	4MG	A204827	001	Dec 10, 2015	Jan DISC
>D>	AB		8MG	A204827	002	Dec 10, 2015	Jan DISC
>A>		@	8MG	A204827	002	Dec 10, 2015	Jan DISC

FLUCONAZOLE

INJECTABLE;INJECTION

FLUCONAZOLE IN SODIUM CHLORIDE 0.9%

>D>	AP	TEVA PHARMS USA	200MG/100ML (2MG/ML)	A076653	001	Jul 29, 2004	Jan DISC
>A>		@	200MG/100ML (2MG/ML)	A076653	001	Jul 29, 2004	Jan DISC
>D>	AP		400MG/200ML (2MG/ML)	A076653	002	Jul 29, 2004	Jan DISC
>A>		@	400MG/200ML (2MG/ML)	A076653	002	Jul 29, 2004	Jan DISC

FLUOROURACIL

INJECTABLE;INJECTION

FLUOROURACIL

>A>		@ SPECTRUM PHARMS	500MG/10ML (50MG/ML)	N012209	001		Jan CAHN
>D>		@ VALEANT	500MG/10ML (50MG/ML)	N012209	001		Jan CAHN

FLUOXETINE HYDROCHLORIDE

TABLET;ORAL

SARAFEM

>A>	AB1	ALLERGAN PHARMS INTL	EQ 10MG BASE	N021860	001	May 19, 2006	Jan CAHN
>A>	AB1		EQ 15MG BASE	N021860	002	May 19, 2006	Jan CAHN
>A>	AB1	+	EQ 20MG BASE	N021860	003	May 19, 2006	Jan CAHN
>D>	AB1	WARNER CHILCOTT LLC	EQ 10MG BASE	N021860	001	May 19, 2006	Jan CAHN
>D>	AB1		EQ 15MG BASE	N021860	002	May 19, 2006	Jan CAHN
>D>	AB1	+	EQ 20MG BASE	N021860	003	May 19, 2006	Jan CAHN

FLUVASTATIN SODIUM

TABLET, EXTENDED RELEASE;ORAL

FLUVASTATIN SODIUM

>A>	AB	TEVA PHARMS USA	80MG	A079011	001	Jan 27, 2016	Jan NEWA
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FOSINOPRIL SODIUM

TABLET;ORAL

FOSINOPRIL SODIUM

>D>	AB	ACTAVIS LABS FL INC	10MG	A076620	001	Oct 15, 2004	Jan DISC
>A>		@	10MG	A076620	001	Oct 15, 2004	Jan DISC
>D>	AB		20MG	A076620	002	Oct 15, 2004	Jan DISC
>A>		@	20MG	A076620	002	Oct 15, 2004	Jan DISC
>D>	AB		40MG	A076620	003	Oct 15, 2004	Jan DISC
>A>		@	40MG	A076620	003	Oct 15, 2004	Jan DISC

FOSINOPRIL SODIUM; HYDROCHLOROTHIAZIDE

TABLET; ORAL

FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE

>D>	AB	ACTAVIS LABS FL INC	10MG;12.5MG	A076608	001	Dec 03, 2004	Jan DISC
>A>		@	10MG;12.5MG	A076608	001	Dec 03, 2004	Jan DISC
>D>	AB		20MG;12.5MG	A076608	002	Dec 03, 2004	Jan DISC
>A>		@	20MG;12.5MG	A076608	002	Dec 03, 2004	Jan DISC

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

>A>		@ EUROHLTH INTL SARL	10MG/ML	A071439	001	Sep 14, 1990	Jan CAHN
>D>		@ HIKMA MAPLE	10MG/ML	A071439	001	Sep 14, 1990	Jan CAHN

TABLET; ORAL

LASIX

>D>	AB	SANOFI AVENTIS US	20MG	N016273	002		Jan CAHN
>D>	AB		40MG	N016273	001		Jan CAHN
>D>	AB	+	80MG	N016273	003		Jan CAHN
>A>	AB	US PHARM HOLDINGS	20MG	N016273	002		Jan CAHN
>A>	AB		40MG	N016273	001		Jan CAHN
>A>	AB	+	80MG	N016273	003		Jan CAHN

GABAPENTIN

TABLET; ORAL

GABAPENTIN

>A>	AB	SCIEGEN PHARMS INC	600MG	A205101	001	Feb 04, 2016	Jan NEWA
>A>	AB		800MG	A205101	002	Feb 04, 2016	Jan NEWA

GLIMEPIRIDE

TABLET; ORAL

GLIMEPIRIDE

>D>	AB	ACTAVIS LABS FL INC	1MG	A076995	001	Apr 27, 2010	Jan DISC
>A>		@	1MG	A076995	001	Apr 27, 2010	Jan DISC
>D>	AB		2MG	A076995	002	Apr 27, 2010	Jan DISC
>A>		@	2MG	A076995	002	Apr 27, 2010	Jan DISC
>D>	AB		4MG	A076995	003	Apr 27, 2010	Jan DISC
>A>		@	4MG	A076995	003	Apr 27, 2010	Jan DISC

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HYDROCHLORIDE

>D>	AB	COREPHARMA	1.25MG;250MG	A076731	001	Nov 19, 2004	Jan DISC
>A>		@	1.25MG;250MG	A076731	001	Nov 19, 2004	Jan DISC
>D>	AB		2.5MG;500MG	A076731	002	Nov 19, 2004	Jan DISC
>A>		@	2.5MG;500MG	A076731	002	Nov 19, 2004	Jan DISC
>D>	AB		5MG;500MG	A076731	003	Nov 19, 2004	Jan DISC
>A>		@	5MG;500MG	A076731	003	Nov 19, 2004	Jan DISC

GLYCOPYRROLATE

TABLET; ORAL

GLYCOPYRROLATE

>A>	AA	RISING PHARMS INC	1MG	A040821	001	Dec 29, 2008	Jan CAHN
>A>	AA		2MG	A040821	002	Dec 29, 2008	Jan CAHN
>D>	AA	VINTAGE	1MG	A040821	001	Dec 29, 2008	Jan CAHN
>D>	AA		2MG	A040821	002	Dec 29, 2008	Jan CAHN
		ROBINUL					
>A>	AA	+ CASPER PHARMA	1MG	N012827	001		Jan CAHN
>D>	AA	+ SHIONOGI INC	1MG	N012827	001		Jan CAHN
		ROBINUL FORTE					
>A>	AA	+ CASPER PHARMA	2MG	N012827	002		Jan CAHN
>D>	AA	+ SHIONOGI INC	2MG	N012827	002		Jan CAHN

GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

>D>	AP	BANNER LIFE SCIENCES	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A078863	001	Jun 30, 2008	Jan CAHN
>D>	AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A078880	001	Jun 30, 2008	Jan CAHN
>A>	AP	BIONPHARMA INC	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A078863	001	Jun 30, 2008	Jan CAHN
>A>	AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A078880	001	Jun 30, 2008	Jan CAHN
>A>	AP	HIKMA FARMACEUTICA	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A078629	001	Dec 23, 2009	Jan CMS1

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

>A>	AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A 078629	002	Dec 23, 2009	Jan CMS1
			GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE				
>D>	AP	BANNER LIFE SCIENCES	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A 078863	002	Jun 30, 2008	Jan CAHN
>A>	AP	BIONPHARMA INC	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A 078863	002	Jun 30, 2008	Jan CAHN
			GRANISTERON HYDROCHLORIDE				
>D>	AP	HIKMA FARMACEUTICA	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A 078629	001	Dec 23, 2009	Jan CMS1
>D>	AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A 078629	002	Dec 23, 2009	Jan CMS1

HALOPERIDOL

TABLET; ORAL

HALOPERIDOL

>D>		@ ROXANE	2MG	A 071130	001	Feb 17, 1987	Jan CAHN
>A>		@	2MG	A 071130	001	Feb 17, 1987	Jan CAHN
>A>		@ VINTAGE	0.5MG	A 071235	002	Nov 03, 1986	Jan CMS1
>A>		@	1MG	A 071235	003	Nov 03, 1986	Jan CMS1
>A>		@	5MG	A 071235	004	Nov 03, 1986	Jan CMS1
>A>		@	10MG	A 071235	005	Jul 20, 1987	Jan CMS1

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

TABLET; ORAL

HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE

>A>		@ ACTAVIS ELIZABETH	1.5MG; 5MG	A 040295	001	Dec 01, 2000	Jan CMS1
			HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE				
>D>		@ ACTAVIS ELIZABETH	1.5MG; 5MG	A 040295	001	Dec 01, 2000	Jan CMS1

HYDROCHLOROTHIAZIDE

TABLET; ORAL

ORETIC

>D>	AB	ABBVIE	50MG	N 011971	002		Jan DISC
>A>		@	50MG	N 011971	002		Jan DISC

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL

IRBESARTAN AND HYDROCHLOROTHIAZIDE

>A>	AB	INTL SPECLT CHEMS	12.5MG; 150MG	A 203036	001	Jan 15, 2016	Jan NEWA
>A>	AB		12.5MG; 300MG	A 203036	002	Jan 15, 2016	Jan NEWA
>A>			25MG; 300MG	A 203036	003	Jan 15, 2016	Jan NEWA

HYDROCHLOROTHIAZIDE; LISINAPRIL

TABLET; ORAL

ZESTORETIC

>D>	AB	ALVOGEN IPCO SARL	12.5MG; 10MG	N 019888	003	Nov 18, 1993	Jan CAHN
>D>	AB	+	12.5MG; 20MG	N 019888	001	Sep 20, 1990	Jan CAHN
>D>	AB	+	25MG; 20MG	N 019888	002	Jul 20, 1989	Jan CAHN
>A>	AB	ALVOGEN MALTA	12.5MG; 10MG	N 019888	003	Nov 18, 1993	Jan CAHN
>A>	AB	+	12.5MG; 20MG	N 019888	001	Sep 20, 1990	Jan CAHN
>A>	AB	+	25MG; 20MG	N 019888	002	Jul 20, 1989	Jan CAHN

HYDROCHLOROTHIAZIDE; VALSARTAN

TABLET; ORAL

VALSARTAN AND HYDROCHLOROTHIAZIDE

>A>	AB	PRINSTON INC	12.5MG; 80MG	A 206083	001	Feb 08, 2016	Jan NEWA
>A>	AB		12.5MG; 160MG	A 206083	002	Feb 08, 2016	Jan NEWA
>A>	AB		12.5MG; 320MG	A 206083	003	Feb 08, 2016	Jan NEWA
>A>	AB		25MG; 160MG	A 206083	004	Feb 08, 2016	Jan NEWA
>A>	AB		25MG; 320MG	A 206083	005	Feb 08, 2016	Jan NEWA

HYDROCODONE BITARTRATE; IBUPROFEN

TABLET; ORAL

HYDROCODONE BITARTRATE AND IBUPROFEN

>D>	AB	ACTAVIS LABS FL INC	5MG; 200MG	A 077454	001	Jun 23, 2010	Jan DISC
>A>		@	5MG; 200MG	A 077454	001	Jun 23, 2010	Jan DISC

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OTIC

PEDIOTIC

>D>	AT	MONARCH PHARMS	1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML	A 062822	001	Sep 29, 1987	Jan DISC
>A>		@	1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML	A 062822	001	Sep 29, 1987	Jan DISC



HYDROXOCOBALAMININJECTABLE; INJECTION  
CYANOKIT

>A>	@ SERB SA	2.5GM/VIAL (5GM/KIT)	N022041	002	Dec 15, 2006	Jan CAHN
>A>	+	5GM/VIAL (5GM/KIT)	N022041	001	Apr 08, 2011	Jan CAHN
>D>	@ SERB SAS	2.5GM/VIAL (5GM/KIT)	N022041	002	Dec 15, 2006	Jan CAHN
>D>	+	5GM/VIAL (5GM/KIT)	N022041	001	Apr 08, 2011	Jan CAHN

HYDROXYPROGESTERONE CAPROATEINJECTABLE; INJECTION  
HYDROXYPROGESTERONE CAPROATE

>A>	+ ASPEN GLOBAL INC	250MG/ML	A200271	001	Aug 24, 2015	Jan CAHN
>D>	+ MCGUFF	250MG/ML	A200271	001	Aug 24, 2015	Jan CAHN

IBANDRONATE SODIUMINJECTABLE; INTRAVENOUS  
IBANDRONATE SODIUM

>A>	AP ACCORD HLTHCARE	EQ 3MG BASE/3ML	A206058	001	Feb 05, 2016	Jan NEWA
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INDIUM IN-111 CHLORIDEINJECTABLE; INJECTION  
INDIUM IN 111 CHLORIDE

>D>	+ MALLINCKRODT	5mCi/0.5ML	N019841	001	Sep 27, 1994	Jan CAHN
>A>	+ MALLINKRODT NUCLEAR	5mCi/0.5ML	N019841	001	Sep 27, 1994	Jan CAHN

INDIUM IN-111 PENTETREOTIDE KITINJECTABLE; INJECTION  
OCTREOSCAN

>D>	+ MALLINCKRODT	3mCi/ML	N020314	001	Jun 02, 1994	Jan CAHN
>A>	+ MALLINKRODT NUCLEAR	3mCi/ML	N020314	001	Jun 02, 1994	Jan CAHN

INDOCYANINE GREENINJECTABLE; INJECTION  
INDOCYANINE GREEN

>A>	AP DIAGNOSTIC GREEN	25MG/VIAL	A040811	001	Nov 21, 2007	Jan CAHN
>D>	AP PULSION MEDCL	25MG/VIAL	A040811	001	Nov 21, 2007	Jan CAHN

>A> INSULIN HUMANSOLUTION; SUBCUTANEOUS  
HUMULIN R

>A>	+ LILLY	10000 UNITS/20ML (500 UNITS/ML)	N018780	004	Mar 31, 1994	Jan CAIN
>A>	HUMULIN R KWIKPEN					
>A>	+ LILLY	1500 UNITS/3ML (500 UNITS/ML)	N018780	002	Dec 29, 2015	Jan NEWA

>D> INSULIN RECOMBINANT HUMANINJECTABLE; INJECTION  
HUMULIN R

>D>	+ LILLY	500 UNITS/ML	N018780	004	Mar 31, 1994	Jan CAIN
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IRINOTECAN HYDROCHLORIDEINJECTABLE; INJECTION  
IRINOTECAN HYDROCHLORIDE

>D>	AP EBEWE PHARMA	40MG/2ML (20MG/ML)	A090137	001	Nov 12, 2009	Jan CAHN
>D>	AP	100MG/5ML (20MG/ML)	A090137	002	Nov 12, 2009	Jan CAHN
>A>	AP SANDOZ INC	40MG/2ML (20MG/ML)	A090137	001	Nov 12, 2009	Jan CAHN
>A>	AP	100MG/5ML (20MG/ML)	A090137	002	Nov 12, 2009	Jan CAHN

ISOSULFAN BLUEINJECTABLE; INJECTION  
ISOSULFAN BLUE

>A>	AP AUROBINDO PHARMA LTD	1%	A206831	001	Feb 02, 2016	Jan NEWA
>D>	+ MYLAN INSTITUTIONAL	1%	A090874	001	Jul 20, 2010	Jan CTEC
>A>	AP	1%	A090874	001	Jul 20, 2010	Jan CTEC

KETOCONAZOLETABLET; ORAL  
KETOCONAZOLE

>D>	@ MUTUAL PHARMA	200MG	A075314	001	Jun 15, 1999	Jan CAHN
>A>	@ SUN PHARM INDS	200MG	A075314	001	Jun 15, 1999	Jan CAHN

LABETALOL HYDROCHLORIDE

INJECTABLE; INJECTION

>A>		LABETALOL HYDROCHLORIDE							
>A>	AP	SAGENT STRIDES	5MG/ML	A079134	001	Feb 03, 2010	Jan	CTNA	
>D>		LABETALOL HYDROCHLORIDE							
>D>	AP	SAGENT STRIDES	5MG/ML	A079134	001	Feb 03, 2010	Jan	CTNA	
		TRANDATE							
>D>		@ PROMETHEUS LABS	5MG/ML	N019425	001	Dec 31, 1985	Jan	CAHN	
>A>		@ SEBELA IRELAND LTD	5MG/ML	N019425	001	Dec 31, 1985	Jan	CAHN	
		TABLET; ORAL							
		LABETALOL HYDROCHLORIDE							
>D>	AB	MUTUAL PHARM	100MG	A075215	001	Jul 29, 1999	Jan	CAHN	
>D>	AB		200MG	A075215	002	Jul 29, 1999	Jan	CAHN	
>D>	AB		300MG	A075215	003	Jul 29, 1999	Jan	CAHN	
>A>	AB	NOSTRUM LABS INC	100MG	A075215	001	Jul 29, 1999	Jan	CAHN	
>A>	AB		200MG	A075215	002	Jul 29, 1999	Jan	CAHN	
>A>	AB		300MG	A075215	003	Jul 29, 1999	Jan	CAHN	

LAMOTRIGINE

TABLET, EXTENDED RELEASE; ORAL

LAMICTAL XR

>D>	AB	GLAXOSMITHKLINE LLC	200MG	N022115	004	May 29, 2009	Jan	CRLD	
>A>	AB	+	200MG	N022115	004	May 29, 2009	Jan	CRLD	

LETROZOLE

TABLET; ORAL

LETROZOLE

>A>	AB	KREMERS URBAN PHARMS	2.5MG	A091098	001	Jun 03, 2011	Jan	CAHN	
>D>	AB	KUDCO IRELAND	2.5MG	A091098	001	Jun 03, 2011	Jan	CAHN	

LEVETIRACETAM

INJECTABLE; IV (INFUSION)

LEVETIRACETAM

>A>	AP	AUROBINDO PHARMA LTD	500MG/5ML (100MG/ML)	A204312	001	Feb 01, 2016	Jan	NEWA	
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LEVOFLOXACIN

INJECTABLE; INJECTION

LEVOFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

>A>	AP	AUROBINDO PHARMA LTD	EQ 250MG/50ML (EQ 5MG/ML)	A206919	001	Feb 10, 2016	Jan	NEWA	
>A>	AP		EQ 500MG/100ML (EQ 5MG/ML)	A206919	002	Feb 10, 2016	Jan	NEWA	
>A>	AP		EQ 750MG/150ML (EQ 5MG/ML)	A206919	003	Feb 10, 2016	Jan	NEWA	

SOLUTION/DROPS; OPHTHALMIC

LEVOFLOXACIN

>D>	AT	+	NEXUS PHARMS	0.5%	A077700	001	Dec 20, 2010	Jan	CAHN
>A>	AT	+	RISING PHARMS INC	0.5%	A077700	001	Dec 20, 2010	Jan	CAHN

LIDOCAINE

OINTMENT; TOPICAL

LIDOCAINE

>A>	AT	TELIGENT PHARMA INC	5%	A205318	001	Feb 01, 2016	Jan	NEWA	
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LIDOCAINE HYDROCHLORIDE

JELLY; TOPICAL

ANESTACON

>D>		@ BANNER LIFE SCIENCES	2%	A080429	001		Jan	CAHN	
>A>		@ BIONPHARMA INC	2%	A080429	001		Jan	CAHN	

LINEZOLID

TABLET; ORAL

LINEZOLID

>A>	AB	GATE PHARMS	600MG	A091210	001	Feb 05, 2016	Jan	NEWA	
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LISINAPRIL

TABLET; ORAL

ZESTRIL

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

TABLET;ORAL

ZESTRIL

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

LITHIUM CARBONATE

CAPSULE;ORAL

LITHIUM CARBONATE

>A>	AB	HIKMA PHARMS	600MG	A078763	001	Apr 15, 2008	Jan CMFD
>D>		@ HIKMA PHARMS LLC	600MG	A078763	001	Apr 15, 2008	Jan CMFD

LOMITAPIDE MESYLATE

CAPSULE;ORAL

JUXTAPID

>D>	+	AEGERION	EQ 20MG BASE	N203858	003	Dec 21, 2012	Jan CRLD
>A>			EQ 20MG BASE	N203858	003	Dec 21, 2012	Jan CRLD
>D>			EQ 60MG BASE	N203858	006	Apr 23, 2015	Jan CRLD
>A>	+		EQ 60MG BASE	N203858	006	Apr 23, 2015	Jan CRLD

MAGNESIUM SULFATE

SOLUTION;INTRAMUSCULAR, INTRAVENOUS

MAGNESIUM SULFATE

>A>	+	FRESENIUS KABI USA	10GM/20ML (500MG/ML)	N019316	003	Jan 29, 2016	Jan NEWA
>A>	+		25GM/50ML (500MG/ML)	N019316	004	Jan 29, 2016	Jan NEWA

MECLIZINE HYDROCHLORIDE

TABLET;ORAL

MECLIZINE HYDROCHLORIDE

>A>		@ RISING PHARMS INC	12.5MG	A040179	001	Jan 30, 1997	Jan CAHN
>A>		@	25MG	A040179	002	Jan 30, 1997	Jan CAHN
>D>		@ VINTAGE PHARMS	12.5MG	A040179	001	Jan 30, 1997	Jan CAHN
>D>		@	25MG	A040179	002	Jan 30, 1997	Jan CAHN

MELOXICAM

TABLET;ORAL

MELOXICAM

>D>		@ MUTUAL PHARM	7.5MG	A077935	001	Jul 19, 2006	Jan CAHN
>D>		@	15MG	A077935	002	Jul 19, 2006	Jan CAHN
>A>		@ SUN PHARM INDS	7.5MG	A077935	001	Jul 19, 2006	Jan CAHN
>A>		@	15MG	A077935	002	Jul 19, 2006	Jan CAHN

MELPHALAN

TABLET;ORAL

ALKERAN

>A>	+	APOTEX INC	2MG	N014691	002		Jan CAHN
>D>	+	GLAXOSMITHKLINE	2MG	N014691	002		Jan CAHN

MELPHALAN HYDROCHLORIDE

INJECTABLE;INJECTION

ALKERAN

>A>	AP	+	APOTEX INC	EQ 50MG BASE/VIAL	N020207	001	Nov 18, 1992	Jan CAHN
>D>	AP	+	GLAXOSMITHKLINE	EQ 50MG BASE/VIAL	N020207	001	Nov 18, 1992	Jan CAHN

MEPERIDINE HYDROCHLORIDE

INJECTABLE;INJECTION

DEMEROL

>D>		@ SANOFI AVENTIS US	25MG/ML	N005010	007		Jan CAHN
>D>		@	50MG/ML	N005010	002		Jan CAHN
>D>		@	75MG/ML	N005010	009		Jan CAHN
>D>		@	100MG/ML	N005010	003		Jan CAHN
>A>		@ US PHARM HOLDINGS	25MG/ML	N005010	007		Jan CAHN
>A>		@	50MG/ML	N005010	002		Jan CAHN
>A>		@	75MG/ML	N005010	009		Jan CAHN
>A>		@	100MG/ML	N005010	003		Jan CAHN

SYRUP;ORAL

DEMEROL

>D>		@ SANOFI AVENTIS US	50MG/5ML	N005010	005		Jan CAHN
>A>		@ US PHARM HOLDINGS	50MG/5ML	N005010	005		Jan CAHN

TABLET;ORAL  
DEMEROL

>D>	AA	+	SANOFI AVENTIS US	50MG	N005010	001		Jan	CAHN
>D>	AA	+		100MG	N005010	004		Jan	CAHN
>A>	AA	+	US PHARM HOLDINGS	50MG	N005010	001		Jan	CAHN
>A>	AA	+		100MG	N005010	004		Jan	CAHN

MERCAPTOPURINE

TABLET;ORAL  
PURINETHOL

>A>		@	STASON PHARMS	50MG	N009053	002		Jan	CAHN
>D>		@	TEVA	50MG	N009053	002		Jan	CAHN

MESALAMINE

CAPSULE, DELAYED RELEASE;ORAL  
DELZICOL

>A>		+	ALLERGAN PHARMS INTL	400MG	N204412	001	Feb 01, 2013	Jan	CAHN
>D>		+	WARNER CHILCOTT LLC	400MG	N204412	001	Feb 01, 2013	Jan	CAHN

TABLET, DELAYED RELEASE;ORAL  
ASACOL

>A>		@	ALLERGAN PHARMS INTL	400MG	N019651	001	Jan 31, 1992	Jan	CAHN
>D>		@	WARNER CHILCOTT LLC	400MG	N019651	001	Jan 31, 1992	Jan	CAHN
>A>		+	ALLERGAN PHARMS INTL	800MG	N021830	001	May 29, 2008	Jan	CAHN
>D>		+	WARNER CHILCOTT LLC	800MG	N021830	001	May 29, 2008	Jan	CAHN

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL  
GLUMETZA

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

METHENAMINE HIPPURATE

TABLET;ORAL  
HIPREX

>D>	AB	+	SANOFI AVENTIS US	1GM	N017681	001		Jan	CAHN
>A>	AB	+	US PHARM HOLDINGS	1GM	N017681	001		Jan	CAHN

METHIMAZOLE

TABLET;ORAL  
METHIMAZOLE

>A>	AB		RISING PHARMS INC	5MG	A202068	001	Mar 07, 2012	Jan	CAHN
>A>	AB			10MG	A202068	002	Mar 07, 2012	Jan	CAHN
>D>	AB		VINTAGE PHARMS	5MG	A202068	001	Mar 07, 2012	Jan	CAHN
>D>	AB			10MG	A202068	002	Mar 07, 2012	Jan	CAHN

METHOTREXATE SODIUM

INJECTABLE;INJECTION  
METHOTREXATE SODIUM PRESERVATIVE FREE

>D>	AP		EBEWE PHARMA	EQ 50MG BASE/2ML (EQ 25MG BASE/ML)	A090039	001	Mar 31, 2009	Jan	CAHN
>D>	AP			EQ 250MG BASE/10ML (EQ 25MG BASE/ML)	A090039	002	Mar 31, 2009	Jan	CAHN
>D>	AP			EQ 1GM BASE/40ML (EQ 25MG BASE/ML)	A090029	001	Mar 31, 2009	Jan	CAHN
>A>	AP		SANDOZ INC	EQ 50MG BASE/2ML (EQ 25MG BASE/ML)	A090039	001	Mar 31, 2009	Jan	CAHN
>A>	AP			EQ 250MG BASE/10ML (EQ 25MG BASE/ML)	A090039	002	Mar 31, 2009	Jan	CAHN
>A>	AP			EQ 1GM BASE/40ML (EQ 25MG BASE/ML)	A090029	001	Mar 31, 2009	Jan	CAHN

METHYLERGONOVINE MALEATE

TABLET;ORAL  
METHERGINE

>D>			EDISON THERAPS LLC	0.2MG	N006035	003		Jan	DISC
>A>		@		0.2MG	N006035	003		Jan	DISC
>D>	AB		NOVEL LABS INC	0.2MG	A091577	001	May 02, 2011	Jan	CRLD
>A>		+		0.2MG	A091577	001	May 02, 2011	Jan	CRLD

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE SODIUM SUCCINATE

>D>	AP	MUSTAFA NEVSAT	EQ 40MG BASE/VIAL	A 040888	001	Jul 18, 2011	Jan CAHN
>D>	AP		EQ 125MG BASE/VIAL	A 040888	002	Jul 18, 2011	Jan CAHN
>D>	AP		EQ 500MG BASE/VIAL	A 040888	003	Jul 18, 2011	Jan CAHN
>D>	AP		EQ 1GM BASE/VIAL	A 040888	004	Jul 18, 2011	Jan CAHN
>D>	AP		EQ 2GM BASE/VIAL	A 040888	005	Jul 18, 2011	Jan CAHN
>A>	AP	SAGENT PHARMS	EQ 40MG BASE/VIAL	A 040888	001	Jul 18, 2011	Jan CAHN
>A>	AP		EQ 125MG BASE/VIAL	A 040888	002	Jul 18, 2011	Jan CAHN
>A>	AP		EQ 500MG BASE/VIAL	A 040888	003	Jul 18, 2011	Jan CAHN
>A>	AP		EQ 1GM BASE/VIAL	A 040888	004	Jul 18, 2011	Jan CAHN
>A>	AP		EQ 2GM BASE/VIAL	A 040888	005	Jul 18, 2011	Jan CAHN

METRONIDAZOLE

TABLET; ORAL

METRONIDAZOLE

>D>	AB	MUTUAL PHARM	250MG	A 070772	001	Jul 16, 1986	Jan CAHN
>D>	AB		500MG	A 070773	001	Jul 16, 1986	Jan CAHN
>A>	AB	NOSTRUM LABS INC	250MG	A 070772	001	Jul 16, 1986	Jan CAHN
>A>	AB		500MG	A 070773	001	Jul 16, 1986	Jan CAHN

MICONAZOLE

TABLET; BUCCAL

ORAVIG

>D>	+	DARA BIOSCIENCES	50MG	N 022404	001	Apr 16, 2010	Jan CAHN
>A>	+	MIDATECH PHARMA US	50MG	N 022404	001	Apr 16, 2010	Jan CAHN

MILNACIPRAN HYDROCHLORIDE

TABLET; ORAL

MILNACIPRAN HYDROCHLORIDE

>A>	@	LIBERTY PHARMA INC	12.5MG	A 205071	001	Jan 27, 2016	Jan DISC
>A>			12.5MG	A 205071	001	Jan 27, 2016	Jan NEWA
>A>	@		25MG	A 205071	002	Jan 27, 2016	Jan DISC
>A>			25MG	A 205071	002	Jan 27, 2016	Jan NEWA
>A>	@		50MG	A 205071	003	Jan 27, 2016	Jan DISC
>A>			50MG	A 205071	003	Jan 27, 2016	Jan NEWA
>A>	@		100MG	A 205071	004	Jan 27, 2016	Jan DISC
>A>			100MG	A 205071	004	Jan 27, 2016	Jan NEWA

MINOCYCLINE HYDROCHLORIDE

TABLET; ORAL

MINOCYCLINE HYDROCHLORIDE

>A>	AB	SUN PHARM INDS	EQ 50MG BASE	A 090217	001	Jan 29, 2016	Jan NEWA
>A>	AB		EQ 75MG BASE	A 090217	002	Jan 29, 2016	Jan NEWA
>A>	AB		EQ 100MG BASE	A 090217	003	Jan 29, 2016	Jan NEWA

MIRTAZAPINE

TABLET; ORAL

MIRTAZAPINE

>D>	AB	ACTAVIS LABS FL INC	15MG	A 076336	001	Jun 20, 2003	Jan DISC
>A>	@		15MG	A 076336	001	Jun 20, 2003	Jan DISC
>D>	AB		30MG	A 076336	002	Jun 20, 2003	Jan DISC
>A>	@		30MG	A 076336	002	Jun 20, 2003	Jan DISC
>D>	AB		45MG	A 076336	003	Jun 20, 2003	Jan DISC
>A>	@		45MG	A 076336	003	Jun 20, 2003	Jan DISC

MITOMYCIN

INJECTABLE; INJECTION

MITOMYCIN

>A>	AP	EUROHLTH INTL SARL	5MG/VIAL	A 064180	001	Dec 23, 1999	Jan CAHN
>A>	AP		20MG/VIAL	A 064180	002	Dec 23, 1999	Jan CAHN
>D>	AP	HIKMA MAPLE	5MG/VIAL	A 064180	001	Dec 23, 1999	Jan CAHN
>D>	AP		20MG/VIAL	A 064180	002	Dec 23, 1999	Jan CAHN

MODAFINIL

TABLET; ORAL

MODAFINIL

>D>	AB	CARLSBAD	100MG	A 076715	001	Nov 01, 2012	Jan CAHN
>D>	AB		200MG	A 076715	002	Nov 01, 2012	Jan CAHN
>A>	AB	WATSON LABS INC	100MG	A 076715	001	Nov 01, 2012	Jan CAHN

		TABLET;ORAL							
		MODAFINIL							
>A>	AB	200MG		A076715	002	Nov 01, 2012	Jan	CAHN	
<u>MOXIFLOXACIN HYDROCHLORIDE</u>									
		TABLET;ORAL							
		MOXIFLOXACIN HYDROCHLORIDE							
>A>	AB	CROSSMEDIKA SA	EQ 400MG BASE	A205348	001	Jan 14, 2016	Jan	NEWA	
<u>NIFEDIPINE</u>									
		TABLET, EXTENDED RELEASE;ORAL							
		NIFEDIPINE							
>D>	AB1	VALEANT INTL	30MG	A075269	001	Dec 04, 2000	Jan	CAHN	
>D>	AB1		60MG	A075269	002	Dec 04, 2000	Jan	CAHN	
>D>	AB1		90MG	A076070	001	Aug 16, 2002	Jan	CAHN	
>A>	AB1	VALEANT PHARMS NORTH	30MG	A075269	001	Dec 04, 2000	Jan	CAHN	
>A>	AB1		60MG	A075269	002	Dec 04, 2000	Jan	CAHN	
>A>	AB1		90MG	A076070	001	Aug 16, 2002	Jan	CAHN	
<u>NIMODIPINE</u>									
		CAPSULE;ORAL							
		NIMODIPINE							
>D>	AB	+ BANNER LIFE SCIENCES	30MG	A076740	001	Jan 17, 2008	Jan	CAHN	
>A>	AB	+ BIONPHARMA INC	30MG	A076740	001	Jan 17, 2008	Jan	CAHN	
<u>NITRIC OXIDE</u>									
		GAS;INHALATION							
		INOMAX							
>D>		@ INO	100PPM	N020845	002	Dec 23, 1999	Jan	CAHN	
>D>		+	800PPM	N020845	003	Dec 23, 1999	Jan	CAHN	
>A>		@ MALLINCKRODT HOSP	100PPM	N020845	002	Dec 23, 1999	Jan	CAHN	
>A>		+	800PPM	N020845	003	Dec 23, 1999	Jan	CAHN	
<u>NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE</u>									
		CAPSULE;ORAL							
		MACROBID							
>D>	AB	+ ALVOGEN INC	75MG;25MG	N020064	001	Dec 24, 1991	Jan	CAHN	
>A>	AB	+ ALVOGEN MALTA	75MG;25MG	N020064	001	Dec 24, 1991	Jan	CAHN	
<u>NOREPINEPHRINE BITARTRATE</u>									
		INJECTABLE;INJECTION							
		NOREPINEPHRINE BITARTRATE							
>A>	AP	CLARIS	EQ 1MG BASE/ML	A040859	001	Mar 27, 2012	Jan	CAHN	
>D>	AP	CLARIS LIFESCIENCES	EQ 1MG BASE/ML	A040859	001	Mar 27, 2012	Jan	CAHN	
<u>NORETHINDRONE</u>									
		TABLET;ORAL-28							
		NOR-QD							
>D>	AB1	+ ACTAVIS LABS UT INC	0.35MG	N017060	001		Jan	CAHN	
>A>	AB1	+ ALLERGAN PHARMS INTL	0.35MG	N017060	001		Jan	CAHN	
<u>OCTREOTIDE ACETATE</u>									
		INJECTABLE;INJECTION							
		OCTREOTIDE ACETATE							
>D>	AP	WOCKHARDT USA	EQ 0.2MG BASE/ML	A090986	001	May 11, 2011	Jan	DISC	
>A>		@	EQ 0.2MG BASE/ML	A090986	001	May 11, 2011	Jan	DISC	
>D>	AP		EQ 1MG BASE/ML	A090986	002	May 11, 2011	Jan	DISC	
>A>		@	EQ 1MG BASE/ML	A090986	002	May 11, 2011	Jan	DISC	
		OCTREOTIDE ACETATE (PRESERVATIVE FREE)							
>D>	AP	WOCKHARDT USA	EQ 0.05MG BASE/ML	A090985	001	May 11, 2011	Jan	DISC	
>A>		@	EQ 0.05MG BASE/ML	A090985	001	May 11, 2011	Jan	DISC	
>D>	AP		EQ 0.1MG BASE/ML	A090985	002	May 11, 2011	Jan	DISC	
>A>		@	EQ 0.1MG BASE/ML	A090985	002	May 11, 2011	Jan	DISC	
>D>	AP		EQ 0.5MG BASE/ML	A090985	003	May 11, 2011	Jan	DISC	
>A>		@	EQ 0.5MG BASE/ML	A090985	003	May 11, 2011	Jan	DISC	
<u>OLANZAPINE</u>									
		TABLET;ORAL							
		OLANZAPINE							
>A>	AB	QILU PHARM CO LTD	2.5MG	A204319	001	Jan 27, 2016	Jan	NEWA	
>A>	AB		5MG	A204319	002	Jan 27, 2016	Jan	NEWA	
>A>	AB		7.5MG	A204319	003	Jan 27, 2016	Jan	NEWA	

TABLET;ORAL  
OLANZAPINE

>A>	AB		10MG	A204319	004	Jan 27, 2016	Jan NEWA
>A>	AB		15MG	A204319	005	Jan 27, 2016	Jan NEWA
>A>	AB		20MG	A204319	006	Jan 27, 2016	Jan NEWA

OMEGA-3-ACID ETHYL ESTERS

CAPSULE;ORAL  
OMEGA-3-ACID ETHYL ESTERS

>D>	AB	AMNEAL PHARMS	1 GM CONTAINS AT LEAST 900MG OF THE ETHYL ESTERS OF OMEGA-3 FATTY ACIDS	A204940	001	Nov 27, 2015	Jan CMS1
>A>	AB		1GM CONTAINS AT LEAST 900MG OF THE ETHYL ESTERS OF OMEGA-3 FATTY ACIDS	A204940	001	Nov 27, 2015	Jan CMS1

OXALIPLATIN

INJECTABLE;IV (INFUSION)  
OXALIPLATIN

>D>	AP	EBEWE PHARMA	50MG/10ML (5MG/ML)	A078812	001	Aug 07, 2009	Jan CAHN
>D>	AP		100MG/20ML (5MG/ML)	A078812	002	Aug 07, 2009	Jan CAHN
>A>	AP	SANDOZ INC	50MG/10ML (5MG/ML)	A078812	001	Aug 07, 2009	Jan CAHN
>A>	AP		100MG/20ML (5MG/ML)	A078812	002	Aug 07, 2009	Jan CAHN

OXYCODONE HYDROCHLORIDE

TABLET;ORAL  
OXYCODONE HYDROCHLORIDE

>D>	AB	ALVOGEN INC	5MG	A202116	001	Dec 30, 2011	Jan CAHN
>D>	AB		15MG	A202116	002	Dec 30, 2011	Jan CAHN
>D>	AB		30MG	A202116	003	Dec 30, 2011	Jan CAHN
>A>	AB	ALVOGEN MALTA	5MG	A202116	001	Dec 30, 2011	Jan CAHN
>A>	AB		15MG	A202116	002	Dec 30, 2011	Jan CAHN
>A>	AB		30MG	A202116	003	Dec 30, 2011	Jan CAHN

PACLITAXEL

INJECTABLE;INJECTION  
PACLITAXEL

>D>	AP	EBEWE PHARMA	6MG/ML	A078167	001	Dec 26, 2007	Jan CAHN
>A>	AP	SANDOZ INC	6MG/ML	A078167	001	Dec 26, 2007	Jan CAHN

PAMIDRONATE DISODIUM

INJECTABLE;INJECTION  
PAMIDRONATE DISODIUM

>D>	AP	MUSTAFA NEVZAT	30MG/10ML (3MG/ML)	A078373	001	Dec 23, 2008	Jan CAHN
>D>	AP		90MG/10ML (9MG/ML)	A078373	002	Dec 23, 2008	Jan CAHN
>A>	AP	SAGENT PHARMS	30MG/10ML (3MG/ML)	A078373	001	Dec 23, 2008	Jan CAHN
>A>	AP		90MG/10ML (9MG/ML)	A078373	002	Dec 23, 2008	Jan CAHN

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE;ORAL  
PANTOPRAZOLE SODIUM

>A>	AB	AMNEAL PHARMS	EQ 20MG BASE	A205119	001	Jan 26, 2016	Jan NEWA
>A>	AB		EQ 40MG BASE	A205119	002	Jan 26, 2016	Jan NEWA

PARICALCITOL

CAPSULE;ORAL  
PARICALCITOL

>D>	AB	BANNER LIFE SCIENCES	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
>A>	AB	BIONPHARMA INC	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

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE;ORAL  
TRENENTAL

>D>		@ SANOFI AVENTIS US	400MG	N018631	001	Aug 30, 1984	Jan CAHN
>A>		@ US PHARM HOLDINGS	400MG	N018631	001	Aug 30, 1984	Jan CAHN

PERPHENAZINE

TABLET;ORAL

PERPHENAZINE

>D>	AB	INDICUS PHARMA	2MG	A205973	001	Dec 17, 2015	Jan	CAHN
>D>	AB		4MG	A205973	002	Dec 17, 2015	Jan	CAHN
>D>	AB		8MG	A205973	003	Dec 17, 2015	Jan	CAHN
>D>	AB		16MG	A205973	004	Dec 17, 2015	Jan	CAHN
>A>	AB	WILSHIRE PHARMS INC	2MG	A205973	001	Dec 17, 2015	Jan	CAHN
>A>	AB		4MG	A205973	002	Dec 17, 2015	Jan	CAHN
>A>	AB		8MG	A205973	003	Dec 17, 2015	Jan	CAHN
>A>	AB		16MG	A205973	004	Dec 17, 2015	Jan	CAHN

PHENAZOPYRIDINE HYDROCHLORIDE; SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET;ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM AND PENAZOPYRIDINE HYDROCHLORIDE

>D>	@	ABLE	200MG,N/A,N/A;N/A,800MG,160MG	N021105	001	Jun 26, 2001	Jan	CMS1
>A>	@	ABLE	200MG,N/A,N/A;N/A,800MG,160MG	N021105	001	Jun 26, 2001	Jan	CMS1

PHENTERMINE HYDROCHLORIDE

TABLET;ORAL

PHENTERMINE HYDROCHLORIDE

>A>	AA	INGENUS PHARMS NJ	37.5MG	A091451	001	Sep 21, 2012	Jan	CAHN
>D>	AA	MIRROR PHARMS	37.5MG	A091451	001	Sep 21, 2012	Jan	CAHN

PHYTONADIONE

INJECTABLE;INJECTION

AQUAMEPHYTON

>D>	@	IGI LABS INC	1MG/0.5ML	N012223	002		Jan	CAHN
>D>	@		10MG/ML	N012223	001		Jan	CAHN
>A>	@	TELIGENT PHARMA INC	1MG/0.5ML	N012223	002		Jan	CAHN
>A>	@		10MG/ML	N012223	001		Jan	CAHN

PIROXICAM

CAPSULE;ORAL

PIROXICAM

>D>	AB	MYLAN PHARMS INC	20MG	A074118	001	Jun 15, 1993	Jan	CAHN
>A>	AB		20MG	A074118	001	Jun 15, 1993	Jan	CAHN

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

POTASSIUM CHLORIDE

>A>	AB	GLENMARK PHARMS LTD	10MEQ	A202868	001	Jan 19, 2016	Jan	NEWA
>A>	AB1	NOVEL LABS INC	10MEQ	A206347	001	Jan 21, 2016	Jan	NEWA
>A>	AB1		20MEQ	A206347	002	Jan 21, 2016	Jan	NEWA

PROGESTERONE

CAPSULE;ORAL

PROGESTERONE

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

PROMETHAZINE HYDROCHLORIDE

TABLET;ORAL

PROMETHAZINE HYDROCHLORIDE

>D>	@	MUTUAL PHARM	50MG	A084557	001		Jan	CAHN
>A>	@	SUN PHARM INDS	50MG	A084557	001		Jan	CAHN

PYRIDOSTIGMINE BROMIDE

TABLET, EXTENDED RELEASE;ORAL

PYRIDOSTIGMINE BROMIDE

>D>	AB	ALVOGEN INC	180MG	A204737	001	Jun 26, 2015	Jan	CAHN
>A>	AB	ALVOGEN MALTA	180MG	A204737	001	Jun 26, 2015	Jan	CAHN



QUINAPRIL HYDROCHLORIDE

## TABLET; ORAL

## QUINAPRIL HYDROCHLORIDE

>D>	AB	ACTAVIS LABS FL INC	EQ 5MG BASE	A076049	001	Jan 14, 2005	Jan DISC
>A>		@	EQ 5MG BASE	A076049	001	Jan 14, 2005	Jan DISC
>D>	AB		EQ 10MG BASE	A076049	002	Jan 14, 2005	Jan DISC
>A>		@	EQ 10MG BASE	A076049	002	Jan 14, 2005	Jan DISC
>D>	AB		EQ 20MG BASE	A076049	003	Jan 14, 2005	Jan DISC
>A>		@	EQ 20MG BASE	A076049	003	Jan 14, 2005	Jan DISC
>D>	AB		EQ 40MG BASE	A076049	004	Jan 14, 2005	Jan DISC
>A>		@	EQ 40MG BASE	A076049	004	Jan 14, 2005	Jan DISC

RANITIDINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## ZANTAC

>D>	AP	+ CONCORDIA PHARMS INC	EQ 25MG BASE/ML	N019090	001	Oct 19, 1984	Jan CAHN
>A>	AP	+ IGI LABS INC	EQ 25MG BASE/ML	N019090	001	Oct 19, 1984	Jan CAHN
		ZANTAC IN PLASTIC CONTAINER					
>D>		@ COVIS INJECTABLES	EQ 1MG BASE/ML	N019593	002	Sep 27, 1991	Jan CAHN
>D>		@	EQ 50MG BASE/100ML	N019593	001	Dec 17, 1986	Jan CAHN
>A>		@ IGI LABS INC	EQ 1MG BASE/ML	N019593	002	Sep 27, 1991	Jan CAHN
>A>		@	EQ 50MG BASE/100ML	N019593	001	Dec 17, 1986	Jan CAHN

RETAPAMULIN

## OINTMENT; TOPICAL

## ALTABAX

>A>		+ AQUA PHARMS LLC	1%	N022055	001	Apr 12, 2007	Jan CAHN
>D>		+ GLAXO GRP LTD	1%	N022055	001	Apr 12, 2007	Jan CAHN

RIFAMPIN

## INJECTABLE; INJECTION

## RIFAMPIN

>A>	AP	WATSON PHARMS INC	600MG/VIAL	A206736	001	Jan 19, 2016	Jan NEWA
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RISEDRONATE SODIUM

## TABLET; ORAL

## ACTONEL

>A>	AB	ALLERGAN PHARMS INTL	5MG	N020835	002	Apr 14, 2000	Jan CAHN
>A>	AB		30MG	N020835	001	Mar 27, 1998	Jan CAHN
>A>	AB	+	35MG	N020835	003	May 25, 2002	Jan CAHN
>A>		@	75MG	N020835	004	Apr 16, 2007	Jan CAHN
>A>	AB	+	150MG	N020835	005	Apr 22, 2008	Jan CAHN
>D>	AB	WARNER CHILCOTT LLC	5MG	N020835	002	Apr 14, 2000	Jan CAHN
>D>	AB		30MG	N020835	001	Mar 27, 1998	Jan CAHN
>D>	AB	+	35MG	N020835	003	May 25, 2002	Jan CAHN
>D>		@	75MG	N020835	004	Apr 16, 2007	Jan CAHN
>D>	AB	+	150MG	N020835	005	Apr 22, 2008	Jan CAHN

## TABLET, DELAYED RELEASE; ORAL

## ATELVIA

>A>	AB	+ ALLERGAN PHARMS INTL	35MG	N022560	001	Oct 08, 2010	Jan CAHN
>D>	AB	+ WARNER CHILCOTT LLC	35MG	N022560	001	Oct 08, 2010	Jan CAHN

RIVASTIGMINE

## FILM, EXTENDED RELEASE; TRANSDERMAL

## RIVASTIGMINE

>A>	AB	ALVOGEN MALTA	4.6MG/24HR	A204403	001	Sep 03, 2015	Jan CAHN
>A>	AB		9.5MG/24HR	A204403	002	Sep 03, 2015	Jan CAHN
>A>	AB		13.3MG/24HR	A204403	003	Aug 31, 2015	Jan CAHN
>D>	AB	ALVOGEN PINE BROOK	4.6MG/24HR	A204403	001	Sep 03, 2015	Jan CAHN
>D>	AB		9.5MG/24HR	A204403	002	Sep 03, 2015	Jan CAHN
>D>	AB		13.3MG/24HR	A204403	003	Aug 31, 2015	Jan CAHN

RIVASTIGMINE TARTRATE

## CAPSULE; ORAL

## EXELON

>D>	AB	NOVARTIS	EQ 6MG BASE	N020823	006	Apr 21, 2000	Jan CRLD
>A>	AB	+	EQ 6MG BASE	N020823	006	Apr 21, 2000	Jan CRLD

RIZATRIPTAN BENZOATE

TABLET;ORAL

RIZATRIPTAN BENZOATE

>A>	AB	NOSTRUM LABS INC	EQ 5MG BASE	A202047	001	Dec 31, 2012	Jan CAHN
>A>	AB		EQ 10MG BASE	A202047	002	Dec 31, 2012	Jan CAHN
>D>	AB	SUN PHARMA GLOBAL	EQ 5MG BASE	A202047	001	Dec 31, 2012	Jan CAHN
>D>	AB		EQ 10MG BASE	A202047	002	Dec 31, 2012	Jan CAHN

SUCRALFATE

TABLET;ORAL

SUCRALFATE

>A>	AB	MYLAN IRELAND LTD	1GM	A074415	001	Jun 08, 1998	Jan CAHN
>D>	AB	MYLAN PHARMS INC	1GM	A074415	001	Jun 08, 1998	Jan CAHN

SUGAMMADEX SODIUM

SOLUTION;INTRAVENOUS

BRIDION

>D>		ORGANON SUB MERCK	200MG/2ML (100MG/ML)	N022225	002	Dec 15, 2015	Jan CPOT
>A>			EQ 200MG BASE/2ML (EQ 100MG BASE/ML)	N022225	002	Dec 15, 2015	Jan CPOT
>D>	+		500MG/5ML (100MG/ML)	N022225	001	Dec 15, 2015	Jan CPOT
>A>	+		EQ 500MG BASE/5ML (EQ 100MG BASE/ML)	N022225	001	Dec 15, 2015	Jan CPOT

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION;ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

>A>		@ ANI PHARMS INC	200MG/5ML;40MG/5ML	A077612	001	Nov 13, 2006	Jan CAHN
>D>		@ TEVA PHARMS	200MG/5ML;40MG/5ML	A077612	001	Nov 13, 2006	Jan CAHN

SUMATRIPTAN SUCCINATE

>A>		POWDER;INHALATION					
>A>		ONZETRA XSAIL					
>A>	+	AVANIR PHARMS	EQ 11MG BASE	N206099	001	Jan 27, 2016	Jan NEWA
>A>		SOLUTION;SUBCUTANEOUS					
>A>		ZEMBRACE SYMTOUCH					
>A>		DR REDDYS LABS LTD	EQ 3MG BASE/0.5ML (EQ 3MG BASE/0.5ML)	N208223	001	Jan 28, 2016	Jan NEWA

TAMOXIFEN CITRATE

SOLUTION;ORAL

SOLTAMOX

>D>		DARA BIOSCIENCES	EQ 10MG BASE/5ML	N021807	001	Oct 29, 2005	Jan CAHN
>A>		MIDATECH PHARMA US	EQ 10MG BASE/5ML	N021807	001	Oct 29, 2005	Jan CAHN

TABLET;ORAL

TAMOXIFEN CITRATE

>D>	AB	ACTAVIS LABS FL INC	EQ 10MG BASE	A076179	001	Feb 20, 2003	Jan DISC
>A>		@	EQ 10MG BASE	A076179	001	Feb 20, 2003	Jan DISC
>A>		@	EQ 20MG BASE	A076179	002	Feb 20, 2003	Jan DISC
>D>	AB	WATSON LABS FLORIDA	EQ 20MG BASE	A076179	002	Feb 20, 2003	Jan DISC

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION;INTRAVENOUS

ULTRA-TECHNEKOW FM

>D>	+	MALLINCKRODT	1-19 CI/GENERATOR	N017243	003	Feb 18, 2014	Jan CAHN
>D>		@	0.25-3 CI/GENERATOR	N017243	002		Jan CAHN
>A>	+	MALLINKRODT NUCLEAR	1-19 CI/GENERATOR	N017243	003	Feb 18, 2014	Jan CAHN
>A>		@	0.25-3 CI/GENERATOR	N017243	002		Jan CAHN

TEGASEROD MALEATE

TABLET;ORAL

ZELNORM

>D>		@ NOVARTIS	EQ 2MG BASE	N021200	001	Jul 24, 2002	Jan CAHN
>D>		@	EQ 6MG BASE	N021200	002	Jul 24, 2002	Jan CAHN
>A>		@ US WORLDMEDS LLC	EQ 2MG BASE	N021200	001	Jul 24, 2002	Jan CAHN
>A>		@	EQ 6MG BASE	N021200	002	Jul 24, 2002	Jan CAHN

TEMOZOLOMIDE

CAPSULE;ORAL  
TEMOZOLOMIDE

>A>	AB	KREMERS URBAN PHARMS	5MG	A203898	001	Feb 10, 2016	Jan	NEWA
>A>	AB		20MG	A203898	002	Feb 10, 2016	Jan	NEWA
>A>	AB		100MG	A203898	003	Feb 10, 2016	Jan	NEWA
>A>	AB		140MG	A203898	004	Feb 10, 2016	Jan	NEWA
>A>	AB		180MG	A203898	005	Feb 10, 2016	Jan	NEWA
>A>	AB		250MG	A203898	006	Feb 10, 2016	Jan	NEWA

TETRABENAZINE

TABLET;ORAL  
TETRABENAZINE

>A>	AB	HETERO LABS LTD V	12.5MG	A204574	001	Feb 03, 2016	Jan	NEWA
>A>	AB		25MG	A204574	002	Feb 03, 2016	Jan	NEWA

THEOPHYLLINE

SOLUTION, ELIXIR;ORAL  
ELIXOPHYLLIN

>A>	+	NOSTRUM LABS INC	80MG/15ML	A085186	001		Jan	CAHN
>D>	+	SUN PHARM INDS INC	80MG/15ML	A085186	001		Jan	CAHN

TABLET, EXTENDED RELEASE;ORAL  
THEOCHRON

>A>	AB	NOSTRUM LABS INC	100MG	A088320	001	Feb 21, 1985	Jan	CAHN
>A>	AB		200MG	A088321	001	Feb 21, 1985	Jan	CAHN
>A>	@		300MG	A087400	002	Jan 11, 1983	Jan	CAHN
>D>	AB	SUN PHARM INDS INC	100MG	A088320	001	Feb 21, 1985	Jan	CAHN
>D>	AB		200MG	A088321	001	Feb 21, 1985	Jan	CAHN
>D>	@		300MG	A087400	002	Jan 11, 1983	Jan	CAHN

THEOPHYLLINE

>A>	AB	MYLAN IRELAND LTD	400MG	A040560	003	Apr 21, 2006	Jan	CAHN
>A>	AB	+	600MG	A040560	002	Apr 21, 2006	Jan	CAHN
>D>	AB	MYLAN PHARMS INC	400MG	A040560	003	Apr 21, 2006	Jan	CAHN
>D>	AB	+	600MG	A040560	002	Apr 21, 2006	Jan	CAHN

TOPIRAMATE

TABLET;ORAL  
TOPIRAMATE

>A>	AB	ACTAVIS TOTOWA	25MG	A078637	001	Feb 27, 2013	Jan	CAHN
>A>	AB		50MG	A078637	002	Feb 27, 2013	Jan	CAHN
>A>	AB		100MG	A078637	003	Feb 27, 2013	Jan	CAHN
>A>	AB		200MG	A078637	004	Feb 27, 2013	Jan	CAHN
>D>	AB	ACTIVIS TOTOWA LLC	25MG	A078637	001	Feb 27, 2013	Jan	CAHN
>D>	AB		50MG	A078637	002	Feb 27, 2013	Jan	CAHN
>D>	AB		100MG	A078637	003	Feb 27, 2013	Jan	CAHN
>D>	AB		200MG	A078637	004	Feb 27, 2013	Jan	CAHN

TRANEXAMIC ACID

INJECTABLE;INJECTION  
TRANEXAMIC ACID

>A>	AP	AUROBINDO PHARMA LTD	100MG/ML	A205035	001	Jan 14, 2016	Jan	NEWA
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TRIMETHOPRIM HYDROCHLORIDE

SOLUTION;ORAL  
PRIMSOL

>A>	@	AYTU PHARMS	EQ 25MG BASE/5ML	A074374	001	Jun 23, 1995	Jan	CAHN
>A>	+		EQ 50MG BASE/5ML	N074973	001	Jan 24, 2000	Jan	CAHN
>D>	@	FSC	EQ 25MG BASE/5ML	A074374	001	Jun 23, 1995	Jan	CAHN
>D>	+		EQ 50MG BASE/5ML	N074973	001	Jan 24, 2000	Jan	CAHN

VALPROIC ACID

CAPSULE;ORAL  
VALPROIC ACID

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

CAPSULE, DELAYED RELEASE;ORAL  
STAVZOR

>D>	@	BANNER LIFE SCIENCES	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
>A>	@	BIONPHARMA INC	125MG	N022152	001	Jul 29, 2008	Jan	CAHN

CAPSULE, DELAYED RELEASE;ORAL  
STAVZOR

>A>	@	250MG	N022152	002	Jul 29, 2008	Jan CAHN
>A>	@	500MG	N022152	003	Jul 29, 2008	Jan CAHN

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION  
VANCOMYCIN HYDROCHLORIDE

>A>	AP	GLAND PHARMA LTD	EQ 500MG BASE/VIAL	A205694	001	Jan 21, 2016	Jan NEWA
>A>	AP		EQ 1GM BASE/VIAL	A205694	002	Jan 21, 2016	Jan NEWA

VECURONIUM BROMIDE

INJECTABLE; INJECTION  
VECURONIUM BROMIDE

>D>	AP	MUSTAFA NEVZAT	10MG/VIAL	A078274	001	Dec 29, 2008	Jan CAHN
>D>	AP		20MG/VIAL	A078274	002	Dec 29, 2008	Jan CAHN
>A>	AP	SAGENT PHARMS	10MG/VIAL	A078274	001	Dec 29, 2008	Jan CAHN
>A>	AP		20MG/VIAL	A078274	002	Dec 29, 2008	Jan CAHN

VORICONAZOLE

TABLET; ORAL  
VORICONAZOLE

>A>	AB	AUROBINDO PHARMA LTD	50MG	A206837	001	Jan 22, 2016	Jan NEWA
>A>	AB		200MG	A206837	002	Jan 22, 2016	Jan NEWA

ZONISAMIDE

CAPSULE; ORAL  
ZONISAMIDE

>D>	AB	BANNER LIFE SCIENCES	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
>A>	AB	BIONPHARMA INC	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

CETIRIZINE HYDROCHLORIDE

CAPSULE;ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

>D>		BANNER LIFE SCIENCES	5MG	N022429	001	Jul 23, 2009	Jan CAHN
>D>	+		10MG	N022429	004	Jul 23, 2009	Jan CAHN
>A>		BIONPHARMA INC	5MG	N022429	001	Jul 23, 2009	Jan CAHN
>A>	+		10MG	N022429	004	Jul 23, 2009	Jan CAHN
		CETIRIZINE HYDROCHLORIDE HIVES RELIEF					
>D>		BANNER LIFE SCIENCES	5MG	N022429	003	Jul 23, 2009	Jan CAHN
>D>	+		10MG	N022429	002	Jul 23, 2009	Jan CAHN
>A>		BIONPHARMA INC	5MG	N022429	003	Jul 23, 2009	Jan CAHN
>A>	+		10MG	N022429	002	Jul 23, 2009	Jan CAHN

DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN

CAPSULE;ORAL

IBUPROFEN AND DIPHENHYDRAMINE HYDROCHLORIDE

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

IBUPROFEN

CAPSULE;ORAL

IBUPROFEN

>D>		BANNER LIFE SCIENCES	EQ 200MG FREE ACID AND POTASSIUM SALT	A078682	001	Mar 24, 2009	Jan CAHN
>A>		BIONPHARMA INC	EQ 200MG FREE ACID AND POTASSIUM SALT	A078682	001	Mar 24, 2009	Jan CAHN
		MIDOL LIQUID GELS					
>D>	+	BANNER LIFE SCIENCES	200MG	N021472	001	Oct 18, 2002	Jan CAHN
>A>	+	BIONPHARMA INC	200MG	N021472	001	Oct 18, 2002	Jan CAHN

LOPERAMIDE HYDROCHLORIDE

CAPSULE;ORAL

LOPERAMIDE HYDROCHLORIDE

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

OXYBUTYNIN

FILM, EXTENDED RELEASE;TRANSDERMAL

OXYTROL FOR WOMEN

>A>	+	ALLERGAN SALES LLC	3.9MG/24HR	N202211	001	Jan 25, 2013	Jan CAHN
>D>	+	BAYER HEALTHCARE LLC	3.9MG/24HR	N202211	001	Jan 25, 2013	Jan CAHN

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

**CUMULATIVE SUPPLEMENT NUMBER 01 JANUARY 2016**

NO JANUARY 2016 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 2016 ADDITIONS



PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2016

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>ACETYLCYSTEINE - CETYLEV</u>						
N 207916	001 >A> 8747894	May 08, 2032	DP U-1373			
<u>ACETYLCYSTEINE - CETYLEV</u>						
N 207916	002 >A> 8747894	May 08, 2032	DP U-1373			
<u>ADAPALENE; BENZOYL PEROXIDE - EPIDUO FORTE</u>						
N 207917	001 >A> 8809305	Dec 23, 2022	U-1078			
<u>ALBUTEROL SULFATE - PROAIR RESPICLICK</u>						
N 205636	001 >A> 8978966	Jan 13, 2032	DP			
	>A> 9216260	Jun 28, 2031	DP			
<u>BALSALAZIDE DISODIUM - GIAZO</u>						
N 022205	001 >A> 9192616	Aug 02, 2026	U-1229			
<u>BIMATOPROST - LATISSE</u>						
N 022369	001 >A> 9216183	Jan 15, 2023	U-1487			
	>A> 9226931	Jan 15, 2023	U-1799			
<u>CARFILZOMIB - KYPROLIS</u>						
N 202714	001			>A> I-722		Jan 21, 2019
				>A> I-723		Jan 21, 2019
<u>CEFIXIME - SUPRAX</u>						
N 202091	001 >A> 9233112	Dec 14, 2028	DP U-1676			
<u>CIPROFLOXACIN - OTIPRIO</u>						
N 207986	001 >A> 9233068	Dec 11, 2029	DP	>A> NP		Dec 10, 2018
<u>CYCLOSPORINE - RESTASIS</u>						
N 050790	001 >A> 9248191	Aug 27, 2024	U-1479			
<u>CYSTEAMINE BITARTRATE - PROCYSBI</u>						
N 203389	001 >A> 9233077	Jun 17, 2034	DP			
<u>CYSTEAMINE BITARTRATE - PROCYSBI</u>						
N 203389	002 >A> 9233077	Jun 17, 2034	DP			
<u>DABRAFENIB MESYLATE - TAFINLAR</u>						
N 202806	001			>A> M-170		Nov 20, 2018
<u>DABRAFENIB MESYLATE - TAFINLAR</u>						
N 202806	002			>A> M-170		Nov 20, 2018
<u>DALBAVANCIN HYDROCHLORIDE - DALVANCE</u>						
N 021883	001			>A> D-154		Jan 20, 2019
<u>DEFERASIROX - JADENU</u>						
N 206910	001			>A> ODE		Jan 23, 2020
<u>DEFERASIROX - JADENU</u>						
N 206910	002			>A> ODE		Jan 23, 2020
<u>DEFERASIROX - JADENU</u>						
N 206910	003			>A> ODE		Jan 23, 2020

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2016

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>DICLOFENAC SODIUM - PENNSAID</u>						
N 204623 001	>A> 9220784	Oct 17, 2027	U-1488			
<u>DOXYCYCLINE - ORACEA</u>						
N 050805 001	>A> 9241946	Apr 05, 2022	U-1063			
<u>ELBASVIR; GRAZOPREVR - ZEPATIER</u>						
N 208261 001					>A> NCE	Jan 28, 2021
<u>EPINEPHRINE - ADRENALIN</u>						
N 204200 001	>A> 9119876	Mar 13, 2035	DP			
<u>ERIBULIN MESYLATE - HALAVEN</u>						
N 201532 001					>A> I-721	Jan 28, 2019
<u>ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO</u>						
N 022511 001	>A> 9220698	Mar 10, 2031	U-1781			
<u>IMATINIB MESYLATE - IMATINIB MESYLATE</u>						
A 078340 001					>A> PC	Jul 30, 2016
<u>IMATINIB MESYLATE - IMATINIB MESYLATE</u>						
A 078340 002					>A> PC	Jul 30, 2016
<u>INSULIN GLARGINE RECOMBINANT - LANTUS SOLOSTAR</u>						
N 021081 002	>A> 9233211	Mar 02, 2024	DP			
<u>INSULIN GLARGINE RECOMBINANT - TOUJEO SOLOSTAR</u>						
N 206538 001	>A> 9233211	Mar 02, 2024	DP			
<u>INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR</u>						
N 021629 003	>A> 9233211	Mar 02, 2024	DP			
<u>INSULIN HUMAN - HUMULIN R</u>						
N 018780 004	>A> 7291132	Aug 09, 2024	DP			
<u>IRINOTECAN HYDROCHLORIDE - ONIVYDE</u>						
N 207793 001					>A> ODE	Oct 22, 2022
<u>IVERMECTIN - SOOLANTRA</u>						
N 206255 001	>A> 9233117	Mar 13, 2034	U-1631			
	>A> 9233118	Mar 13, 2034	U-1631			
<u>IXAZOMIB CITRATE - NINLARO</u>						
N 208462 001	>A> 9233115	Aug 12, 2024	U-1778			
<u>IXAZOMIB CITRATE - NINLARO</u>						
N 208462 002	>A> 9233115	Aug 12, 2024	U-1778			
<u>IXAZOMIB CITRATE - NINLARO</u>						
N 208462 003	>A> 9233115	Aug 12, 2024	U-1778			
<u>KETOROLAC TROMETHAMINE - ACULAR LS</u>						
N 021528 001	>A> 9216127	May 28, 2024	U-1800			
<u>LESINURAD - ZURAMPIC</u>						
N 207988 001	>A> 8003681	Aug 25, 2025	DS			
	>A> 8084483	Aug 17, 2029	U-1801			
	>A> 8283369	Nov 26, 2028	U-1802			
	>A> 8283369	Nov 26, 2028	U-1804			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2016

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>LESINURAD - ZURAMPIC</u>						
N 207988 001	>A> 8357713	Nov 26, 2028	DP U-1801			
	>A> 8357713	Nov 26, 2028	DP U-1802			
	>A> 8357713	Nov 26, 2028	DP U-1803			
	>A> 8546436	Feb 29, 2032	DS DP			
	>A> 8546437	Apr 29, 2029	U-1803			
<u>LULICONAZOLE - LUZU</u>						
N 204153 001	>A> 9199977	Sep 06, 2033	DS DP			
<u>METFORMIN HYDROCHLORIDE - METFORMIN HYDROCHLORIDE</u>						
A 091664 001					>A> PC	Jul 30, 2016
<u>METFORMIN HYDROCHLORIDE - METFORMIN HYDROCHLORIDE</u>						
A 091664 002					>A> PC	Jul 30, 2016
<u>NALOXONE HYDROCHLORIDE - EVZIO</u>						
N 205787 001	>A> 9238108	Jan 22, 2027	DP			
<u>OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u>						
N 021636 001	>A> 5840737	Jul 15, 2016	U-588			
	>A> 6780882	Jul 15, 2016	DS DP			
	>A> 7399772	Jul 15, 2016	U-588			
<u>OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u>						
N 021636 002	>A> 5840737	Jul 15, 2016	U-623			
	>A> 5840737	Jul 15, 2016	U-624			
	>A> 6780882	Jul 15, 2016	DS DP			
	>A> 7399772	Jul 15, 2016	U-623			
	>A> 7399772	Jul 15, 2016	U-624			
<u>OSIMERTINIB MESYLATE - TAGRISSO</u>						
N 208065 001					>A> ODE	Nov 13, 2022
<u>OSIMERTINIB MESYLATE - TAGRISSO</u>						
N 208065 002					>A> ODE	Nov 13, 2022
<u>OSPHEMIFENE - OSPHENA</u>						
N 203505 001	>A> 9241915	Feb 13, 2024	U-1369			
	>A> 9241915	Feb 13, 2024	U-1370			
<u>PROPOFOL - PROPOFOL</u>						
A 205307 001					>A> PC	Feb 24, 2016
<u>SAPROPTERIN DIHYDROCHLORIDE - KUVAN</u>						
N 205065 001	>A> 9216178	Nov 01, 2032	DP			
<u>SAPROPTERIN DIHYDROCHLORIDE - KUVAN</u>						
N 205065 002	>A> 7612073	Nov 17, 2024	U-1010			
	>A> 7612073*PED	May 17, 2025				
	>A> 9216178	Nov 01, 2032	DP			
	>A> RE43797	Nov 17, 2024	U-1590			
	>A> RE43797*PED	May 17, 2025				
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 001	>A> 7205302	Apr 04, 2023	DS DP U-1797			
	>A> 8791122	Aug 01, 2030	DS DP			
	>A> 9173881	Aug 12, 2029	U-1798			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 002	>A> 7205302	Apr 04, 2023	DS DP U-1797			
	>A> 8791122	Aug 01, 2030	DS DP			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 002	>A> 9173881	Aug 12, 2029	U-1798			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 003	>A> 7205302	Apr 04, 2023	DS DP U-1797			
	>A> 8791122	Aug 01, 2030	DS DP			
	>A> 9173881	Aug 12, 2029	U-1798			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 004	>A> 7205302	Apr 04, 2023	DS DP U-1797			
	>A> 8791122	Aug 01, 2030	DS DP			
	>A> 9173881	Aug 12, 2029	U-1798			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 005	>A> 7205302	Apr 04, 2023	DS DP U-1797			
	>A> 8791122	Aug 01, 2030	DS DP			
	>A> 9173881	Aug 12, 2029	U-1798			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 006	>A> 7205302	Apr 04, 2023	DS DP U-1797			
	>A> 8791122	Aug 01, 2030	DS DP			
	>A> 9173881	Aug 12, 2029	U-1798			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 007	>A> 7205302	Apr 04, 2023	DS DP U-1797			
	>A> 8791122	Aug 01, 2030	DS DP			
	>A> 9173881	Aug 12, 2029	U-1798			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 008	>A> 7205302	Apr 04, 2023	DS DP U-1797			
	>A> 8791122	Aug 01, 2030	DS DP			
	>A> 9173881	Aug 12, 2029	U-1798			
<u>SEVELAMER CARBONATE - RENVELA</u>						
N 022318 001	>A> 9095509	Dec 06, 2030	DP			
<u>SEVELAMER CARBONATE - RENVELA</u>						
N 022318 002	>A> 9095509	Dec 06, 2030	DP			
<u>SUGAMMADEX SODIUM - BRIDION</u>						
N 022225 001	>A> 7265099	Aug 07, 2020	U-1795			
<u>SUGAMMADEX SODIUM - BRIDION</u>						
N 022225 002	>A> 7265099	Aug 07, 2020	U-1795			
<u>TESTOSTERONE - ANDROGEL</u>						
N 021015 001	>A> 9125816	Aug 30, 2020	U-490			
	>A> 9125816*PED	Mar 02, 2021				
	>A> 9132089	Aug 30, 2020	U-490			
	>A> 9132089*PED	Mar 02, 2021				
<u>TESTOSTERONE - ANDROGEL</u>						
N 021015 002	>A> 9125816	Aug 30, 2020	U-490			
	>A> 9125816*PED	Mar 02, 2021				
	>A> 9132089	Aug 30, 2020	U-490			
	>A> 9132089*PED	Mar 02, 2021				
<u>TESTOSTERONE - ANDROGEL</u>						
N 021015 003	>A> 9125816	Aug 30, 2020	U-490			
	>A> 9125816*PED	Mar 02, 2021				
	>A> 9132089	Aug 30, 2020	U-490			
	>A> 9132089*PED	Mar 02, 2021				

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>TESTOSTERONE - ANDROGEL</u>						
N 021015 003	>A> 9125816	Aug 30, 2020	U-490			
	>A> 9125816*PED	Mar 02, 2021				
	>A> 9132089	Aug 30, 2020	U-490			
	>A> 9132089*PED	Mar 02, 2021				
<u>TESTOSTERONE - ANDROGEL</u>						
N 022309 001	>A> 6503894	Aug 30, 2020	U-1103			
	>A> 6503894*PED	Mar 02, 2021				
	>A> 9125816	Aug 30, 2020	U-1103			
	>A> 9125816*PED	Mar 02, 2021				
	>A> 9132089	Aug 30, 2020	U-1103			
	>A> 9132089*PED	Mar 02, 2021				
<u>TESTOSTERONE - ANDROGEL</u>						
N 022309 002	>A> 6503894	Aug 30, 2020	U-1103			
	>A> 6503894*PED	Mar 02, 2021				
	>A> 9125816	Aug 30, 2020	U-1103			
	>A> 9125816*PED	Mar 02, 2021				
	>A> 9132089	Aug 30, 2020	U-1103			
	>A> 9132089*PED	Mar 02, 2021				
<u>TESTOSTERONE - ANDROGEL</u>						
N 022309 003	>A> 6503894	Aug 30, 2020	U-1103			
	>A> 6503894*PED	Mar 02, 2021				
	>A> 9125816	Aug 30, 2020	U-1103			
	>A> 9125816*PED	Mar 02, 2021				
	>A> 9132089	Aug 30, 2020	U-1103			
	>A> 9132089*PED	Mar 02, 2021				
<u>TRAMETINIB DIMETHYL SULFOXIDE - MEKINIST</u>						
N 204114 001				>A> M-170		Nov 20, 2018
<u>TRAMETINIB DIMETHYL SULFOXIDE - MEKINIST</u>						
N 204114 003				>A> M-170		Nov 20, 2018
<u>VORTIOXETINE HYDROBROMIDE - BRINTELLIX</u>						
N 204447 001	>A> 9227946	Jun 15, 2027	U-1668			
<u>VORTIOXETINE HYDROBROMIDE - BRINTELLIX</u>						
N 204447 002	>A> 9227946	Jun 15, 2027	U-1668			
<u>VORTIOXETINE HYDROBROMIDE - BRINTELLIX</u>						
N 204447 003	>A> 9227946	Jun 15, 2027	U-1668			
<u>VORTIOXETINE HYDROBROMIDE - BRINTELLIX</u>						
N 204447 004	>A> 9227946	Jun 15, 2027	U-1668			

## 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, 36<sup>th</sup> Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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

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