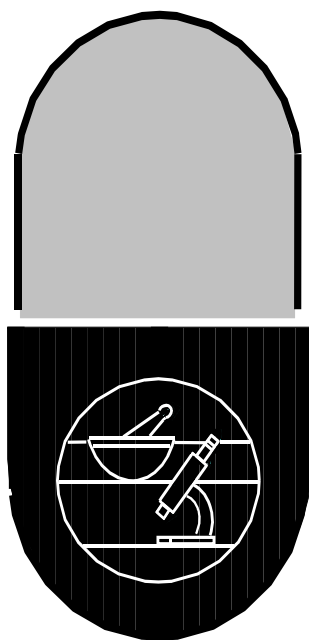


**CUMULATIVE  
SUPPLEMENT 1  
JANUARY 2017**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**37th 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**

**2017**

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

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with  
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**37<sup>th</sup> EDITION**

**Cumulative Supplement 1  
January 2017**

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

**37<sup>th</sup> EDITION**

**CUMULATIVE SUPPLEMENT 1**  
**January 2017**

**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, 31<sup>th</sup> Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; approved over-the-counter (OTC) drug products for those drugs that may not be marketed without NDAs or ANDAs because they are not covered under existing OTC monographs; drug products with approval under Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) administered by the Center for Biologics Evaluation and Research; and approved products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.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, Discontinued Drug Product, 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, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons 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 12<sup>th</sup> 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.

<u>FORMER APPLICANT NAME</u> <u>(FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME</u> <u>(NEW ABBREVIATED NAME)</u>
JAI PHARMA LTD (JAI PHARMA LTD)	MYLAN LABORATORIES LTD (MYLAN LABS LTD)

### 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 076187), Levoxyl (King Pharms NDA 021301), Synthroid (Abbvie NDA 021402), and Levo-T (Alara NDA 021342) 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 076187), and Unithroid (Jerome Stevens NDA 021210) tablets have been determined to be therapeutically equivalent to corresponding strengths of Synthroid (Abbvie NDA 021402) tablets.

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

Levothyroxine Sodium (Mylan ANDA 076187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levotheroid (Lloyd NDA 021116) tablets.

The chart outlines TE codes for all 0.025mg products in the active section of the Orange Book. 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	Strength	TE Code	Appl No	Product No
UNITHROID	STEVENS J	0.025MG	AB1	021210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB1	076187	001
LEVOXYL	KING PHARMS	0.025MG	AB1	021301	001
SYNTHROID	ABBVIE	0.025MG	AB1	021402	001
LEVO-T	ALARA PHARM	0.025MG	AB1	021342	001
SYNTHROID	ABBVIE	0.025MG	AB2	021402	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB2	076187	001
LEVO-T	ALARA PHARM	0.025MG	AB2	021342	001
UNITHROID	STEVENS J	0.025MG	AB2	021210	001
LEVOXYL	KING PHARMS	0.025MG	AB3	021301	001
LEVO-T	ALARA PHARM	0.025MG	AB3	021342	001
UNITHROID	STEVENS J	0.025MG	AB3	021210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB3	076187	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB4	076187	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 2016</u>	<u>MAR 2017</u>	<u>JUN 2017</u>	<u>SEP 2017</u>	<u>DEC 2017</u>
DRUG PRODUCTS LISTED SINGLE SOURCE	18130				
	2646				
	(14.6%)				
MULTISOURCE	15484				
	(85.4%)				
THERAPEUTICALLY EQUIVALENT	15335				
	(84.7%)				
NOT THERAPEUTICALLY EQUIVALENT	129				
	(0.7%)				
EXCEPTIONS <sup>1</sup>	73				
	(0.4%)				
NEW MOLECULAR ENTITIES APPROVED	7				
NUMBER OF APPLICANTS	1051				

<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 of Administration and then by trade name (or established name of the active ingredient, if no trade name exists).

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, new route(s) of administration, 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.
CHRS	Change. Reference Standard.
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.

**\*\*Note:**

The Cumulative Supplement (CS) currently displays a condensed 20 character collapsed applicant holder firm name and the Electronic Orange Book(EOB)query may display up to a 240 character full applicant holder firm name. An applicant holder firm name change usually changes both the collapsed name and long name. On occasion, only the long name is changed resulting in the CS displaying only the collapsed name for the >D> and >A> action. The new firm long name will display in the EOB query.

ACETAMINOPHEN

SOLUTION;IV (INFUSION)  
 ACETAMINOPHEN

>A>	AP	CUSTOPHARM INC	1GM/100ML (10MG/ML)	A202605	001	Jun 13, 2016	Jan	CAHN
>D>	AP	PADDOCK LLC	1GM/100ML (10MG/ML)	A202605	001	Jun 13, 2016	Jan	CAHN

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET;ORAL  
 PERCO CET

>A>	AA	!	VINTAGE PHARMS LLC	325MG;7.5MG	A040330	003	Nov 23, 2001	Jan	CMS1
>A>	AA	!		325MG;10MG	A040330	004	Nov 23, 2001	Jan	CMS1

ACYCLOVIR

CAPSULE;ORAL  
 ACYCLOVIR

>A>		@	CHARTWELL MOLECULES	200MG	A074872	001	Apr 22, 1997	Jan	CAHN
>D>		@	DAVA PHARMS INC	200MG	A074872	001	Apr 22, 1997	Jan	CAHN

ZOVIRAX

>D>	AB	+	DELCOR ASSET CORP	200MG	N018828	001	Jan 25, 1985	Jan	CAHN
>A>	AB	+	MYLAN PHARMS INC	200MG	N018828	001	Jan 25, 1985	Jan	CAHN

SUSPENSION;ORAL

ZOVIRAX

>D>	AB	+	DELCOR ASSET	200MG/5ML	N019909	001	Dec 22, 1989	Jan	CAHN
>A>	AB	+	MYLAN PHARMS INC	200MG/5ML	N019909	001	Dec 22, 1989	Jan	CAHN

TABLET;ORAL

ACYCLOVIR

>A>		@	CHARTWELL MOLECULES	400MG	A074834	001	Apr 24, 1997	Jan	CAHN
>A>		@		800MG	A074834	002	Apr 24, 1997	Jan	CAHN
>D>		@	DAVA PHARMS INC	400MG	A074834	001	Apr 24, 1997	Jan	CAHN
>D>		@		800MG	A074834	002	Apr 24, 1997	Jan	CAHN

ZOVIRAX

>D>	AB		DELCOR ASSET CORP	400MG	N020089	001	Apr 30, 1991	Jan	CAHN
>D>	AB	+		800MG	N020089	002	Apr 30, 1991	Jan	CAHN
>A>	AB	+	MYLAN PHARMS INC	400MG	N020089	001	Apr 30, 1991	Jan	CAHN
>A>	AB	+		800MG	N020089	002	Apr 30, 1991	Jan	CAHN

ADENOSINE

INJECTABLE;INJECTION  
 ADENOSINE

>D>	AP		EUROHLTH INTL SARL	3MG/ML	A076404	001	Jun 16, 2004	Jan	CAHN
>D>	AP			3MG/ML	A076500	001	Jun 16, 2004	Jan	CAHN
>D>		@		3MG/ML	A076501	001	Jun 16, 2004	Jan	CAHN
>A>	AP		WEST-WARD PHARMS INT	3MG/ML	A076404	001	Jun 16, 2004	Jan	CAHN
>A>	AP			3MG/ML	A076500	001	Jun 16, 2004	Jan	CAHN
>A>		@		3MG/ML	A076501	001	Jun 16, 2004	Jan	CAHN

ALPRAZOLAM

TABLET, EXTENDED RELEASE;ORAL  
 ALPRAZOLAM

>A>	AB		AUROBINDO PHARMA LTD	0.5MG	A090871	001	Jun 07, 2011	Jan	CAHN
>A>	AB			1MG	A090871	002	Jun 07, 2011	Jan	CAHN
>A>	AB			2MG	A090871	003	Jun 07, 2011	Jan	CAHN
>A>	AB			3MG	A090871	004	Jun 07, 2011	Jan	CAHN
>D>	AB		AUROBINDO PHARMA USA	0.5MG	A090871	001	Jun 07, 2011	Jan	CAHN
>D>	AB			1MG	A090871	002	Jun 07, 2011	Jan	CAHN
>D>	AB			2MG	A090871	003	Jun 07, 2011	Jan	CAHN
>D>	AB			3MG	A090871	004	Jun 07, 2011	Jan	CAHN

AMANTADINE HYDROCHLORIDE

SYRUP;ORAL  
 SYMMETREL

>D>		@	ENDO PHARMS	50MG/5ML	N016023	002		Jan	CRLD
>A>		+	@	50MG/5ML	N016023	002		Jan	CRLD

TABLET;ORAL

AMANTADINE HYDROCHLORIDE

>A>	AB		NEWGEN PHARMS LLC	100MG	A207571	001	Jan 31, 2017	Jan	NEWA
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AMIODARONE HYDROCHLORIDE

TABLET; ORAL

AMIODARONE HYDROCHLORIDE

>A>	AB	MAYNE PHARMA INC	200MG	A 075389	001	Jan 25, 2001	Jan CAHN
>D>	AB	SWAN PHARMS LLC	200MG	A 075389	001	Jan 25, 2001	Jan CAHN
>D>		CORDARONE					
>D>	AB	+! WYETH PHARMS INC	200MG	N 018972	001	Dec 24, 1985	Jan DISC
>A>		+ @	200MG	N 018972	001	Dec 24, 1985	Jan DISC

AMMONIUM LACTATE

LOTION; TOPICAL

LAC-HYDRIN

>D>		@ RANBAXY	EQ 12% BASE	N 019155	001	Apr 24, 1985	Jan CRLD
>A>		+ @	EQ 12% BASE	N 019155	001	Apr 24, 1985	Jan CRLD

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

>D>		@ EUROHLTH INTL SARL	EQ 125MG BASE/VIAL	A 062692	001	Jun 24, 1986	Jan CAHN
>D>		@	EQ 250MG BASE/VIAL	A 062692	002	Jun 24, 1986	Jan CAHN
>D>		@	EQ 500MG BASE/VIAL	A 062692	003	Jun 24, 1986	Jan CAHN
>D>		@	EQ 1GM BASE/VIAL	A 062692	004	Jun 24, 1986	Jan CAHN
>D>		@	EQ 2GM BASE/VIAL	A 062692	005	Jun 24, 1986	Jan CAHN
>D>		@	EQ 10GM BASE/VIAL	A 062692	006	Jun 24, 1986	Jan CAHN
>A>		@ WEST-WARD PHARMS INT	EQ 125MG BASE/VIAL	A 062692	001	Jun 24, 1986	Jan CAHN
>A>		@	EQ 250MG BASE/VIAL	A 062692	002	Jun 24, 1986	Jan CAHN
>A>		@	EQ 500MG BASE/VIAL	A 062692	003	Jun 24, 1986	Jan CAHN
>A>		@	EQ 1GM BASE/VIAL	A 062692	004	Jun 24, 1986	Jan CAHN
>A>		@	EQ 2GM BASE/VIAL	A 062692	005	Jun 24, 1986	Jan CAHN
>A>		@	EQ 10GM BASE/VIAL	A 062692	006	Jun 24, 1986	Jan CAHN

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE; INJECTION

AMPICILLIN AND SULBACTAM

>D>	AP	EUROHLTH INTL SARL	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A 065074	001	Mar 19, 2002	Jan CAHN
>D>	AP		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A 065074	002	Mar 19, 2002	Jan CAHN
>D>	AP		EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	A 065076	001	Mar 19, 2002	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A 065074	001	Mar 19, 2002	Jan CAHN
>A>	AP		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A 065074	002	Mar 19, 2002	Jan CAHN
>A>	AP		EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	A 065076	001	Mar 19, 2002	Jan CAHN

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

FIORINAL

>D>		@ ALLERGAN SALES LLC	325MG;50MG;40MG	N 017534	003	Apr 16, 1986	Jan CRLD
>A>		+ @	325MG;50MG;40MG	N 017534	003	Apr 16, 1986	Jan CRLD

ASPIRIN; DIPYRIDAMOLE

CAPSULE, EXTENDED RELEASE; ORAL

ASPIRIN AND DIPYRIDAMOLE

>A>	AB	IMPAX LABS INC	25MG;200MG	A 206964	001	Jan 18, 2017	Jan NEWA
>A>	AB	PAR PHARM INC	25MG;200MG	A 207944	001	Jan 18, 2017	Jan NEWA
>A>	AB	SANDOZ INC	25MG;200MG	A 206739	001	Jan 18, 2017	Jan NEWA

AZITHROMYCIN

INJECTABLE; INJECTION

AZITHROMYCIN

>A>	AP	MYLAN LABS LTD	EQ 500MG BASE/VIAL	A 204732	001	Jan 26, 2017	Jan NEWA
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BETAMETHASONE DIPROPIONATE

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

>D>	AB	! FOUGERA	EQ 0.05% BASE	A 070275	001	Aug 12, 1985	Jan CAHN
>A>	AB	! FOUGERA PHARMS INC	EQ 0.05% BASE	A 070275	001	Aug 12, 1985	Jan CAHN
		DIPROSONE					
>D>		@ SCHERING	EQ 0.05% BASE	N 017781	001		Jan CRLD
>A>		+ @	EQ 0.05% BASE	N 017781	001		Jan CRLD

BETAMETHASONE VALERATEAEROSOL, FOAM;TOPICAL  
LUXIQ

>D>	AB	+	DELCOR ASSET CORP	0.12%	N020934	001	Feb 28, 1999	Jan	CAHN
>A>	AB	+!	MYLAN PHARMS INC	0.12%	N020934	001	Feb 28, 1999	Jan	CAHN

BETHANECHOL CHLORIDETABLET;ORAL  
BETHANECHOL CHLORIDE

>A>		@	IMPAX LABS	5MG	A040721	001	Nov 01, 2006	Jan	CMS1
>A>		@		10MG	A040721	002	Nov 01, 2006	Jan	CMS1
>A>		@		25MG	A040721	003	Nov 01, 2016	Jan	CMS1

BISOPROLOL FUMARATETABLET;ORAL  
BISOPROLOL FUMARATE

>A>	AB		ORIT LABS LLC	5MG	A204891	001	Jan 11, 2017	Jan	NEWA
>A>	AB			10MG	A204891	002	Jan 11, 2017	Jan	NEWA

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDETABLET;ORAL  
ZIAC

>A>	AB	+	TEVA BRANDED PHARM	2.5MG; 6.25MG	N020186	003	Mar 26, 1993	Jan	CAHN
>A>	AB	+		5MG; 6.25MG	N020186	001	Mar 26, 1993	Jan	CAHN
>A>	AB	+!		10MG; 6.25MG	N020186	002	Mar 26, 1993	Jan	CAHN
>D>	AB	+	TEVA WOMENS	2.5MG; 6.25MG	N020186	003	Mar 26, 1993	Jan	CAHN
>D>	AB	+		5MG; 6.25MG	N020186	001	Mar 26, 1993	Jan	CAHN
>D>	AB	+!		10MG; 6.25MG	N020186	002	Mar 26, 1993	Jan	CAHN

BRETYLIUM TOSYLATEINJECTABLE;INJECTION  
BRETYLIUM TOSYLATE

>D>		@	EUROHLTH INTL SARL	50MG/ML	A070545	001	May 14, 1986	Jan	CAHN
>A>		@	WEST-WARD PHARMS INT	50MG/ML	A070545	001	May 14, 1986	Jan	CAHN

BUMETANIDEINJECTABLE;INJECTION  
BUMETANIDE

>D>	AP		EUROHLTH INTL SARL	0.25MG/ML	A079196	001	Apr 30, 2008	Jan	CAHN
>A>	AP		WEST-WARD PHARMS INT	0.25MG/ML	A079196	001	Apr 30, 2008	Jan	CAHN

BUPRENORPHINE HYDROCHLORIDEFILM;BUCCAL  
BELBUCA

>A>		+	BDSI	EQ 0.075MG BASE	N207932	001	Oct 23, 2015	Jan	CAHN
>A>		+		EQ 0.15MG BASE	N207932	002	Oct 23, 2015	Jan	CAHN
>A>		+		EQ 0.3MG BASE	N207932	003	Oct 23, 2015	Jan	CAHN
>A>		+		EQ 0.45MG BASE	N207932	004	Oct 23, 2015	Jan	CAHN
>A>		+		EQ 0.6MG BASE	N207932	005	Oct 23, 2015	Jan	CAHN
>A>		+		EQ 0.75MG BASE	N207932	006	Oct 23, 2015	Jan	CAHN
>A>		+!		EQ 0.9MG BASE	N207932	007	Oct 23, 2015	Jan	CAHN
>D>			ENDO PHARMS INC	EQ 0.075MG BASE	N207932	001	Oct 23, 2015	Jan	CAHN
>D>				EQ 0.15MG BASE	N207932	002	Oct 23, 2015	Jan	CAHN
>D>				EQ 0.3MG BASE	N207932	003	Oct 23, 2015	Jan	CAHN
>D>				EQ 0.45MG BASE	N207932	004	Oct 23, 2015	Jan	CAHN
>D>				EQ 0.6MG BASE	N207932	005	Oct 23, 2015	Jan	CAHN
>D>				EQ 0.75MG BASE	N207932	006	Oct 23, 2015	Jan	CAHN
>D>		+		EQ 0.9MG BASE	N207932	007	Oct 23, 2015	Jan	CAHN

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDETABLET;SUBLINGUAL  
ZUBSOLV

>D>		+!	OREXO US INC	EQ 5.7MG BASE;EQ 1.4MG BASE	N204242	002	Jul 03, 2013	Jan	CHRS
>A>		+		EQ 5.7MG BASE;EQ 1.4MG BASE	N204242	002	Jul 03, 2013	Jan	CHRS
>D>		+		EQ 11.4MG BASE;EQ 2.9MG BASE	N204242	004	Dec 11, 2014	Jan	CHRS
>A>		+!		EQ 11.4MG BASE;EQ 2.9MG BASE	N204242	004	Dec 11, 2014	Jan	CHRS

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL  
FORFIVO XL

>A>	+	ALVOGEN	450MG	N022497	001	Nov 10, 2011	Jan CAHN
>D>	+	EDGEMONT PHARMS LLC	450MG	N022497	001	Nov 10, 2011	Jan CAHN

BUTORPHANOL TARTRATE

INJECTABLE;INJECTION  
BUTORPHANOL TARTRATE PRESERVATIVE FREE

>D>	AP	EUROHLTH INTL SARL	1MG/ML	A075045	001	Aug 12, 1998	Jan CAHN
>D>	AP		2MG/ML	A075045	002	Aug 12, 1998	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	1MG/ML	A075045	001	Aug 12, 1998	Jan CAHN
>A>	AP		2MG/ML	A075045	002	Aug 12, 1998	Jan CAHN

CALCIPOTRIENE

AEROSOL, FOAM;TOPICAL  
SORILUX

>A>	+	MAYNE PHARMA	0.005%	N022563	001	Oct 06, 2010	Jan CAHN
>D>	+	STIEFEL LABS INC	0.005%	N022563	001	Oct 06, 2010	Jan CAHN

CARBAMAZEPINE

SOLUTION;IV (INFUSION)  
CARNEPIX

>D>	+	LUNDBECK LLC	200MG/20ML (10MG/ML)	N206030	001	Oct 07, 2016	Jan CAHN
>A>	+	LUNDBECK PHARMS LLC	200MG/20ML (10MG/ML)	N206030	001	Oct 07, 2016	Jan CAHN

CARBOPLATIN

INJECTABLE;IV (INFUSION)  
CARBOPLATIN

>A>	AP	ACCORD HLTHCARE	50MG/5ML (10MG/ML)	A206775	001	Feb 09, 2017	Jan NEWA
>A>	AP		150MG/15ML (10MG/ML)	A206775	002	Feb 09, 2017	Jan NEWA
>A>	AP		450MG/45ML (10MG/ML)	A206775	003	Feb 09, 2017	Jan NEWA
>A>	AP		600MG/60ML (10MG/ML)	A206775	004	Feb 09, 2017	Jan NEWA
>A>	AP	GLAND PHARMA LTD	50MG/5ML (10MG/ML)	A207324	001	Feb 15, 2017	Jan NEWA
>A>	AP		150MG/15ML (10MG/ML)	A207324	002	Feb 15, 2017	Jan NEWA
>A>	AP		450MG/45ML (10MG/ML)	A207324	003	Feb 15, 2017	Jan NEWA
>A>	AP		600MG/60ML (10MG/ML)	A207324	004	Feb 15, 2017	Jan NEWA

CEFDINIR

CAPSULE;ORAL  
OMNICEF

>D>	@	ABBVIE	300MG	N050739	001	Dec 04, 1997	Jan CRLD
>A>	+	@	300MG	N050739	001	Dec 04, 1997	Jan CRLD

FOR SUSPENSION;ORAL  
OMNICEF

>D>	@	ABBVIE	125MG/5ML	N050749	001	Dec 04, 1997	Jan CRLD
>A>	+	@	125MG/5ML	N050749	001	Dec 04, 1997	Jan CRLD
>D>	@		250MG/5ML	N050749	002	Jul 29, 2004	Jan CRLD
>A>	+	@	250MG/5ML	N050749	002	Jul 29, 2004	Jan CRLD

CEFIXIME

FOR SUSPENSION;ORAL  
CEFIXIME

>A>	AB	BELCHER PHARMS LLC	100MG/5ML	A206938	001	Feb 06, 2017	Jan NEWA
>A>	AB		200MG/5ML	A206938	002	Feb 06, 2017	Jan NEWA
>A>	AB		500MG/5ML	A206939	001	Feb 06, 2017	Jan NEWA

SUPRAX

>D>	+	LUPIN LTD	500MG/5ML	N202091	001	Feb 20, 2013	Jan CFTG
>A>	AB	+	500MG/5ML	N202091	001	Feb 20, 2013	Jan CFTG

CEFOXITIN SODIUM

INJECTABLE;INJECTION  
CEFOXITIN

>D>	AP	EUROHLTH INTL SARL	EQ 1GM BASE/VIAL	A065051	001	Sep 11, 2000	Jan CAHN
>D>	AP		EQ 2GM BASE/VIAL	A065051	002	Sep 11, 2000	Jan CAHN
>D>	AP		EQ 10GM BASE/VIAL	A065050	001	Sep 11, 2000	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	EQ 1GM BASE/VIAL	A065051	001	Sep 11, 2000	Jan CAHN
>A>	AP		EQ 2GM BASE/VIAL	A065051	002	Sep 11, 2000	Jan CAHN
>A>	AP		EQ 10GM BASE/VIAL	A065050	001	Sep 11, 2000	Jan CAHN

CEFPROZILTABLET; ORAL  
CEFPROZIL

>D>	AB	AUROBINDO PHARMA LTD	250MG	A065340	001	May 24, 2007	Jan	CAHN
>A>	AB		250MG	A065340	001	May 24, 2007	Jan	CAHN
>D>	AB		500MG	A065340	002	May 24, 2007	Jan	CAHN
>A>	AB		500MG	A065340	002	May 24, 2007	Jan	CAHN

CEFTRIAZONE SODIUMINJECTABLE; INJECTION  
CEFTRIAZONE SODIUM

>A>	AP	SAGENT PHARMS	EQ 10GM BASE/VIAL	A091117	001	Jan 20, 2017	Jan	NEWA
		ROCEPHIN W/ DEXTROSE IN	PLASTIC CONTAINER					
>D>		@ HOFFMANN LA ROCHE	EQ 10MG BASE/ML	N050624	001	Feb 11, 1987	Jan	CRLD
>A>		+ @	EQ 10MG BASE/ML	N050624	001	Feb 11, 1987	Jan	CRLD
>D>		@	EQ 20MG BASE/ML	N050624	002	Feb 11, 1987	Jan	CRLD
>A>		+ @	EQ 20MG BASE/ML	N050624	002	Feb 11, 1987	Jan	CRLD
>D>		@	EQ 40MG BASE/ML	N050624	003	Feb 11, 1987	Jan	CRLD
>A>		+ @	EQ 40MG BASE/ML	N050624	003	Feb 11, 1987	Jan	CRLD

CEFUROXIME AXETILTABLET; ORAL  
CEFUROXIME AXETIL

>D>	AB	AUROBINDO PHARMA LTD	EQ 125MG BASE	A065308	001	Mar 29, 2006	Jan	CAHN
>A>	AB		EQ 125MG BASE	A065308	001	Mar 29, 2006	Jan	CAHN
>D>	AB		EQ 250MG BASE	A065308	002	Mar 29, 2006	Jan	CAHN
>A>	AB		EQ 250MG BASE	A065308	002	Mar 29, 2006	Jan	CAHN
>D>	AB		EQ 500MG BASE	A065308	003	Mar 29, 2006	Jan	CAHN
>A>	AB		EQ 500MG BASE	A065308	003	Mar 29, 2006	Jan	CAHN

CEPHALEXINCAPSULE; ORAL  
CEPHALEXIN

>D>	AB	AUROBINDO PHARMA LTD	EQ 250MG BASE	A065253	001	Nov 16, 2005	Jan	CAHN
>A>	AB		EQ 250MG BASE	A065253	001	Nov 16, 2005	Jan	CAHN
>D>	AB		EQ 500MG BASE	A065253	002	Nov 16, 2005	Jan	CAHN
>A>	AB		EQ 500MG BASE	A065253	002	Nov 16, 2005	Jan	CAHN

CEPHAPIRIN SODIUMINJECTABLE; INJECTION  
CEPHAPIRIN SODIUM

>D>		@ EUROHLTH INTL SARL	EQ 500MG BASE/VIAL	A062720	001	Jul 02, 1987	Jan	CAHN
>D>		@	EQ 1GM BASE/VIAL	A062720	002	Jul 02, 1987	Jan	CAHN
>D>		@	EQ 2GM BASE/VIAL	A062720	003	Jul 02, 1987	Jan	CAHN
>D>		@	EQ 20GM BASE/VIAL	A062720	004	Jul 02, 1987	Jan	CAHN
>A>		@ WEST-WARD PHARMS INT	EQ 500MG BASE/VIAL	A062720	001	Jul 02, 1987	Jan	CAHN
>A>		@	EQ 1GM BASE/VIAL	A062720	002	Jul 02, 1987	Jan	CAHN
>A>		@	EQ 2GM BASE/VIAL	A062720	003	Jul 02, 1987	Jan	CAHN
>A>		@	EQ 20GM BASE/VIAL	A062720	004	Jul 02, 1987	Jan	CAHN

CHLORPROMAZINE HYDROCHLORIDEINJECTABLE; INJECTION  
CHLORPROMAZINE HYDROCHLORIDE

>D>		+ EUROHLTH INTL SARL	25MG/ML	A083329	001		Jan	CAHN
>A>		! WEST-WARD PHARMS INT	25MG/ML	A083329	001		Jan	CAHN

CHLORPROPAMIDETABLET; ORAL  
CHLORPROPAMIDE

>A>		@ ANI PHARMS INC	250MG	A087353	001		Jan	CAHN
>D>		@ TEVA PHARMS USA	250MG	A087353	001		Jan	CAHN

CILOSTAZOLTABLET; ORAL  
PLETAL

>D>		@ OTSUKA	50MG	N020863	001	Jan 15, 1999	Jan	CRLD
>A>		+ @	50MG	N020863	001	Jan 15, 1999	Jan	CRLD
>D>		@	100MG	N020863	002	Jan 15, 1999	Jan	CRLD
>A>		+ @	100MG	N020863	002	Jan 15, 1999	Jan	CRLD

CIMETIDINE

## TABLET;ORAL

## CIMETIDINE

>A>	@	CHARTWELL MOLECULES	200MG	A 074281	001	May 17, 1994	Jan	CAHN
>A>	@		300MG	A 074281	002	May 17, 1994	Jan	CAHN
>A>	@		400MG	A 074281	003	May 17, 1994	Jan	CAHN
>A>	@		800MG	A 074329	001	May 17, 1994	Jan	CAHN
>D>	@	VINTAGE PHARMS LLC	200MG	A 074281	001	May 17, 1994	Jan	CAHN
>D>	@		300MG	A 074281	002	May 17, 1994	Jan	CAHN
>D>	@		400MG	A 074281	003	May 17, 1994	Jan	CAHN
>D>	@		800MG	A 074329	001	May 17, 1994	Jan	CAHN

CISATRACURIUM BESYLATE

## INJECTABLE;INJECTION

## CISATRACURIUM BESYLATE PRESERVATIVE FREE

>A>	AP	JIANGSU HENGRUI MED	EQ 2MG BASE/ML	A 204960	001	Jan 27, 2017	Jan	NEWA
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CITALOPRAM HYDROBROMIDE

## SOLUTION;ORAL

## CITALOPRAM HYDROBROMIDE

>D>	AA	AUROBINDO PHARMA LTD	EQ 10MG BASE/5ML	A 077812	001	Aug 28, 2006	Jan	CAHN
>A>	AA		EQ 10MG BASE/5ML	A 077812	001	Aug 28, 2006	Jan	CAHN

CLINDAMYCIN PHOSPHATE

## AEROSOL, FOAM;TOPICAL

## EVOCLIN

>D>	AT	+ DELCOR ASSET CORP	1%	N 050801	001	Oct 22, 2004	Jan	CAHN
>A>	AT	+! MYLAN PHARMS INC	1%	N 050801	001	Oct 22, 2004	Jan	CAHN

## INJECTABLE;INJECTION

## CLINDAMYCIN PHOSPHATE

>D>	AP	EUROHLTH INTL SARL	EQ 150MG BASE/ML	A 065206	001	Sep 24, 2004	Jan	CAHN
>A>	AP	WEST-WARD PHARMS INT	EQ 150MG BASE/ML	A 065206	001	Sep 24, 2004	Jan	CAHN

## SOLUTION;TOPICAL

## CLINDAMYCIN PHOSPHATE

>D>	AT	FOUGERA	EQ 1% BASE	A 064159	001	Jun 05, 1997	Jan	CAHN
>A>	AT	FOUGERA PHARMS INC	EQ 1% BASE	A 064159	001	Jun 05, 1997	Jan	CAHN

CLOBAZAM

## SUSPENSION;ORAL

## ONFI

>D>		+! LUNDBECK LLC	2.5MG/ML	N 203993	001	Dec 14, 2012	Jan	CAHN
>A>		+! LUNDBECK PHARMS LLC	2.5MG/ML	N 203993	001	Dec 14, 2012	Jan	CAHN

## TABLET;ORAL

## ONFI

>D>		@ LUNDBECK LLC	5MG	N 202067	001	Oct 21, 2011	Jan	CAHN
>D>		+	10MG	N 202067	002	Oct 21, 2011	Jan	CAHN
>D>		+!	20MG	N 202067	003	Oct 21, 2011	Jan	CAHN
>A>		@ LUNDBECK PHARMS LLC	5MG	N 202067	001	Oct 21, 2011	Jan	CAHN
>A>		+	10MG	N 202067	002	Oct 21, 2011	Jan	CAHN
>A>		+!	20MG	N 202067	003	Oct 21, 2011	Jan	CAHN

CLOBETASOL PROPIONATE

## AEROSOL, FOAM;TOPICAL

## OLUX

>D>	AB1	+ DELCOR ASSET CORP	0.05%	N 021142	001	May 26, 2000	Jan	CAHN
>A>	AB1	+! MYLAN PHARMS INC	0.05%	N 021142	001	May 26, 2000	Jan	CAHN

## OLUX E

>D>	AB2	+ DELCOR ASSET	0.05%	N 022013	001	Jan 12, 2007	Jan	CAHN
>A>	AB2	+! MYLAN PHARMS INC	0.05%	N 022013	001	Jan 12, 2007	Jan	CAHN

## CREAM;TOPICAL

## CLOBETASOL PROPIONATE

>D>	AB1	FOUGERA	0.05%	A 074392	001	Sep 30, 1996	Jan	CAHN
>A>	AB1	FOUGERA PHARMS INC	0.05%	A 074392	001	Sep 30, 1996	Jan	CAHN
>A>		@ MYLAN PHARMS INC	0.05%	A 075338	001	Feb 09, 2001	Jan	CAHN
>D>		@ RENAISSANCE PHARMA	0.05%	A 075338	001	Feb 09, 2001	Jan	CAHN

## OINTMENT;TOPICAL

## CLOBETASOL PROPIONATE

>A>		@ MYLAN PHARMS INC	0.05%	A 075057	001	Aug 12, 1998	Jan	CAHN
>D>		@ RENAISSANCE PHARMA	0.05%	A 075057	001	Aug 12, 1998	Jan	CAHN



## OINTMENT;TOPICAL

## TEMOVATE

>D>	@	FOUGERA PHARMS	0.05%	N019323	001	Dec 27, 1985	Jan CRLD
>A>	+	@	0.05%	N019323	001	Dec 27, 1985	Jan CRLD

CLOPIDOGREL BISULFATE

## TABLET;ORAL

## CLOPIDOGREL BISULFATE

>A>	AB	CSPC OUYI PHARM CO	EQ 75MG BASE	A204359	001	Feb 02, 2017	Jan NEWA
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CODEINE SULFATE

## SOLUTION;ORAL

## CODEINE SULFATE

>D>	@	ROXANE	30MG/5ML	N202245	001	Jun 30, 2011	Jan CAHN
>A>	@	WEST-WARD PHARMS INT	30MG/5ML	N202245	001	Jun 30, 2011	Jan CAHN

## TABLET;ORAL

## CODEINE SULFATE

>D>	AB	+	ROXANE	15MG	N022402	001	Jul 16, 2009	Jan CAHN
>D>	AB	+		30MG	N022402	002	Jul 16, 2009	Jan CAHN
>D>	AB	+	!	60MG	N022402	003	Jul 16, 2009	Jan CAHN
>A>	AB	+	WEST-WARD PHARMS INT	15MG	N022402	001	Jul 16, 2009	Jan CAHN
>A>	AB	+		30MG	N022402	002	Jul 16, 2009	Jan CAHN
>A>	AB	+	!	60MG	N022402	003	Jul 16, 2009	Jan CAHN

CYCLOPHOSPHAMIDE

## CAPSULE;ORAL

## CYCLOPHOSPHAMIDE

>D>		ROXANE	25MG	N203856	001	Sep 16, 2013	Jan CAHN	
>D>		+	50MG	N203856	002	Sep 16, 2013	Jan CAHN	
>A>		+	WEST-WARD PHARMS INT	25MG	N203856	001	Sep 16, 2013	Jan CAHN
>A>		+	!	50MG	N203856	002	Sep 16, 2013	Jan CAHN

CYPROHEPTADINE HYDROCHLORIDE

## SYRUP;ORAL

## PERIACTIN

>D>	@	MERCK	2MG/5ML	N013220	002		Jan CRLD
>A>	+	@	2MG/5ML	N013220	002		Jan CRLD

## TABLET;ORAL

## CYPROHEPTADINE HYDROCHLORIDE

>A>	AA	APNAR PHARMA LP	4MG	A207555	001	Jan 31, 2017	Jan NEWA
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DALFAMPRIDINE

## TABLET, EXTENDED RELEASE;ORAL

## AMPYRA

>D>	+	ACORDA	10MG	N022250	001	Jan 22, 2010	Jan CFTG	
>A>	AB	+	!	10MG	N022250	001	Jan 22, 2010	Jan CFTG
>A>			DALFAMPRIDINE					
>A>	AB		ACTAVIS LABS FL INC	10MG	A206836	001	Jan 23, 2017	Jan NEWA
>A>	AB		AUROBINDO PHARMA LTD	10MG	A206811	001	Jan 23, 2017	Jan NEWA

DESOXIMETASONE

## GEL;TOPICAL

## TOPICORT

>D>	@	TARO PHARMS NORTH	0.05%	N018586	001	Mar 29, 1982	Jan CRLD
>A>	+	@	0.05%	N018586	001	Mar 29, 1982	Jan CRLD

## SPRAY;TOPICAL

## DESOXIMETASONE

>A>	AT	PERRIGO ISRAEL	0.25%	A206441	001	Jan 20, 2017	Jan NEWA	
>D>		+	TARO	0.25%	N204141	001	Apr 11, 2013	Jan CFTG
>A>	AT	+	!	0.25%	N204141	001	Apr 11, 2013	Jan CFTG

DICLOFENAC SODIUM; MISOPROSTOL

## TABLET, DELAYED RELEASE;ORAL

## DICLOFENAC SODIUM AND MISOPROSTOL

>A>	AB	EAGLE PHARMS	50MG;0.2MG	A200540	001	Mar 14, 2014	Jan CAHN
>A>	AB		75MG;0.2MG	A200540	002	Mar 14, 2014	Jan CAHN
>D>	AB	EXELA PHARMA SCS LLC	50MG;0.2MG	A200540	001	Mar 14, 2014	Jan CAHN
>D>	AB		75MG;0.2MG	A200540	002	Mar 14, 2014	Jan CAHN

DIGOXINELIXIR; ORAL  
DIGOXIN

>D>	+	ROXANE	0.05MG/ML	N021648	001	Aug 26, 2004	Jan CAHN
>A>	+	WEST-WARD PHARMS INT	0.05MG/ML	N021648	001	Aug 26, 2004	Jan CAHN

DIHYDROERGOTAMINE MESYLATEINJECTABLE; INJECTION  
DIHYDROERGOTAMINE MESYLATE

>D>	AP	EUROHLTH INTL SARL	1MG/ML	A040453	001	Jun 09, 2003	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	1MG/ML	A040453	001	Jun 09, 2003	Jan CAHN

DILTIAZEM HYDROCHLORIDEINJECTABLE; INJECTION  
DILTIAZEM HYDROCHLORIDE

>D>	AP	EUROHLTH INTL SARL	5MG/ML	A078538	001	Dec 17, 2008	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	5MG/ML	A078538	001	Dec 17, 2008	Jan CAHN

DISULFIRAMTABLET; ORAL  
DISULFIRAM

>A>	AB	CHARTWELL MOLECULES	250MG	A091563	001	Dec 31, 2012	Jan CAHN
>A>	AB		500MG	A091563	002	Dec 31, 2012	Jan CAHN
>D>	AB	VINTAGE PHARMS	250MG	A091563	001	Dec 31, 2012	Jan CAHN
>D>	AB		500MG	A091563	002	Dec 31, 2012	Jan CAHN

DOCETAXELINJECTABLE; INJECTION  
DOCETAXEL

>A>	AP	DFB ONCOLOGY LTD	20MG/ML (20MG/ML)	A206177	001	Jan 20, 2017	Jan NEWA
>A>	AP		80MG/4ML (20MG/ML)	A206177	002	Jan 20, 2017	Jan NEWA
>A>			200MG/10ML (20MG/ML)	A206177	003	Jan 20, 2017	Jan NEWA
>A>	+	HOSPIRA INC	160MG/8ML (20MG/ML)	N022234	007	Jan 24, 2017	Jan NEWA
>A>	!	JIANGSU HENGRUI MED	40MG/ML	A203170	001	Feb 15, 2017	Jan NEWA
>D>		PFIZER LABS	20MG/2ML (10MG/ML)	N202356	001	Mar 13, 2014	Jan DISC
>A>	@		20MG/2ML (10MG/ML)	N202356	001	Mar 13, 2014	Jan DISC
>D>			80MG/8ML (10MG/ML)	N202356	002	Mar 13, 2014	Jan DISC
>A>	@		80MG/8ML (10MG/ML)	N202356	002	Mar 13, 2014	Jan DISC
>D>			130MG/13ML (10MG/ML)	N202356	003	Mar 13, 2014	Jan DISC
>A>	@		130MG/13ML (10MG/ML)	N202356	003	Mar 13, 2014	Jan DISC
>D>			200MG/20ML (10MG/ML)	N202356	004	Mar 13, 2014	Jan DISC
>A>	@		200MG/20ML (10MG/ML)	N202356	004	Mar 13, 2014	Jan DISC

DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

>A>		MEMANTINE HYDROCHLORIDE AND DONEPEZIL HYDROCHLORIDE					
>A>	AB	AMNEAL PHARMS	10MG;14MG	A208328	001	Jan 27, 2017	Jan NEWA
>A>	AB		10MG;28MG	A208328	002	Jan 27, 2017	Jan NEWA
		NAMZARIC					
>D>	+	FOREST LABS LLC	10MG;14MG	N206439	001	Dec 23, 2014	Jan CFTG
>A>	AB	+	10MG;14MG	N206439	001	Dec 23, 2014	Jan CFTG
>D>	+	!	10MG;28MG	N206439	002	Dec 23, 2014	Jan CFTG
>A>	AB	+	10MG;28MG	N206439	002	Dec 23, 2014	Jan CFTG

DOXEPIN HYDROCHLORIDECREAM; TOPICAL  
ZONALON

>D>	+	DELCOR ASSET CORP	5%	N020126	001	Apr 01, 1994	Jan CAHN
>A>	+	MYLAN PHARMS INC	5%	N020126	001	Apr 01, 1994	Jan CAHN

DOXYCYCLINE HYCLATEINJECTABLE; INJECTION  
VIBRAMYCIN

>D>	@	PFIZER	EQ 100MG BASE/VIAL	N050442	002		Jan CRLD
>A>	+	@	EQ 100MG BASE/VIAL	N050442	002		Jan CRLD
>D>	@		EQ 200MG BASE/VIAL	N050442	001		Jan CRLD
>A>	+	@	EQ 200MG BASE/VIAL	N050442	001		Jan CRLD

TABLET; ORAL

DOXYCYCLINE HYCLATE

>D>	@	BLU CARIBE INC	EQ 50MG BASE	A062269	003		Jan CAHN
>D>	AB		EQ 100MG BASE	A062269	002	Nov 08, 1982	Jan CAHN

TABLET;ORAL

DOXYCYCLINE HYCLATE

>A> @ CARIBE HOLDINGS EQ 50MG BASE A062269 003 Jan CAHN  
 >A> AB EQ 100MG BASE A062269 002 Nov 08, 1982 Jan CAHN

EPHEDRINE SULFATE

SOLUTION;IV (INFUSION)

>A> CORPHEDRA  
 >A> PAR STERILE PRODUCTS 50MG/ML (50MG/ML) N208943 001 Jan 27, 2017 Jan NEWA

EPLERENONE

TABLET;ORAL

EPLERENONE

>A> AB MYLAN PHARMS INC 25MG A203896 001 Feb 02, 2017 Jan NEWA  
 >A> AB 50MG A203896 002 Feb 02, 2017 Jan NEWA

ERYTHROMYCIN

GEL;TOPICAL

E-GLADES

>A> @ MYLAN PHARMS INC 2% A065009 001 Mar 18, 2002 Jan CAHN  
 >D> @ RENAISSANCE PHARMA 2% A065009 001 Mar 18, 2002 Jan CAHN  
 ERYGEL  
 >D> AT + DELCOR ASSET CORP 2% N050617 001 Oct 21, 1987 Jan CAHN  
 >A> AT +! MYLAN PHARMS INC 2% N050617 001 Oct 21, 1987 Jan CAHN

SWAB;TOPICAL

ERYTHROMYCIN

>A> @ MYLAN PHARMS INC 2% A064128 001 Jul 03, 1996 Jan CAHN  
 >D> @ RENAISSANCE PHARMA 2% A064128 001 Jul 03, 1996 Jan CAHN

ESTRADIOL; NORETHINDRONE ACETATE

TABLET;ORAL

ESTRADIOL AND NORETHINDRONE ACETATE

>A> AB MYLAN LABS LTD 0.5MG;0.1MG A207261 001 Feb 10, 2017 Jan NEWA  
 >A> AB 1MG;0.5MG A207261 002 Feb 10, 2017 Jan NEWA

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE

TABLET;ORAL-28

ETHYNODIOL DIACETATE AND ETHINYL ESTRADIOL

>A> AB JAI PHARMA LTD 0.035MG;1MG A204703 001 Jul 28, 2016 Jan NEWA

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET, CHEWABLE;ORAL

NEXESTA FE

>A>  
 >A> AB AUROBINDO PHARMA LTD 0.035MG;0.4MG A207535 001 Feb 02, 2017 Jan NEWA

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET;ORAL

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL

>A> AB MYLAN LABS LTD 0.0025MG;0.5MG A207260 001 Feb 02, 2017 Jan NEWA

ETODOLAC

CAPSULE;ORAL

ETODOLAC

>A> @ CHARTWELL PHARMS LLC 200MG A074842 001 Jul 17, 1997 Jan CAHN  
 >A> @ 300MG A074842 002 Jul 17, 1997 Jan CAHN  
 >D> @ VINTAGE PHARMS LLC 200MG A074842 001 Jul 17, 1997 Jan CAHN  
 >D> @ 300MG A074842 002 Jul 17, 1997 Jan CAHN

TABLET;ORAL

ETODOLAC

>A> @ CHARTWELL MOLECULES 400MG A074841 001 Jun 27, 1997 Jan CAHN  
 >D> @ VINTAGE PHARMS LLC 400MG A074841 001 Jun 27, 1997 Jan CAHN

ETOMIDATE

INJECTABLE;INJECTION

ETOMIDATE

>D> AP EUROHLTH INTL SARL 2MG/ML A074593 001 Nov 04, 1996 Jan CAHN  
 >A> AP MYLAN LABS LTD 2MG/ML A201044 001 Feb 07, 2017 Jan NEWA  
 >A> AP WEST-WARD PHARMS INT 2MG/ML A074593 001 Nov 04, 1996 Jan CAHN

FAMCICLOVIR

## TABLET; ORAL

## FAMCICLOVIR

>D>	AB	TEVA PHARMS	500MG	A077487	003	Aug 24, 2007	Jan	CHRS
>A>	AB	!	500MG	A077487	003	Aug 24, 2007	Jan	CHRS
FAMVIR								
>D>	AB	+ NOVARTIS	125MG	N020363	003	Dec 11, 1995	Jan	DISC
>A>		+ @	125MG	N020363	003	Dec 11, 1995	Jan	DISC
>D>	AB	+	250MG	N020363	001	Apr 26, 1996	Jan	DISC
>A>		+ @	250MG	N020363	001	Apr 26, 1996	Jan	DISC
>D>	AB	+!	500MG	N020363	002	Jun 29, 1994	Jan	DISC
>A>		+ @	500MG	N020363	002	Jun 29, 1994	Jan	DISC

FLUCONAZOLE

## FOR SUSPENSION; ORAL

## FLUCONAZOLE

>D>	AB	AUROBINDO PHARM	50MG/5ML	A079150	001	Sep 18, 2009	Jan	CAHN
>D>	AB		200MG/5ML	A079150	002	Sep 18, 2009	Jan	CAHN
>A>	AB	AUROBINDO PHARMA LTD	50MG/5ML	A079150	001	Sep 18, 2009	Jan	CAHN
>A>	AB		200MG/5ML	A079150	002	Sep 18, 2009	Jan	CAHN

## INJECTABLE; INJECTION

## FLUCONAZOLE IN SODIUM CHLORIDE 0.9%

>D>		EUROHLTH INTL SARL	100MG/50ML (2MG/ML)	A076087	002	Sep 26, 2008	Jan	CAHN
>D>	AP		200MG/100ML (2MG/ML)	A076087	001	Jul 29, 2004	Jan	CAHN
>D>	AP		400MG/200ML (2MG/ML)	A076087	003	Jul 29, 2004	Jan	CAHN
>A>		WEST-WARD PHARMS INT	100MG/50ML (2MG/ML)	A076087	002	Sep 26, 2008	Jan	CAHN
>A>	AP		200MG/100ML (2MG/ML)	A076087	001	Jul 29, 2004	Jan	CAHN
>A>	AP		400MG/200ML (2MG/ML)	A076087	003	Jul 29, 2004	Jan	CAHN

## FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

>D>	AP	EUROHLTH INTL SARL	200MG/100ML (2MG/ML)	A078107	001	Jul 30, 2008	Jan	CAHN
>D>	AP		400MG/200ML (2MG/ML)	A078107	002	Jul 30, 2008	Jan	CAHN
>A>	AP	WEST-WARD PHARMS INT	200MG/100ML (2MG/ML)	A078107	001	Jul 30, 2008	Jan	CAHN
>A>	AP		400MG/200ML (2MG/ML)	A078107	002	Jul 30, 2008	Jan	CAHN

FLUMAZENIL

## INJECTABLE; INJECTION

## FLUMAZENIL

>D>	AP	EUROHLTH INTL SARL	0.5MG/5ML (0.1MG/ML)	A076256	002	Oct 12, 2004	Jan	CAHN
>D>	AP		0.5MG/5ML (0.1MG/ML)	A076787	002	Oct 12, 2004	Jan	CAHN
>D>	AP		1MG/10ML (0.1MG/ML)	A076256	001	Oct 12, 2004	Jan	CAHN
>D>	AP		1MG/10ML (0.1MG/ML)	A076787	001	Oct 12, 2004	Jan	CAHN
>A>	AP	WEST-WARD PHARMS INT	0.5MG/5ML (0.1MG/ML)	A076256	002	Oct 12, 2004	Jan	CAHN
>A>	AP		0.5MG/5ML (0.1MG/ML)	A076787	002	Oct 12, 2004	Jan	CAHN
>A>	AP		1MG/10ML (0.1MG/ML)	A076256	001	Oct 12, 2004	Jan	CAHN
>A>	AP		1MG/10ML (0.1MG/ML)	A076787	001	Oct 12, 2004	Jan	CAHN

FLUOCINOLONE ACETONIDE

## CREAM; TOPICAL

## FLUOCINOLONE ACETONIDE

>D>	AT	FOUGERA	0.01%	A088170	001	Dec 16, 1982	Jan	CAHN
>D>	AT		0.025%	A088169	001	Dec 16, 1982	Jan	CAHN
>A>	AT	FOUGERA PHARMS INC	0.01%	A088170	001	Dec 16, 1982	Jan	CAHN
>A>	AT		0.025%	A088169	001	Dec 16, 1982	Jan	CAHN

## OINTMENT; TOPICAL

## FLUOCINOLONE ACETONIDE

>D>	AT	FOUGERA	0.025%	A088168	001	Dec 16, 1982	Jan	CAHN
>A>	AT	FOUGERA PHARMS INC	0.025%	A088168	001	Dec 16, 1982	Jan	CAHN

## SOLUTION; TOPICAL

## FLUOCINOLONE ACETONIDE

>D>	AT	FOUGERA	0.01%	A088167	001	Dec 16, 1982	Jan	CAHN
>A>	AT	FOUGERA PHARMS INC	0.01%	A088167	001	Dec 16, 1982	Jan	CAHN

FLUOCINONIDE

## CREAM; TOPICAL

## FLUOCINONIDE

>D>	AB1	FOUGERA	0.05%	A073030	001	Oct 17, 1994	Jan	CAHN
>A>	AB1	FOUGERA PHARMS INC	0.05%	A073030	001	Oct 17, 1994	Jan	CAHN

## GEL; TOPICAL

## FLUOCINONIDE

>D>	AB	FOUGERA	0.05%	A072933	001	Dec 30, 1994	Jan	CAHN
>A>	AB	FOUGERA PHARMS INC	0.05%	A072933	001	Dec 30, 1994	Jan	CAHN

FLUOROURACILINJECTABLE; INJECTION  
FLUOROURACIL

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

FLUOXETINE HYDROCHLORIDESOLUTION; ORAL  
FLUOXETINE HYDROCHLORIDE

>D>	AA AUROBINDO PHARM	EQ 20MG BASE/5ML	A079209	001	Mar 20, 2009	Jan	CAHN
>A>	AA AUROBINDO PHARMA LTD	EQ 20MG BASE/5ML	A079209	001	Mar 20, 2009	Jan	CAHN

TABLET; ORAL  
FLUOXETINE HYDROCHLORIDE

>A>	+! ALVOGEN	EQ 60MG BASE	N202133	001	Oct 06, 2011	Jan	CAHN
>D>	+ EDMONT PHARMS LLC	EQ 60MG BASE	N202133	001	Oct 06, 2011	Jan	CAHN

FLUPHENAZINE HYDROCHLORIDECONCENTRATE; ORAL  
FLUPHENAZINE HYDROCHLORIDE

>A>	@ ANI PHARMS INC	5MG/ML	A073058	001	Aug 30, 1991	Jan	CAHN
>D>	@ TEVA PHARMS	5MG/ML	A073058	001	Aug 30, 1991	Jan	CAHN

FLURAZEPAM HYDROCHLORIDECAPSULE; ORAL  
FLURAZEPAM HYDROCHLORIDE

>A>	@ AUROLIFE PHARMA LLC	15MG	A071717	002	Jul 31, 1991	Jan	CMS1
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FLUTICASONE PROPIONATEPOWDER; INHALATION  
ARMONAIR RESPICLICK

>A>	+ TEVA PHARM	0.055MG/INH	N208798	001	Jan 27, 2017	Jan	NEWA
>A>	+	0.113MG/INH	N208798	002	Jan 27, 2017	Jan	NEWA
>A>	+!	0.232MG/INH	N208798	003	Jan 27, 2017	Jan	NEWA

FLUTICASONE PROPIONATE; SALMETEROL XINAFOATEPOWDER; INHALATION  
AIRDUO RESPICLICK

>A>	+ TEVA PHARM	0.055MG/INH; EQ 0.014MG BASE/INH	N208799	001	Jan 27, 2017	Jan	NEWA
>A>	+	0.113MG/INH; EQ 0.014MG BASE/INH	N208799	002	Jan 27, 2017	Jan	NEWA
>A>	+!	0.232MG/INH; EQ 0.014MG BASE/INH	N208799	003	Jan 27, 2017	Jan	NEWA

FOSINOPRIL SODIUMTABLET; ORAL  
MONOPRIL

>D>	@ BRISTOL MYERS SQUIBB	10MG	N019915	002	May 16, 1991	Jan	CRLD
>A>	+ @	10MG	N019915	002	May 16, 1991	Jan	CRLD
>D>	@	20MG	N019915	003	May 16, 1991	Jan	CRLD
>A>	+ @	20MG	N019915	003	May 16, 1991	Jan	CRLD
>D>	@	40MG	N019915	004	Mar 28, 1995	Jan	CRLD
>A>	+ @	40MG	N019915	004	Mar 28, 1995	Jan	CRLD

FOSPHENYTOIN SODIUMINJECTABLE; INJECTION  
FOSPHENYTOIN SODIUM

>D>	AP EUROHLTH INTL SARL	EQ 50MG PHENYTOIN NA/ML	A077481	001	Aug 06, 2007	Jan	CAHN
>D>	AP	EQ 50MG PHENYTOIN NA/ML	A077989	001	Aug 06, 2007	Jan	CAHN
>A>	AP WEST-WARD PHARMS INT	EQ 50MG PHENYTOIN NA/ML	A077481	001	Aug 06, 2007	Jan	CAHN
>A>	AP	EQ 50MG PHENYTOIN NA/ML	A077989	001	Aug 06, 2007	Jan	CAHN

FUROSEMIDETABLET; ORAL  
FUROSEMIDE

>D>	AB ROXANE	20MG	N018823	001	Nov 10, 1983	Jan	CAHN
>D>	AB	40MG	N018823	002	Nov 10, 1983	Jan	CAHN
>A>	AB WEST-WARD PHARMS INT	20MG	N018823	001	Nov 10, 1983	Jan	CAHN
>A>	AB	40MG	N018823	002	Nov 10, 1983	Jan	CAHN

GABAPENTINCAPSULE;ORAL  
GABAPENTIN

>D>	AB	AUROBINDO PHARM	100MG	A 078787	001	Jan 31, 2008	Jan CAHN
>D>	AB		300MG	A 078787	002	Jan 31, 2008	Jan CAHN
>D>	AB		400MG	A 078787	003	Jan 31, 2008	Jan CAHN
>A>	AB	AUROBINDO PHARMA LTD	100MG	A 078787	001	Jan 31, 2008	Jan CAHN
>A>	AB		300MG	A 078787	002	Jan 31, 2008	Jan CAHN
>A>	AB		400MG	A 078787	003	Jan 31, 2008	Jan CAHN

GEMFIBROZILTABLET;ORAL  
GEMFIBROZIL

>D>	AB	BLU CARIBE	600MG	A 078012	001	Mar 26, 2007	Jan CAHN
>A>	AB	CARIBE HOLDINGS	600MG	A 078012	001	Mar 26, 2007	Jan CAHN

GENTAMICIN SULFATECREAM;TOPICAL  
GENTAMICIN SULFATE

>D>	AT	PERRIGO NEW YORK	EQ 0.1% BASE	A 062307	001		Jan CHRS
>A>	AT	!	EQ 0.1% BASE	A 062307	001		Jan CHRS
>D>	AT	TARO	EQ 0.1% BASE	A 062427	001	May 26, 1983	Jan DISC
>A>		@	EQ 0.1% BASE	A 062427	001	May 26, 1983	Jan DISC

OINTMENT;TOPICAL  
GENTAMICIN SULFATE

>D>	AT	FOUGERA	EQ 0.1% BASE	A 062533	001	Oct 05, 1984	Jan CAHN
>A>	AT	FOUGERA PHARMS INC	EQ 0.1% BASE	A 062533	001	Oct 05, 1984	Jan CAHN

GLIPIZIDE; METFORMIN HYDROCHLORIDETABLET;ORAL  
METAGLIP

>D>		@ BRISTOL MYERS SQUIBB	2.5MG;250MG	N 021460	001	Oct 21, 2002	Jan CRLD
>A>		+ @	2.5MG;250MG	N 021460	001	Oct 21, 2002	Jan CRLD
>D>		@	2.5MG;500MG	N 021460	002	Oct 21, 2002	Jan CRLD
>A>		+ @	2.5MG;500MG	N 021460	002	Oct 21, 2002	Jan CRLD
>D>		@	5MG;500MG	N 021460	003	Oct 21, 2002	Jan CRLD
>A>		+ @	5MG;500MG	N 021460	003	Oct 21, 2002	Jan CRLD

GLYCOPYRROLATEPOWDER;INHALATION  
SEEBRI

>D>		+! NOVARTIS PHARMS CORP	15.6MCG/INH	N 207923	001	Oct 29, 2015	Jan CAHN
>A>		+! SUNOVION PHARMS INC	15.6MCG/INH	N 207923	001	Oct 29, 2015	Jan CAHN

GLYCOPYRROLATE ; INDACATEROL MALEATEPOWDER;INHALATION  
UTIBRON

>D>		+! NOVARTIS PHARMS CORP	15.6MCG/INH;27.5MCG/INH	N 207930	001	Oct 29, 2015	Jan CAHN
>A>		+! SUNOVION PHARMS INC	15.6MCG/INH;27.5MCG/INH	N 207930	001	Oct 29, 2015	Jan CAHN

GONADOTROPIN, CHORIONICINJECTABLE;INJECTION  
CHORIONIC GONADOTROPIN

>D>		@ FERRING	5,000 UNITS/VIAL	N 017016	006		Jan CMFD
>A>		+!	5,000 UNITS/VIAL	N 017016	006		Jan CMFD

GRANISETRON HYDROCHLORIDEINJECTABLE;INJECTION  
GRANISETRON HYDROCHLORIDE

>D>	AP	EUROHLTH INTL SARL	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A 077913	001	Jun 26, 2008	Jan CAHN
>D>	AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A 077186	001	Jun 30, 2008	Jan CAHN
>D>	AP		EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A 077187	001	Jun 30, 2008	Jan CAHN
>D>	AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A 077177	001	Dec 31, 2007	Jan CAHN
>A>	AP	MYLAN LABS LTD	EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A 203453	001	Jan 31, 2017	Jan NEWA
>A>	AP	WEST-WARD PHARMS INT	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A 077913	001	Jun 26, 2008	Jan CAHN
>A>	AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A 077186	001	Jun 30, 2008	Jan CAHN
>A>	AP		EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A 077187	001	Jun 30, 2008	Jan CAHN
>A>	AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A 077177	001	Dec 31, 2007	Jan CAHN

HEPARIN SODIUM

INJECTABLE; INJECTION  
HEPARIN SODIUM

>A> AP GLAND PHARMA LTD 5,000 UNITS/ML A205323 001 Feb 06, 2017 Jan NEWA

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL  
HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

>A> AA NOVEL LABS INC 1.5MG/5ML; 5MG/5ML A203535 001 Feb 13, 2017 Jan NEWA  
>A> AA PADDOCK LLC 1.5MG/5ML; 5MG/5ML A205731 001 Feb 15, 2017 Jan NEWA

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL  
PRINZIDE

>D> @ MERCK 12.5MG; 10MG N019778 003 Nov 18, 1993 Jan CRLD  
>A> + @ 12.5MG; 10MG N019778 003 Nov 18, 1993 Jan CRLD  
>D> @ 12.5MG; 20MG N019778 001 Feb 16, 1989 Jan CRLD  
>A> + @ 12.5MG; 20MG N019778 001 Feb 16, 1989 Jan CRLD

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL  
MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>A> AB HERITAGE PHARMS INC 12.5MG; 7.5MG A202150 001 Mar 07, 2014 Jan CMS1  
>A> AB 12.5MG; 15MG A202150 002 Mar 07, 2014 Jan CMS1  
>A> AB 25MG; 15MG A202150 003 Mar 07, 2014 Jan CMS1  
MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE  
>D> AB HERITAGE PHARMS INC 12.5MG; 7.5MG A202150 001 Mar 07, 2014 Jan CMS1  
>D> AB 12.5MG; 15MG A202150 002 Mar 07, 2014 Jan CMS1  
>D> AB 25MG; 15MG A202150 003 Mar 07, 2014 Jan CMS1

HYDROCODONE BITARTRATE

TABLET, EXTENDED RELEASE; ORAL

>A> VANTRELA ER  
>A> + TEVA BRANDED PHARM 15MG N207975 001 Jan 17, 2017 Jan NEWA  
>A> + 30MG N207975 002 Jan 17, 2017 Jan NEWA  
>A> + 45MG N207975 003 Jan 17, 2017 Jan NEWA  
>A> + 60MG N207975 004 Jan 17, 2017 Jan NEWA  
>A> + 90MG N207975 005 Jan 17, 2017 Jan NEWA

HYDROCORTISONE

CREAM; TOPICAL  
HYDROCORTISONE

>D> AT ! FOUGERA 1% A080693 003 Jan CAHN  
>D> AT ! 2.5% A089414 001 Dec 16, 1986 Jan CAHN  
>A> AT ! FOUGERA PHARMS INC 1% A080693 003 Jan CAHN  
>A> AT ! 2.5% A089414 001 Dec 16, 1986 Jan CAHN

OINTMENT; TOPICAL  
HYDROCORTISONE

>D> AT ! FOUGERA 2.5% A081203 001 May 28, 1993 Jan CAHN  
>A> AT ! FOUGERA PHARMS INC 2.5% A081203 001 May 28, 1993 Jan CAHN

HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION  
DILAUDID

>A> AP +! FRESENIUS KABI USA 1MG/ML N019034 003 Apr 30, 2009 Jan CAHN  
>A> AP +! 2MG/ML N019034 004 Apr 30, 2009 Jan CAHN  
>A> AP +! 4MG/ML N019034 005 Apr 30, 2009 Jan CAHN  
>D> AP +! PURDUE PHARM PRODS 1MG/ML N019034 003 Apr 30, 2009 Jan CAHN  
>D> AP +! 2MG/ML N019034 004 Apr 30, 2009 Jan CAHN  
>D> AP +! 4MG/ML N019034 005 Apr 30, 2009 Jan CAHN  
DILAUDID-HP  
>A> AP +! FRESENIUS KABI USA 10MG/ML N019034 001 Jan 11, 1984 Jan CAHN  
>A> @ 250MG/VIAL N019034 002 Aug 04, 1994 Jan CAHN  
>D> AP +! PURDUE PHARM PRODS 10MG/ML N019034 001 Jan 11, 1984 Jan CAHN  
>D> @ 250MG/VIAL N019034 002 Aug 04, 1994 Jan CAHN

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION  
VISTARIL

>D>	@	PFIZER	25MG/ML	N011111	001		Jan	CRLD
>A>	+	@	25MG/ML	N011111	001		Jan	CRLD
>D>	@		50MG/ML	N011111	002		Jan	CRLD
>A>	+	@	50MG/ML	N011111	002		Jan	CRLD

TABLET; ORAL

HYDROXYZINE HYDROCHLORIDE

>A>	@	AUROLIFE PHARMA LLC	10MG	A087871	002	Dec 20, 1982	Jan	CMS1
>A>	@		25MG	A087871	003	Dec 20, 1982	Jan	CMS1

IBUPROFEN

SUSPENSION; ORAL  
MOTRIN

>D>	@	MCNEIL CONSUMER	100MG/5ML	N019842	001	Sep 19, 1989	Jan	CRLD
>A>	+	@	100MG/5ML	N019842	001	Sep 19, 1989	Jan	CRLD

INDACATEROL MALEATE

POWDER; INHALATION  
ARCAPTA NEOHALER

>D>	+	NOVARTIS	EQ 75MCG BASE	N022383	001	Jul 01, 2011	Jan	CAHN
>A>	+	SUNOVION PHARMS INC	EQ 75MCG BASE	N022383	001	Jul 01, 2011	Jan	CAHN

IOPAMIDOL

INJECTABLE; INJECTION  
SCANLUX-300

>D>	AP	MYLAN INSTITUTIONAL	61%	A090394	001	Jun 18, 2010	Jan	CAHN
>A>	AP	MYLAN IRELAND LTD	61%	A090394	001	Jun 18, 2010	Jan	CAHN
SCANLUX-370								
>D>	AP	MYLAN INSTITUTIONAL	76%	A090394	002	Jun 18, 2010	Jan	CAHN
>A>	AP	MYLAN IRELAND LTD	76%	A090394	002	Jun 18, 2010	Jan	CAHN

IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION  
IRINOTECAN HYDROCHLORIDE

>D>	AP	EUROHLTH INTL SARL	40MG/2ML (20MG/ML)	A078753	001	Dec 24, 2008	Jan	CAHN
>D>	AP		100MG/5ML (20MG/ML)	A078753	002	Dec 24, 2008	Jan	CAHN
>A>	AP	WEST-WARD PHARMS INT	40MG/2ML (20MG/ML)	A078753	001	Dec 24, 2008	Jan	CAHN
>A>	AP		100MG/5ML (20MG/ML)	A078753	002	Dec 24, 2008	Jan	CAHN

KANAMYCIN SULFATE

INJECTABLE; INJECTION  
KANAMYCIN

>D>	@	EUROHLTH INTL SARL	EQ 75MG BASE/2ML	A062324	001		Jan	CAHN
>D>	@		EQ 500MG BASE/2ML	A062324	002		Jan	CAHN
>D>	@		EQ 1GM BASE/3ML	A062324	003		Jan	CAHN
>A>	@	WEST-WARD PHARMS INT	EQ 75MG BASE/2ML	A062324	001		Jan	CAHN
>A>	@		EQ 500MG BASE/2ML	A062324	002		Jan	CAHN
>A>	@		EQ 1GM BASE/3ML	A062324	003		Jan	CAHN

KETOCONAZOLE

AEROSOL, FOAM; TOPICAL  
EXTINA

>D>	AT	+	DELCOR ASSET CORP	2%	N021738	001	Jun 12, 2007	Jan	CAHN
>A>	AT	+	MYLAN PHARMS INC	2%	N021738	001	Jun 12, 2007	Jan	CAHN

LAMOTRIGINE

TABLET, EXTENDED RELEASE; ORAL  
LAMOTRIGINE

>A>	AB	HANDA PHARMS LLC	25MG	A202887	001	Jun 17, 2013	Jan	CAHN
>A>	AB		50MG	A202887	002	Jun 17, 2013	Jan	CAHN
>A>	AB		100MG	A202887	003	Jun 17, 2013	Jan	CAHN
>A>	AB		200MG	A202887	004	Jun 17, 2013	Jan	CAHN
>D>	AB	WILSHIRE PHARMS INC	25MG	A202887	001	Jun 17, 2013	Jan	CAHN
>D>	AB		50MG	A202887	002	Jun 17, 2013	Jan	CAHN
>D>	AB		100MG	A202887	003	Jun 17, 2013	Jan	CAHN
>D>	AB		200MG	A202887	004	Jun 17, 2013	Jan	CAHN



LEVALBUTEROL HYDROCHLORIDE

SOLUTION; INHALATION  
LEVALBUTEROL HYDROCHLORIDE

>A> AN AUROBINDO PHARMA LTD EQ 0.25% BASE A207628 001 Jan 31, 2017 Jan NEWA

LEVETIRACETAM

SOLUTION; ORAL  
LEVETIRACETAM

>D> AA AUROBINDO PHARM 100MG/ML A079063 001 Jan 15, 2009 Jan CAHN  
>A> AA AUROBINDO PHARMA LTD 100MG/ML A079063 001 Jan 15, 2009 Jan CAHN

LEVOFLOXACIN

INJECTABLE; INJECTION  
LEVAQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER

>D> @ JANSSEN PHARMS EQ 250MG/50ML (EQ 5MG/ML) N020635 002 Dec 20, 1996 Jan CRLD  
>A> + @ EQ 250MG/50ML (EQ 5MG/ML) N020635 002 Dec 20, 1996 Jan CRLD  
>D> @ EQ 500MG/100ML (EQ 5MG/ML) N020635 003 Dec 20, 1996 Jan CRLD  
>A> + @ EQ 500MG/100ML (EQ 5MG/ML) N020635 003 Dec 20, 1996 Jan CRLD  
>D> @ EQ 750MG/150ML (EQ 5MG/ML) N020635 005 Dec 20, 1996 Jan CRLD  
>A> + @ EQ 750MG/150ML (EQ 5MG/ML) N020635 005 Dec 20, 1996 Jan CRLD

LEVOLEUCOVORIN CALCIUM

POWDER; IV (INFUSION)  
LEVOLEUCOVORIN CALCIUM

>A> AP ACTAVIS LLC EQ 50MG BASE/VIAL A206516 001 Feb 13, 2017 Jan NEWA  
>A> AP AMNEAL PHARMS CO EQ 50MG BASE/VIAL A207547 001 Feb 13, 2017 Jan NEWA

LIDOCAINE

OINTMENT; TOPICAL  
LIDOCAINE

>D> AT ! FOUGERA 5% A080198 001 Jan CAHN  
>A> AT ! FOUGERA PHARMS INC 5% A080198 001 Jan CAHN  
XYLOCAINE  
>D> @ ASTRAZENECA 5% N008048 001 Jan CRLD  
>A> + @ 5% N008048 001 Jan CRLD

LINACLOTIDE

CAPSULE; ORAL  
LINZESS

>A> + FOREST LABS LLC 72MCG N202811 003 Jan 25, 2017 Jan NEWA

LISDEXAMFETAMINE DIMESYLATE

>A> TABLET, CHEWABLE; ORAL  
>A> VYVANSE  
>A> + SHIRE DEV LLC 10MG N208510 001 Jan 28, 2017 Jan NEWA  
>A> + 20MG N208510 002 Jan 28, 2017 Jan NEWA  
>A> + 30MG N208510 003 Jan 28, 2017 Jan NEWA  
>A> + 40MG N208510 004 Jan 28, 2017 Jan NEWA  
>A> + 50MG N208510 005 Jan 28, 2017 Jan NEWA  
>A> + 60MG N208510 006 Jan 28, 2017 Jan NEWA

LITHIUM CARBONATE

CAPSULE; ORAL  
LITHIUM CARBONATE

>D> AB DELCOR ASSET CORP 150MG A076243 002 Feb 24, 2003 Jan CAHN  
>D> AB 300MG A076243 001 Jun 27, 2002 Jan CAHN  
>D> AB 600MG A078763 001 Apr 15, 2008 Jan CAHN  
>A> AB MYLAN PHARMS INC 150MG A076243 002 Feb 24, 2003 Jan CAHN  
>A> AB 300MG A076243 001 Jun 27, 2002 Jan CAHN  
>A> AB 600MG A078763 001 Apr 15, 2008 Jan CAHN  
>D> AB ROXANE 150MG N017812 002 Jan 28, 1987 Jan CAHN  
>D> AB 300MG N017812 001 Jan CAHN  
>D> AB + 600MG N017812 003 Jan 28, 1987 Jan CAHN  
>A> AB + WEST-WARD PHARMS INT 150MG N017812 002 Jan 28, 1987 Jan CAHN  
>A> AB + 300MG N017812 001 Jan CAHN  
>A> AB +! 600MG N017812 003 Jan 28, 1987 Jan CAHN

TABLET; ORAL  
LITHIUM CARBONATE

>D> AB + ROXANE 300MG N018558 001 Jan 29, 1982 Jan CAHN  
>A> AB +! WEST-WARD PHARMS INT 300MG N018558 001 Jan 29, 1982 Jan CAHN

LITHIUM CITRATE

SYRUP;ORAL  
LITHIUM CITRATE

>D>	AA	+	ROXANE	EQ 300MG CARBONATE/5ML	N018421	001		Jan	CAHN
>A>	AA	+	WEST-WARD PHARMS INT	EQ 300MG CARBONATE/5ML	N018421	001		Jan	CAHN

MEDROXYPROGESTERONE ACETATE

INJECTABLE;INJECTION  
MEDROXYPROGESTERONE ACETATE

>D>	AB		TEVA PHARMS USA	150MG/ML	A076553	001	Jul 28, 2004	Jan	CAHN
>A>	AB			150MG/ML	A076553	001	Jul 28, 2004	Jan	CAHN

MEPERIDINE HYDROCHLORIDE

INJECTABLE;INJECTION  
MEPERIDINE HYDROCHLORIDE

>D>	AP		EUROHLTH INTL SARL	25MG/ML	A080445	001		Jan	CAHN
>D>	AP			25MG/ML	A080455	007		Jan	CAHN
>D>	AP			50MG/ML	A080445	002		Jan	CAHN
>D>	AP			50MG/ML	A080455	008		Jan	CAHN
>D>	AP			75MG/ML	A080445	003		Jan	CAHN
>D>	AP			75MG/ML	A080455	009		Jan	CAHN
>D>	AP			100MG/ML	A080445	004		Jan	CAHN
>D>	AP			100MG/ML	A080455	010		Jan	CAHN
>A>	AP		WEST-WARD PHARMS INT	25MG/ML	A080445	001		Jan	CAHN
>A>	AP			25MG/ML	A080455	007		Jan	CAHN
>A>	AP			50MG/ML	A080445	002		Jan	CAHN
>A>	AP			50MG/ML	A080455	008		Jan	CAHN
>A>	AP			75MG/ML	A080445	003		Jan	CAHN
>A>	AP			75MG/ML	A080455	009		Jan	CAHN
>A>	AP			100MG/ML	A080445	004		Jan	CAHN
>A>	AP			100MG/ML	A080455	010		Jan	CAHN

METHADONE HYDROCHLORIDE

SYRUP;ORAL  
DOLOPHINE HYDROCHLORIDE

>D>		@	ROXANE	10MG/30ML	N006134	004		Jan	CAHN
>A>		@	WEST-WARD PHARMS INT	10MG/30ML	N006134	004		Jan	CAHN

TABLET;ORAL  
DOLOPHINE HYDROCHLORIDE

>D>	AA	+	ROXANE	5MG	N006134	002		Jan	CAHN
>D>	AA	+		10MG	N006134	010		Jan	CAHN
>A>	AA	+	WEST-WARD PHARMS INT	5MG	N006134	002		Jan	CAHN
>A>	AA	+		10MG	N006134	010		Jan	CAHN

TABLET, FOR SUSPENSION;ORAL  
METHADONE HYDROCHLORIDE

>D>	AA	+	ROXANE	40MG	N017058	001		Jan	CAHN
>A>	AA	+	WEST-WARD PHARMS INT	40MG	N017058	001		Jan	CAHN

METHOCARBAMOL

SOLUTION;IM-IV  
METHOCARBAMOL

>A>	AP		RENAISSANCE PHARMA	1GM/10ML (100MG/ML)	A208116	001	Jan 19, 2017	Jan	NEWA
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TABLET;ORAL  
METHOCARBAMOL

>A>	AA		ATLAS PHARMS LLC	500MG	A203550	001	Feb 08, 2017	Jan	NEWA
>A>	AA			750MG	A203550	002	Feb 08, 2017	Jan	NEWA

METHOTREXATE SODIUM

TABLET;ORAL  
METHOTREXATE SODIUM

>A>	AB		ZYDUS PHARMS USA INC	EQ 2.5MG BASE	A207812	001	Jan 13, 2017	Jan	NEWA
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METHYLDOPATE HYDROCHLORIDE

INJECTABLE;INJECTION  
METHYLDOPATE HYDROCHLORIDE

>D>	AP	!	LUITPOLD	50MG/ML	A071279	001	Oct 02, 1987	Jan	CTEC
>A>		!		50MG/ML	A071279	001	Oct 02, 1987	Jan	CTEC

METHYLPHENIDATE HYDROCHLORIDE

TABLET, CHEWABLE;ORAL

METHYLPHENIDATE HYDROCHLORIDE

>A>	AB	NOSTRUM LABS INC	2.5MG	A204954	001	Jan 26, 2017	Jan NEWA
>A>	AB		5MG	A204954	002	Jan 26, 2017	Jan NEWA
>A>	AB		10MG	A204954	003	Jan 26, 2017	Jan NEWA

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE;INJECTION

A-METHAPRED

>D>	AP	HOSPIRA INC	EQ 40MG BASE/VIAL	A040793	001	Nov 25, 2008	Jan DISC
>A>		@	EQ 40MG BASE/VIAL	A040793	001	Nov 25, 2008	Jan DISC
>D>	AP		EQ 125MG BASE/VIAL	A040827	001	Nov 25, 2008	Jan DISC
>A>		@	EQ 125MG BASE/VIAL	A040827	001	Nov 25, 2008	Jan DISC

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE;ORAL

TOPROL-XL

>A>	AB	+ ARALEZ PHARMS	EQ 25MG TARTRATE	N019962	004	Feb 05, 2001	Jan CAHN
>A>	AB	+	EQ 50MG TARTRATE	N019962	001	Jan 10, 1992	Jan CAHN
>A>	AB	+	EQ 100MG TARTRATE	N019962	002	Jan 10, 1992	Jan CAHN
>A>	AB	+	EQ 200MG TARTRATE	N019962	003	Jan 10, 1992	Jan CAHN
>D>	AB	+ ASTRAZENECA PHARMS	EQ 25MG TARTRATE	N019962	004	Feb 05, 2001	Jan CAHN
>D>	AB	+	EQ 50MG TARTRATE	N019962	001	Jan 10, 1992	Jan CAHN
>D>	AB	+	EQ 100MG TARTRATE	N019962	002	Jan 10, 1992	Jan CAHN
>D>	AB	+	EQ 200MG TARTRATE	N019962	003	Jan 10, 1992	Jan CAHN

METOPROLOL TARTRATE

INJECTABLE;INJECTION

METOPROLOL TARTRATE

>D>	AP	EUROHLTH INTL SARL	1MG/ML	A076495	001	Jul 07, 2003	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	1MG/ML	A076495	001	Jul 07, 2003	Jan CAHN

MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE

OINTMENT;TOPICAL

VUSION

>D>		+ DELCOR ASSET CORP	0.25%;81.35%;15%	N021026	001	Feb 16, 2006	Jan CAHN
>A>		+! MYLAN PHARMS INC	0.25%;81.35%;15%	N021026	001	Feb 16, 2006	Jan CAHN

MIDAZOLAM HYDROCHLORIDE

INJECTABLE;INJECTION

MIDAZOLAM HYDROCHLORIDE

>D>	AP	EUROHLTH INTL SARL	EQ 1MG BASE/ML	A075243	001	Jun 20, 2000	Jan CAHN
>D>	AP		EQ 1MG BASE/ML	A075247	002	Jun 23, 2000	Jan CAHN
>D>	AP		EQ 1MG BASE/ML	A075421	002	Jun 20, 2000	Jan CAHN
>D>	AP		EQ 5MG BASE/ML	A075243	002	Jun 20, 2000	Jan CAHN
>D>	AP		EQ 5MG BASE/ML	A075247	001	Jun 23, 2000	Jan CAHN
>D>	AP		EQ 5MG BASE/ML	A075421	001	Jun 20, 2000	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	EQ 1MG BASE/ML	A075243	001	Jun 20, 2000	Jan CAHN
>A>	AP		EQ 1MG BASE/ML	A075247	002	Jun 23, 2000	Jan CAHN
>A>	AP		EQ 1MG BASE/ML	A075421	002	Jun 20, 2000	Jan CAHN
>A>	AP		EQ 5MG BASE/ML	A075243	002	Jun 20, 2000	Jan CAHN
>A>	AP		EQ 5MG BASE/ML	A075247	001	Jun 23, 2000	Jan CAHN
>A>	AP		EQ 5MG BASE/ML	A075421	001	Jun 20, 2000	Jan CAHN

MILRINONE LACTATE

INJECTABLE;INJECTION

MILRINONE LACTATE

>D>	AP	EUROHLTH INTL SARL	EQ 1MG BASE/ML	A075530	001	May 28, 2002	Jan CAHN
>D>	AP		EQ 1MG BASE/ML	A075660	001	May 28, 2002	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	EQ 1MG BASE/ML	A075530	001	May 28, 2002	Jan CAHN
>A>	AP		EQ 1MG BASE/ML	A075660	001	May 28, 2002	Jan CAHN
		MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER					
>D>	AP	EUROHLTH INTL SARL	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	A078113	001	May 21, 2008	Jan CAHN
>D>	AP		EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	A078113	002	May 21, 2008	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	A078113	001	May 21, 2008	Jan CAHN
>A>	AP		EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	A078113	002	May 21, 2008	Jan CAHN

INJECTABLE; INJECTION

PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER

>D>	@	SANOFI AVENTIS US	EQ 10MG BASE/100ML	N020343	001	Aug 09, 1994	Jan	CRLD
>A>	+	@	EQ 10MG BASE/100ML	N020343	001	Aug 09, 1994	Jan	CRLD
>D>	@		EQ 15MG BASE/100ML	N020343	002	Aug 09, 1994	Jan	CRLD
>A>	+	@	EQ 15MG BASE/100ML	N020343	002	Aug 09, 1994	Jan	CRLD
>D>	@		EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	N020343	003	Aug 09, 1994	Jan	CRLD
>A>	+	@	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	N020343	003	Aug 09, 1994	Jan	CRLD
>D>	@		EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	N020343	004	Aug 09, 1994	Jan	CRLD
>A>	+	@	EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	N020343	004	Aug 09, 1994	Jan	CRLD

MIRTAZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL

MIRTAZAPINE

>D>	AB	AUROBINDO PHARMA LTD	15MG	A077376	002	Dec 08, 2005	Jan	CAHN
>A>	AB		15MG	A077376	002	Dec 08, 2005	Jan	CAHN
>D>	AB		30MG	A077376	003	Dec 08, 2005	Jan	CAHN
>A>	AB		30MG	A077376	003	Dec 08, 2005	Jan	CAHN
>D>	AB		45MG	A077376	004	Feb 28, 2006	Jan	CAHN
>A>	AB		45MG	A077376	004	Feb 28, 2006	Jan	CAHN

MITOMYCIN

INJECTABLE; INJECTION

MITOMYCIN

>D>	AP	EUROHLTH INTL SARL	5MG/VIAL	A064117	001	Apr 19, 1995	Jan	CAHN
>D>	AP		5MG/VIAL	A064180	001	Dec 23, 1999	Jan	CAHN
>D>	AP		20MG/VIAL	A064117	002	Apr 19, 1995	Jan	CAHN
>D>	AP		20MG/VIAL	A064180	002	Dec 23, 1999	Jan	CAHN
>A>	AP	WEST-WARD PHARMS INT	5MG/VIAL	A064117	001	Apr 19, 1995	Jan	CAHN
>A>	AP		5MG/VIAL	A064180	001	Dec 23, 1999	Jan	CAHN
>A>	AP		20MG/VIAL	A064117	002	Apr 19, 1995	Jan	CAHN
>A>	AP		20MG/VIAL	A064180	002	Dec 23, 1999	Jan	CAHN

MUTAMYCIN

>D>	@	BRISTOL	5MG/VIAL	N050450	001		Jan	CRLD
>A>	+	@	5MG/VIAL	N050450	001		Jan	CRLD
>D>	@		20MG/VIAL	N050450	002		Jan	CRLD
>A>	+	@	20MG/VIAL	N050450	002		Jan	CRLD

MORPHINE SULFATE

SOLUTION; ORAL

MORPHINE SULFATE

>D>	AA	+	ROXANE	10MG/5ML	N022195	001	Mar 17, 2008	Jan	CAHN
>D>	AA	+		20MG/5ML	N022195	002	Mar 17, 2008	Jan	CAHN
>D>	AA	+	!	100MG/5ML	N022195	003	Jan 25, 2010	Jan	CAHN
>A>	AA	+	WEST-WARD PHARMS INT	10MG/5ML	N022195	001	Mar 17, 2008	Jan	CAHN
>A>	AA	+		20MG/5ML	N022195	002	Mar 17, 2008	Jan	CAHN
>A>	AA	+	!	100MG/5ML	N022195	003	Jan 25, 2010	Jan	CAHN

TABLET; ORAL

MORPHINE SULFATE

>D>	+	ROXANE	15MG	N022207	001	Mar 17, 2008	Jan	CAHN
>D>	+	!	30MG	N022207	002	Mar 17, 2008	Jan	CAHN
>A>	+	WEST-WARD PHARMS INT	15MG	N022207	001	Mar 17, 2008	Jan	CAHN
>A>	+	!	30MG	N022207	002	Mar 17, 2008	Jan	CAHN

TABLET, EXTENDED RELEASE; ORAL

ARYMO ER

>A>	+	EGALET	15MG	N208603	001	Jan 09, 2017	Jan	NEWA
>A>	+		30MG	N208603	002	Jan 09, 2017	Jan	NEWA
>A>	+		60MG	N208603	003	Jan 09, 2017	Jan	NEWA

MORPHABOND

>D>	+	DAIICHI SANKYO INC	15MG	N206544	001	Oct 02, 2015	Jan	CTNA
>D>	+		30MG	N206544	002	Oct 02, 2015	Jan	CTNA
>D>	+		60MG	N206544	003	Oct 02, 2015	Jan	CTNA
>D>	+	!	100MG	N206544	004	Oct 02, 2015	Jan	CTNA

MORPHABOND ER

>A>	+	DAIICHI SANKYO INC	15MG	N206544	001	Oct 02, 2015	Jan	CTNA
>A>	+		30MG	N206544	002	Oct 02, 2015	Jan	CTNA
>A>	+		60MG	N206544	003	Oct 02, 2015	Jan	CTNA
>A>	+	!	100MG	N206544	004	Oct 02, 2015	Jan	CTNA

MOXIFLOXACIN HYDROCHLORIDE

TABLET; ORAL

MOXIFLOXACIN HYDROCHLORIDE

>A>	AB	NOVEL LABS INC	EQ 400MG BASE	A207285	001	Feb 13, 2017	Jan	NEWA
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NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE

>D>		@ EUROHLTH INTL SARL	0.4MG/ML	A070298	001	Sep 24, 1986	Jan	CAHN
>D>		@	0.4MG/ML	A070496	001	Sep 24, 1986	Jan	CAHN
>A>		@ WEST-WARD PHARMS INT	0.4MG/ML	A070298	001	Sep 24, 1986	Jan	CAHN
>A>		@	0.4MG/ML	A070496	001	Sep 24, 1986	Jan	CAHN

SPRAY, METERED; NASAL

NARCAN

>A>		+ ADAPT	2MG/SPRAY	N208411	002	Jan 24, 2017	Jan	NEWA
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NAPROXEN

TABLET; ORAL

NAPROXEN

>A>	AB	AUROBINDO PHARMA LTD	250MG	A200429	001	Nov 08, 2011	Jan	CAHN
>A>	AB		375MG	A200429	002	Nov 08, 2011	Jan	CAHN
>A>	AB		500MG	A200429	003	Nov 08, 2011	Jan	CAHN
>D>	AB	AUROBINDO PHARMA USA	250MG	A200429	001	Nov 08, 2011	Jan	CAHN
>D>	AB		375MG	A200429	002	Nov 08, 2011	Jan	CAHN
>D>	AB		500MG	A200429	003	Nov 08, 2011	Jan	CAHN

NATAMYCIN

SUSPENSION; OPHTHALMIC

NATACYN

>D>		+ ALCON	5%	N050514	001		Jan	CAHN
>A>		+! NOVARTIS PHARMS CORP	5%	N050514	001		Jan	CAHN

NELFINAVIR MESYLATE

POWDER; ORAL

VIRACEPT

>D>		@ AGOURON	EQ 50MG BASE/SCOOPFUL	N020778	001	Mar 14, 1997	Jan	CAHN
>A>		@ AGOURON PHARMS	EQ 50MG BASE/SCOOPFUL	N020778	001	Mar 14, 1997	Jan	CAHN

TABLET; ORAL

VIRACEPT

>D>		+! AGOURON	EQ 250MG BASE	N020779	001	Mar 14, 1997	Jan	CAHN
>D>		+!	EQ 625MG BASE	N021503	001	Apr 30, 2003	Jan	CAHN
>A>		+! AGOURON PHARMS	EQ 250MG BASE	N020779	001	Mar 14, 1997	Jan	CAHN
>A>		+!	EQ 625MG BASE	N021503	001	Apr 30, 2003	Jan	CAHN

NICARDIPINE HYDROCHLORIDE

INJECTABLE; INJECTION

NICARDIPINE HYDROCHLORIDE

>D>	AP	EUROHLTH INTL SARL	25MG/10ML (2.5MG/ML)	A078714	001	Dec 28, 2009	Jan	CAHN
>A>	AP	WEST-WARD PHARMS INT	25MG/10ML (2.5MG/ML)	A078714	001	Dec 28, 2009	Jan	CAHN

NITROGLYCERIN

OINTMENT; TRANSDERMAL

NITROGLYCERIN

>D>		! FOUGERA	2%	A087355	001	Jul 08, 1988	Jan	CAHN
>A>		! FOUGERA PHARMS INC	2%	A087355	001	Jul 08, 1988	Jan	CAHN

NOREPINEPHRINE BITARTRATE

INJECTABLE; INJECTION

NOREPINEPHRINE BITARTRATE

>D>	AP	EUROHLTH INTL SARL	EQ 1MG BASE/ML	A040462	001	Oct 31, 2003	Jan	CAHN
>A>	AP	WEST-WARD PHARMS INT	EQ 1MG BASE/ML	A040462	001	Oct 31, 2003	Jan	CAHN

NYSTATIN

SUSPENSION; ORAL

NYSTATIN

>D>	AA	FOUGERA	100,000 UNITS/ML	A062517	001	Jun 07, 1984	Jan	CAHN
>A>	AA	FOUGERA PHARMS INC	100,000 UNITS/ML	A062517	001	Jun 07, 1984	Jan	CAHN

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

MYCOLOG-II

>D>	@ DELCOR ASSET CORP	100,000 UNITS/GM;0.1%	A062606	001	May 15, 1985	Jan CAHN
>A>	@ MYLAN PHARMS INC	100,000 UNITS/GM;0.1%	A062606	001	May 15, 1985	Jan CAHN

NYSTATIN AND TRIAMCINOLONE ACETONIDE

>D>	AT	FOUGERA	100,000 UNITS/GM;0.1%	A062599	001	Oct 08, 1985	Jan CAHN
>A>	AT	FOUGERA PHARMS INC	100,000 UNITS/GM;0.1%	A062599	001	Oct 08, 1985	Jan CAHN

OINTMENT; TOPICAL

MYCOLOG-II

>D>	@ DELCOR ASSET CORP	100,000 UNITS/GM;0.1%	A060572	001	Jun 28, 1985	Jan CAHN
>A>	@ MYLAN PHARMS INC	100,000 UNITS/GM;0.1%	A060572	001	Jun 28, 1985	Jan CAHN

NYSTATIN AND TRIAMCINOLONE ACETONIDE

>A>	AT	DR REDDYS LABS LTD	100,000 UNITS/GM;0.1%	A207741	001	Jan 31, 2017	Jan NEWA
>D>	AT	FOUGERA	100,000 UNITS/GM;0.1%	A062602	001	Oct 09, 1985	Jan CAHN
>A>	AT	FOUGERA PHARMS INC	100,000 UNITS/GM;0.1%	A062602	001	Oct 09, 1985	Jan CAHN

OLOPATADINE HYDROCHLORIDE

SPRAY, METERED; NASAL

OLOPATADINE HYDROCHLORIDE

>A>	AB	PERRIGO ISRAEL	0.665MG/SPRAY	A202853	001	Jan 31, 2017	Jan NEWA
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OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

OMEPRAZOLE

>A>	AB	AUROBINDO PHARMA LTD	10MG	A203270	001	Aug 19, 2015	Jan CAHN
>A>	AB		20MG	A203270	002	Aug 19, 2015	Jan CAHN
>A>	AB		40MG	A203270	003	Aug 19, 2015	Jan CAHN
>D>	AB	AUROBINDO PHARMA USA	10MG	A203270	001	Aug 19, 2015	Jan CAHN
>D>	AB		20MG	A203270	002	Aug 19, 2015	Jan CAHN
>D>	AB		40MG	A203270	003	Aug 19, 2015	Jan CAHN

OMEPRAZOLE; SODIUM BICARBONATE

FOR SUSPENSION; ORAL

OMEPRAZOLE AND SODIUM BICARBONATE

>D>	AA	AJANTA PHARMA LTD	20MG/PACKET;1.68GM/PACKET	A205545	001	Jul 27, 2016	Jan CTEC
>A>	AB		20MG/PACKET;1.68GM/PACKET	A205545	001	Jul 27, 2016	Jan CTEC
>D>	AA		40MG/PACKET;1.68GM/PACKET	A205545	002	Jul 27, 2016	Jan CTEC
>A>	AB		40MG/PACKET;1.68GM/PACKET	A205545	002	Jul 27, 2016	Jan CTEC
>D>		@ PAR PHARM	20MG/PACKET;1.68GM/PACKET	A079182	001	Apr 19, 2013	Jan CMFD
>A>	AB		20MG/PACKET;1.68GM/PACKET	A079182	001	Apr 19, 2013	Jan CMFD
>D>		@	40MG/PACKET;1.68GM/PACKET	A079182	002	Apr 19, 2013	Jan CMFD
>A>	AB		40MG/PACKET;1.68GM/PACKET	A079182	002	Apr 19, 2013	Jan CMFD

ZEGERID

>D>	AA	SANTARUS INC	20MG/PACKET;1.68GM/PACKET	N021636	001	Jun 15, 2004	Jan CTEC
>A>	AB	+	20MG/PACKET;1.68GM/PACKET	N021636	001	Jun 15, 2004	Jan CTEC
>D>	AA	+	40MG/PACKET;1.68GM/PACKET	N021636	002	Dec 21, 2004	Jan CTEC
>A>	AB	+	40MG/PACKET;1.68GM/PACKET	N021636	002	Dec 21, 2004	Jan CTEC

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

>D>	AP	EUROHLTH INTL SARL	EQ 2MG BASE/ML	A076967	001	Dec 26, 2006	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	EQ 2MG BASE/ML	A076967	001	Dec 26, 2006	Jan CAHN

ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE

>D>	AP	EUROHLTH INTL SARL	EQ 2MG BASE/ML	A077011	001	Dec 26, 2006	Jan CAHN
>D>	AP		EQ 2MG BASE/ML	A077541	001	Dec 26, 2006	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	EQ 2MG BASE/ML	A077011	001	Dec 26, 2006	Jan CAHN
>A>	AP		EQ 2MG BASE/ML	A077541	001	Dec 26, 2006	Jan CAHN

OXALIPLATIN

INJECTABLE; IV (INFUSION)

ELOXATIN

>D>	@	SANOFI AVENTIS US	200MG/40ML (5MG/ML)	N021759	003	Nov 17, 2006	Jan CRLD
>A>	+	@	200MG/40ML (5MG/ML)	N021759	003	Nov 17, 2006	Jan CRLD

OXALIPLATIN

>A>	AP	CIPLA LTD	50MG/10ML (5MG/ML)	A208523	001	Feb 10, 2017	Jan NEWA
>A>	AP		100MG/20ML (5MG/ML)	A208523	002	Feb 10, 2017	Jan NEWA
>A>	AP	FRESENIUS KABI USA	50MG/10ML (5MG/ML)	A090030	001	Jan 31, 2017	Jan NEWA
>A>	AP		100MG/20ML (5MG/ML)	A090030	002	Jan 31, 2017	Jan NEWA
>A>	AP		200MG/40ML (5MG/ML)	A090030	003	Jan 31, 2017	Jan NEWA

INJECTABLE; IV (INFUSION)

OXALIPLATIN

>A>	AP	GLAND PHARMA LTD	50MG/10ML (5MG/ML)	A207325	001	Feb 10, 2017	Jan NEWA
>A>	AP		100MG/20ML (5MG/ML)	A207325	002	Feb 10, 2017	Jan NEWA
>D>	!	QILU PHARM CO LTD	200MG/40ML (5MG/ML)	A204368	003	Jun 07, 2016	Jan CTEC
>A>	AP	!	200MG/40ML (5MG/ML)	A204368	003	Jun 07, 2016	Jan CTEC

OXAZEPAM

TABLET; ORAL

OXAZEPAM

>D>	@	FRONTIDA BIOPHARM	15MG	A070683	001	Jan 16, 1987	Jan CAHN
>A>	@	SUN PHARM INDS	15MG	A070683	001	Jan 16, 1987	Jan CAHN

OXYBUTYNIN CHLORIDE

SYRUP; ORAL

DITROPAN

>D>	@	ORTHO MCNEIL JANSSEN	5MG/5ML	N018211	001		Jan CRLD
>A>	+	@	5MG/5ML	N018211	001		Jan CRLD

OXYMETAZOLINE HYDROCHLORIDE

CREAM; TOPICAL

RHOFADE

>A>	+	ALLERGAN INC	1%	N208552	001	Jan 18, 2017	Jan NEWA
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PAROXETINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

PAROXETINE HYDROCHLORIDE

>A>	AB	LUPIN LTD	EQ 12.5MG BASE	A204134	001	Jan 20, 2017	Jan NEWA
>A>	AB		EQ 25MG BASE	A204134	002	Jan 20, 2017	Jan NEWA
>A>	AB		EQ 37.5MG BASE	A204134	003	Jan 20, 2017	Jan NEWA

PENCICLOVIR

CREAM; TOPICAL

DENA VIR

>D>	+	DENCO ASSET	1%	N020629	001	Sep 24, 1996	Jan CAHN
>A>	+	MYLAN PHARMS INC	1%	N020629	001	Sep 24, 1996	Jan CAHN

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL

TRENTAL

>D>	@	US PHARM HOLDINGS	400MG	N018631	001	Aug 30, 1984	Jan CRLD
>A>	+	@	400MG	N018631	001	Aug 30, 1984	Jan CRLD

PERMETHRIN

CREAM; TOPICAL

ELIMITE

>A>	AB	+	MYLAN PHARMS INC	5%	N019855	001	Aug 25, 1989	Jan CAHN
>D>	AB	+	RENAISSANCE PHARMA	5%	N019855	001	Aug 25, 1989	Jan CAHN

PERPHENAZINE

TABLET; ORAL

PERPHENAZINE

>A>	@	ANI PHARMS INC	4MG	A089708	001	Sep 10, 1987	Jan CAHN
>D>	@	TEVA PHARMS USA	4MG	A089708	001	Sep 10, 1987	Jan CAHN

PHENOXYBENZAMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENOXYBENZAMINE HYDROCHLORIDE

>A>	AB	PAR PHARM INC	10MG	A204522	001	Jan 24, 2017	Jan NEWA
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PHENYLEPHRINE HYDROCHLORIDE

SOLUTION; IV (INFUSION)

VAZCULEP

>A>	+	AVADEL LEGACY	10MG/ML (10MG/ML)	N204300	001	Jun 27, 2014	Jan CAHN
>A>	+		50MG/5ML (10MG/ML)	N204300	002	Jun 27, 2014	Jan CAHN
>A>	+	!	100MG/10ML (10MG/ML)	N204300	003	Jun 27, 2014	Jan CAHN
>D>	+	ECLAT PHARMS LLC	10MG/ML (10MG/ML)	N204300	001	Jun 27, 2014	Jan CAHN
>D>	+		50MG/5ML (10MG/ML)	N204300	002	Jun 27, 2014	Jan CAHN
>D>	+	!	100MG/10ML (10MG/ML)	N204300	003	Jun 27, 2014	Jan CAHN

PIPERACILLIN SODIUM; TAZOBACTAM SODIUMINJECTABLE; INJECTION  
PIPERACILLIN AND TAZOBACTAM

>A>	AP	APOLLO PHARMS INC	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	A207847	001	Jan 13, 2017	Jan NEWA
>A>	AP		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	A207847	002	Jan 13, 2017	Jan NEWA
>A>	AP		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A207848	002	Jan 13, 2017	Jan NEWA
>A>	AP		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A207847	003	Jan 13, 2017	Jan NEWA

PIRFENIDONE

>A>		TABLET; ORAL					
>A>		ESBRIET					
>A>	+	GENENTECH INC	267MG	N208780	001	Jan 11, 2017	Jan NEWA
>A>	+ @		534MG	N208780	002	Jan 11, 2017	Jan DISC
>A>	+!		801MG	N208780	003	Jan 11, 2017	Jan NEWA

PITAVASTATIN CALCIUMTABLET; ORAL  
PITAVASTATIN CALCIUM

>A>	AB	ORIENT PHARMA CO LTD	EQ 1MG BASE	A205932	001	Feb 03, 2017	Jan NEWA
>A>	AB		EQ 2MG BASE	A205932	002	Feb 03, 2017	Jan NEWA
>A>	AB		EQ 4MG BASE	A205932	003	Feb 03, 2017	Jan NEWA
>A>	AB	SAWAI USA	EQ 1MG BASE	A205955	001	Feb 03, 2017	Jan NEWA
>A>	AB		EQ 2MG BASE	A205955	002	Feb 03, 2017	Jan NEWA
>A>	AB		EQ 4MG BASE	A205955	003	Feb 03, 2017	Jan NEWA

PLECANATIDE

>A>		TABLET; ORAL					
>A>		TRULANCE					
>A>	+	SYNERGY PHARMS	3MG	N208745	001	Jan 19, 2017	Jan NEWA

PRAMIPEXOLE DIHYDROCHLORIDETABLET; ORAL  
PRAMIPEXOLE DIHYDROCHLORIDE

>D>	AB	ACTAVIS GRP PTC	0.125MG	A091254	001	Nov 30, 2010	Jan DISC
>A>		@	0.125MG	A091254	001	Nov 30, 2010	Jan DISC
>D>	AB		0.25MG	A091254	002	Nov 30, 2010	Jan DISC
>A>		@	0.25MG	A091254	002	Nov 30, 2010	Jan DISC
>D>	AB		0.5MG	A091254	003	Nov 30, 2010	Jan DISC
>A>		@	0.5MG	A091254	003	Nov 30, 2010	Jan DISC
>D>	AB		0.75MG	A091254	004	Nov 30, 2010	Jan DISC
>A>		@	0.75MG	A091254	004	Nov 30, 2010	Jan DISC
>D>	AB		1MG	A091254	005	Nov 30, 2010	Jan DISC
>A>		@	1MG	A091254	005	Nov 30, 2010	Jan DISC
>D>	AB		1.5MG	A091254	006	Nov 30, 2010	Jan DISC
>A>		@	1.5MG	A091254	006	Nov 30, 2010	Jan DISC

TABLET, EXTENDED RELEASE; ORAL  
PRAMIPEXOLE DIHYDROCHLORIDE

>A>	AB	MACLEODS PHARMS LTD	3.75MG	A206156	007	Jan 23, 2017	Jan NEWA
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PRAVASTATIN SODIUMTABLET; ORAL  
PRAVASTATIN SODIUM

>A>	AB	AUROBINDO PHARMA LTD	10MG	A203367	001	Feb 02, 2017	Jan NEWA
>A>	AB		20MG	A203367	002	Feb 02, 2017	Jan NEWA
>A>	AB		40MG	A203367	003	Feb 02, 2017	Jan NEWA
>A>	AB		80MG	A203367	004	Feb 02, 2017	Jan NEWA

PREDNISONETABLET; ORAL  
PREDNISONE

>D>	AB	DELCOR ASSET CORP	5MG	A080292	001		Jan CAHN
>D>	AB		10MG	A088832	001	Dec 04, 1985	Jan CAHN
>D>	AB		20MG	A083677	001		Jan CAHN
>A>	AB	MYLAN PHARMS INC	5MG	A080292	001		Jan CAHN
>A>	AB		10MG	A088832	001	Dec 04, 1985	Jan CAHN
>A>	AB		20MG	A083677	001		Jan CAHN



PROBENECID

TABLET; ORAL  
BENEMID

>D> @ MERCK 500MG N007898 004 Jan CRLD  
>A> + @ 500MG N007898 004 Jan CRLD

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION  
PROCAINAMIDE HYDROCHLORIDE

>D> @ EUROHLTH INTL SARL 100MG/ML A089029 001 Apr 17, 1986 Jan CAHN  
>A> @ WEST-WARD PHARMS INT 100MG/ML A089029 001 Apr 17, 1986 Jan CAHN

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION  
PROCHLORPERAZINE EDISYLATE

>D> @ EUROHLTH INTL SARL EQ 5MG BASE/ML A089523 001 May 03, 1988 Jan CAHN  
>D> AP EQ 5MG BASE/ML A089903 001 Aug 29, 1989 Jan CAHN  
>A> @ WEST-WARD PHARMS INT EQ 5MG BASE/ML A089523 001 May 03, 1988 Jan CAHN  
>A> AP EQ 5MG BASE/ML A089903 001 Aug 29, 1989 Jan CAHN

PROMETHAZINE HYDROCHLORIDE

SUPPOSITORY; RECTAL  
PHENERGAN

>D> @ DELCOR ASSET CORP 50MG N011689 001 Jan CAHN  
>A> + @ MYLAN PHARMS INC 50MG N011689 001 Jan CAHN

PROPIOMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION  
LARGON

>D> @ EUROHLTH INTL SARL 20MG/ML N012382 002 Jan CAHN  
>A> @ WEST-WARD PHARMS INT 20MG/ML N012382 002 Jan CAHN

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL  
INDERAL

>D> @ WYETH PHARMS INC 40MG N016418 002 Jan CRLD  
>A> + @ 40MG N016418 002 Jan CRLD

PROTAMINE SULFATE

INJECTABLE; INJECTION  
PROTAMINE SULFATE

>D> @ EUROHLTH INTL SARL 10MG/ML A089475 001 Nov 05, 1986 Jan CAHN  
>A> @ WEST-WARD PHARMS INT 10MG/ML A089475 001 Nov 05, 1986 Jan CAHN

RABEPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL  
RABEPRAZOLE SODIUM

>D> AB KREMERS URBAN DEV 20MG A090678 001 Nov 08, 2013 Jan CAHN  
>A> AB KREMERS URBAN PHARMS 20MG A090678 001 Nov 08, 2013 Jan CAHN

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION  
ZANTAC

>D> AP +! IGI LABS INC EQ 25MG BASE/ML N019090 001 Oct 19, 1984 Jan CAHN  
>A> AP +! TELIGENT PHARMA INC EQ 25MG BASE/ML N019090 001 Oct 19, 1984 Jan CAHN

SYRUP; ORAL

RANITIDINE HYDROCHLORIDE

>D> AA AUROBINDO PHARM EQ 15MG BASE/ML A090623 001 Jul 28, 2010 Jan CAHN  
>A> AA AUROBINDO PHARMA LTD EQ 15MG BASE/ML A090623 001 Jul 28, 2010 Jan CAHN

RIBAVIRIN

CAPSULE; ORAL  
RIBASPHERE

>A> AB KADMON PHARMS LLC 200MG A076203 001 Apr 06, 2004 Jan CAHN  
>D> AB THREE RIVERS PHARMS 200MG A076203 001 Apr 06, 2004 Jan CAHN

TABLET; ORAL  
RIBAVIRIN

>A> AB KADMON PHARMS LLC 200MG A077456 001 Dec 05, 2005 Jan CAHN  
>A> AB 400MG A077456 002 Dec 05, 2005 Jan CAHN  
>A> AB ! 600MG A077456 003 Dec 05, 2005 Jan CAHN  
>D> AB THREE RIVERS PHARMS 200MG A077456 001 Dec 05, 2005 Jan CAHN

TABLET;ORAL  
RIBAVIRIN

>D>	AB		400MG	A077456	002	Dec 05, 2005	Jan CAHN
>A>	AB	!	600MG	A077456	003	Dec 05, 2005	Jan CAHN

RIFAMPIN

INJECTABLE;INJECTION  
RIFAMPIN

>D>	AP	EUROHLTH INTL SARL	600MG/VIAL	A064217	001	Oct 29, 1999	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	600MG/VIAL	A064217	001	Oct 29, 1999	Jan CAHN

RIVASTIGMINE TARTRATE

CAPSULE;ORAL  
RIVASTIGMINE TARTRATE

>A>	AB	CADILA PHARMS LTD	EQ 1.5MG BASE	A203844	001	Feb 13, 2017	Jan NEWA
>A>	AB		EQ 3MG BASE	A203844	002	Feb 13, 2017	Jan NEWA
>A>	AB		EQ 4.5MG BASE	A203844	003	Feb 13, 2017	Jan NEWA
>A>	AB		EQ 6MG BASE	A203844	004	Feb 13, 2017	Jan NEWA

RIZATRIPTAN BENZOATE

TABLET, ORALLY DISINTEGRATING;ORAL  
RIZATRIPTAN BENZOATE

>A>	AB	PANACEA BIOTEC LTD	EQ 5MG BASE	A204722	001	Jan 11, 2017	Jan NEWA
>A>	AB		EQ 10MG BASE	A204722	002	Jan 11, 2017	Jan NEWA

SELEGILINE HYDROCHLORIDE

TABLET;ORAL  
SELEGILINE HYDROCHLORIDE

>A>		@ CHARTWELL MOLECULES	5MG	A074565	001	Aug 02, 1996	Jan CAHN
>A>		@	5MG	A074641	001	Aug 02, 1996	Jan CAHN
>D>		@ DAVA PHARMS INC	5MG	A074641	001	Aug 02, 1996	Jan CAHN
>D>		@ VINTAGE PHARMS LLC	5MG	A074565	001	Aug 02, 1996	Jan CAHN

SIMVASTATIN

SUSPENSION;ORAL  
SIMVASTATIN

>D>		ROSEMONT PHARMS LTD	20MG/5ML	N206679	001	Apr 21, 2016	Jan CAHN
>D>	+		40MG/5ML	N206679	002	Apr 21, 2016	Jan CAHN
>A>	+	TCG FLUENT PHARMA	20MG/5ML	N206679	001	Apr 21, 2016	Jan CAHN
>A>	+	!	40MG/5ML	N206679	002	Apr 21, 2016	Jan CAHN

SODIUM CHLORIDE

INJECTABLE;INJECTION  
SODIUM CHLORIDE 0.9%

>D>	AP	EUROHLTH INTL SARL	9MG/ML	A201850	001	Jan 20, 2012	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	9MG/ML	A201850	001	Jan 20, 2012	Jan CAHN
>D>		EUROHLTH INTL SARL	9MG/ML	A201833	001	Sep 24, 2013	Jan CAHN
>A>		WEST-WARD PHARMS INT	9MG/ML	A201833	001	Sep 24, 2013	Jan CAHN
>D>		SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER					
>D>		@ ABRAXIS PHARM	234MG/ML	N019329	001	Apr 22, 1987	Jan CRLD
>A>		+ @	234MG/ML	N019329	001	Apr 22, 1987	Jan CRLD

SODIUM OXYBATE

SOLUTION;ORAL  
SODIUM OXYBATE

>A>	AA	WEST-WARD PHARMS INT	500MG/ML	A202090	001	Jan 17, 2017	Jan NEWA
>D>		XYREM					
>D>	+	JAZZ PHARMS	500MG/ML	N021196	001	Jul 17, 2002	Jan CFTG
>A>	AA	+	500MG/ML	N021196	001	Jul 17, 2002	Jan CFTG

STERILE WATER FOR INJECTION

LIQUID;N/A  
STERILE WATER FOR INJECTION

>D>	AP	EUROHLTH INTL SARL	100%	A206369	001	Sep 02, 2015	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	100%	A206369	001	Sep 02, 2015	Jan CAHN

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET;ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

>A>	AB	CHARTWELL PHARMS LLC	400MG;80MG	A078060	002	Jan 25, 2007	Jan CAHN
>A>	AB		800MG;160MG	A078060	001	Jan 25, 2007	Jan CAHN
>D>	AB	VINTAGE	400MG;80MG	A078060	002	Jan 25, 2007	Jan CAHN
>D>	AB		800MG;160MG	A078060	001	Jan 25, 2007	Jan CAHN

SUMATRIPTAN SUCCINATE

INJECTABLE;SUBCUTANEOUS

SUMATRIPTAN SUCCINATE

>D>	AP	EUROHLTH INTL SARL	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A079123	001	Feb 06, 2009	Jan CAHN
>A>	AP	WEST-WARD PHARMS INT	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A079123	001	Feb 06, 2009	Jan CAHN
>D>		SYSTEM;IONTOPHORESIS					
>D>		ZECUITY					
>D>	+	TEVA BRANDED PHARM	EQ 6.5MG BASE/4HR	N202278	001	Jan 17, 2013	Jan DISC
>A>	+ @		EQ 6.5MG BASE/4HR	N202278	001	Jan 17, 2013	Jan DISC

TAMSULOSIN HYDROCHLORIDE

CAPSULE;ORAL

TAMSULOSIN HYDROCHLORIDE

>A>	AB	MACLEODS PHARMS LTD	0.4MG	A204645	001	Jan 20, 2017	Jan NEWA
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TAZAROTENE

AEROSOL, FOAM;TOPICAL

FABIOR

>A>	+	MAYNE PHARMA	0.1%	N202428	001	May 11, 2012	Jan CAHN
>D>	+	STIEFEL LABS INC	0.1%	N202428	001	May 11, 2012	Jan CAHN

TERBUTALINE SULFATE

TABLET;ORAL

TERBUTALINE SULFATE

>D>		LANNETT	5MG	A077152	002	Mar 25, 2005	Jan CHRS
>A>	!		5MG	A077152	002	Mar 25, 2005	Jan CHRS

TESTOSTERONE CYPIONATE

INJECTABLE;INJECTION

TESTOSTERONE CYPIONATE

>D>	AO	EUROHLTH INTL SARL	100MG/ML	A090387	001	Jul 15, 2010	Jan CAHN
>D>	AO		200MG/ML	A090387	002	Jul 15, 2010	Jan CAHN
>A>	AO	WEST-WARD PHARMS INT	100MG/ML	A090387	001	Jul 15, 2010	Jan CAHN
>A>	AO		200MG/ML	A090387	002	Jul 15, 2010	Jan CAHN

TETRABENAZINE

TABLET;ORAL

TETRABENAZINE

>A>	AB	APICORE US	12.5MG	A207682	001	Jan 31, 2017	Jan NEWA
>A>	AB		25MG	A207682	002	Jan 31, 2017	Jan NEWA

TETRACYCLINE HYDROCHLORIDE

CAPSULE;ORAL

ACHROMYCIN V

>A>	AB	+	HERITAGE PHARMA	250MG	N050278	003	Jan CAHN
>A>	AB	+	!	500MG	N050278	001	Jan CAHN
>D>	AB		HERITAGE PHARMS INC	250MG	N050278	003	Jan CAHN
>D>	AB	+		500MG	N050278	001	Jan CAHN

THIAMINE HYDROCHLORIDE

INJECTABLE;INJECTION

THIAMINE HYDROCHLORIDE

>D>		@	EUROHLTH INTL SARL	100MG/ML	A080575	001	Jan CAHN
>A>		@	WEST-WARD PHARMS INT	100MG/ML	A080575	001	Jan CAHN

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE;ORAL

THIORIDAZINE HYDROCHLORIDE

>A>		@	ANI PHARMS INC	30MG/ML	A089602	001	Nov 09, 1987	Jan CAHN
>D>		@	TEVA PHARMS	30MG/ML	A089602	001	Nov 09, 1987	Jan CAHN

THIOTEPA

POWDER;IV (INFUSION)

>A>	TEPADINA							
>A>	+!	ADIENNE SA	15MG/VIAL	N208264	001	Jan 26, 2017	Jan	NEWA
>A>	+!		100MG/VIAL	N208264	002	Jan 26, 2017	Jan	NEWA

TICAGRELOR

TABLET;ORAL

BRILINTA

>D>	+	ASTRAZENECA LP	60MG	N022433	002	Sep 03, 2015	Jan	CAHN
>D>	+!		90MG	N022433	001	Jul 20, 2011	Jan	CAHN
>A>	+	ASTRAZENECA PHARMS	60MG	N022433	002	Sep 03, 2015	Jan	CAHN
>A>	+!		90MG	N022433	001	Jul 20, 2011	Jan	CAHN

TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC

TIMOLOL MALEATE

>D>	AT	ALCON RES LTD	EQ 0.25% BASE	A074261	001	Apr 28, 1995	Jan	CHRS
>A>	AT	!	EQ 0.25% BASE	A074261	001	Apr 28, 1995	Jan	CHRS
>D>	AT1		EQ 0.5% BASE	A074262	001	Apr 28, 1995	Jan	CHRS
>A>	AT1	!	EQ 0.5% BASE	A074262	001	Apr 28, 1995	Jan	CHRS
		TIMOPTIC						
>D>	AT	+	ATON	N018086	001		Jan	DISC
>A>		+	@	N018086	001		Jan	DISC
>D>	AT1	+		N018086	002		Jan	DISC
>A>		+	@	N018086	002		Jan	DISC

TINIDAZOLE

TABLET;ORAL

TINIDAZOLE

>D>	BX	UNIQUE PHARM LABS	250MG	A202489	001	Oct 09, 2013	Jan	CTEC
>A>	AB		250MG	A202489	001	Oct 09, 2013	Jan	CTEC
>D>	BX		500MG	A202489	002	Oct 09, 2013	Jan	CTEC
>A>	AB		500MG	A202489	002	Oct 09, 2013	Jan	CTEC

TIZANIDINE HYDROCHLORIDE

TABLET;ORAL

TIZANIDINE HYDROCHLORIDE

>A>	AB	PAR PHARM INC	EQ 2MG BASE	A207170	001	Jan 26, 2017	Jan	NEWA
>A>	AB		EQ 4MG BASE	A207170	002	Jan 26, 2017	Jan	NEWA

TOREMIFENE CITRATE

TABLET;ORAL

FARESTON

>A>	+!	KYOWA KIRIN	EQ 60MG BASE	N020497	001	May 29, 1997	Jan	CAHN
>D>	+!	PROSTRAKAN INC	EQ 60MG BASE	N020497	001	May 29, 1997	Jan	CAHN

TRANEXAMIC ACID

INJECTABLE;INJECTION

TRANEXAMIC ACID

>A>	AP	GLAND PHARMA LTD	100MG/ML	A207239	001	Feb 13, 2017	Jan	NEWA
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TRIAMCINOLONE ACETONIDE

CREAM;TOPICAL

TRIAMCINOLONE ACETONIDE

>D>	AT	DELCOR ASSET CORP	0.025%	N011601	003		Jan	CAHN
>D>	AT		0.1%	N011601	006		Jan	CAHN
>A>	AT	LUPIN ATLANTIS	0.025%	A208763	001	Feb 01, 2017	Jan	NEWA
>A>	AT		0.1%	A208763	002	Feb 01, 2017	Jan	NEWA
>A>	AT		0.5%	A208763	003	Feb 01, 2017	Jan	NEWA
>A>	AT	+	MYLAN PHARMS INC	N011601	003		Jan	CAHN
>A>	AT	+		N011601	006		Jan	CAHN

OINTMENT;TOPICAL

KENALOG

>D>	AT	DELCOR ASSET CORP	0.025%	N011600	003		Jan	CAHN
>D>	AT		0.1%	N011600	001		Jan	CAHN
>A>	AT	MYLAN PHARMS INC	0.025%	N011600	003		Jan	CAHN
>A>	AT		0.1%	N011600	001		Jan	CAHN

PASTE;DENTAL

TRIAMCINOLONE ACETONIDE

>A>	AT	G AND W LABS INC	0.1%	A205592	001	Jan 12, 2017	Jan	NEWA
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SPRAY, METERED;NASAL  
 TRIAMCINOLONE ACETONIDE

>A>	@ PERRIGO ISRAEL	0.055MG/SPRAY	A078104	001	Jul 30, 2009	Jan CAHN
>D>	@ TEVA PHARMS	0.055MG/SPRAY	A078104	001	Jul 30, 2009	Jan CAHN

ULIPRISTAL ACETATE

TABLET;ORAL  
 ELLA

>D>	+! LAB HRA PHARMA	30MG	N022474	001	Aug 13, 2010	Jan CFTG
>A> AB	+!	30MG	N022474	001	Aug 13, 2010	Jan CFTG
>A>	LOGILIA					
>A> AB	TEVA PHARMS USA	30MG	A207952	001	Feb 13, 2017	Jan NEWA

VECURONIUM BROMIDE

INJECTABLE;INJECTION  
 VECURONIUM BROMIDE

>D> AP	EUROHLTH INTL SARL	10MG/VIAL	A075549	001	Jun 13, 2000	Jan CAHN
>D> AP		20MG/VIAL	A075549	002	Jun 13, 2000	Jan CAHN
>A> AP	WEST-WARD PHARMS INT	10MG/VIAL	A075549	001	Jun 13, 2000	Jan CAHN
>A> AP		20MG/VIAL	A075549	002	Jun 13, 2000	Jan CAHN

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL  
 CALAN SR

>D>	@ PFIZER	180MG	N019152	002	Dec 15, 1989	Jan CRLD
>A>	+ @	180MG	N019152	002	Dec 15, 1989	Jan CRLD
>D>	COVERA-HS					
>D> BC	+ GD SEARLE LLC	180MG	N020552	001	Feb 26, 1996	Jan DISC
>A>	@	180MG	N020552	001	Feb 26, 1996	Jan DISC
>D> BC	+	240MG	N020552	002	Feb 26, 1996	Jan DISC
>A>	@	240MG	N020552	002	Feb 26, 1996	Jan DISC

VIGABATRIN

FOR SOLUTION;ORAL  
 SABRIL

>D>	+! LUNDBECK LLC	500MG/PACKET	N022006	001	Aug 21, 2009	Jan CAHN
>A>	+! LUNDBECK PHARMS LLC	500MG/PACKET	N022006	001	Aug 21, 2009	Jan CAHN
>D>	+! LUNDBECK LLC	500MG	N020427	001	Aug 21, 2009	Jan CAHN
>A>	+! LUNDBECK PHARMS LLC	500MG	N020427	001	Aug 21, 2009	Jan CAHN

VINORELBINE TARTRATE

INJECTABLE;INJECTION  
 VINORELBINE TARTRATE

>D> AP	EUROHLTH INTL SARL	EQ 10MG BASE/ML	A076461	001	Dec 11, 2003	Jan CAHN
>A> AP	WEST-WARD PHARMS INT	EQ 10MG BASE/ML	A076461	001	Dec 11, 2003	Jan CAHN

ZOLEDRONIC ACID

INJECTABLE;IV (INFUSION)  
 ZOLEDRONIC ACID

>A> AP	MYLAN LABS LTD	EQ 5MG BASE/100ML	A203841	001	Feb 14, 2017	Jan NEWA
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ZOLPIDEM TARTRATE

TABLET, EXTENDED RELEASE;ORAL  
 ZOLPIDEM TARTRATE

>A> AB	SUN PHARMA GLOBAL	6.25MG	A204170	001	Jan 24, 2017	Jan NEWA
>A> AB		12.5MG	A204170	002	Jan 24, 2017	Jan NEWA

>A>	<u>LEVOCETIRIZINE DIHYDROCHLORIDE</u>				
>A>	SOLUTION;ORAL				
>A>	XYZAL ALLERGY 24HR				
>A>	+ UCB INC	2.5MG/5ML (0.5MG/ML)	N209090	001	Jan 31, 2017 Jan NEWA
>A>	TABLET;ORAL				
>A>	XYZAL ALLERGY 24HR				
>A>	+ UCB INC	5MG	N209089	001	Jan 31, 2017 Jan NEWA
	<u>LOPERAMIDE HYDROCHLORIDE</u>				
>D>	TABLET, CHEWABLE;ORAL				
>D>	IMODIUM A-D EZ CHEWS				
>D>	+ J AND J CONSUMER INC	2MG	N020448	001	Jul 24, 1997 Jan DISC
>A>	+ @	2MG	N020448	001	Jul 24, 1997 Jan DISC
	<u>LOPERAMIDE HYDROCHLORIDE; SIMETHICONE</u>				
>D>	TABLET, CHEWABLE;ORAL				
>D>	IMODIUM MULTI-SYMP TOM RELIEF				
>D>	+ J AND J CONSUMER INC	2MG;125MG	N020606	001	Jun 26, 1996 Jan DISC
>A>	+ @	2MG;125MG	N020606	001	Jun 26, 1996 Jan DISC
	LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE				
>D>	PERRIGO	2MG;125MG	A076029	001	Aug 30, 2002 Jan CHRS
>A>	!	2MG;125MG	A076029	001	Aug 30, 2002 Jan CHRS
	<u>NAPROXEN SODIUM</u>				
	TABLET;ORAL				
	NAPROXEN SODIUM				
>A>	LNK INTL INC	EQ 200MG BASE	A204872	001	Jan 23, 2017 Jan NEWA
	<u>RANITIDINE HYDROCHLORIDE</u>				
	TABLET;ORAL				
	RANITIDINE HYDROCHLORIDE				
>A>	STRIDES PHARMA	EQ 150MG BASE	A200536	001	Jun 28, 2011 Jan CAHN
>D>	SVADS HOLDINGS SA	EQ 150MG BASE	A200536	001	Jun 28, 2011 Jan CAHN
	<u>TRIAMCINOLONE ACETONIDE</u>				
	SPRAY, METERED;NASAL				
	TRIAMCINOLONE ACETONIDE				
>A>	PERRIGO ISRAEL	0.055MG/SPRAY	A078104	002	Nov 14, 2014 Jan CAHN
>D>	TEVA PHARMS	0.055MG/SPRAY	A078104	002	Nov 14, 2014 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 2017**

NO JANUARY 2017 APPROVALS

## ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The 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 2017 ADDITIONS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2017

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>ACETAMINOPHEN - OFIRMEV</u>						
N 022450	001				>A> M-196 >A> PED	Jan 27, 2020 Jul 27, 2020
<u>AFATINIB DIMALEATE - GILOTTRIF</u>						
N 201292	001 >A>	9539258	Nov 09, 2026	U-1950		
<u>AFATINIB DIMALEATE - GILOTTRIF</u>						
N 201292	002 >A>	9539258	Nov 09, 2026	U-1950		
<u>AFATINIB DIMALEATE - GILOTTRIF</u>						
N 201292	003 >A>	9539258	Nov 09, 2026	U-1950		
<u>ALOGLIPTIN BENZOATE - NESINA</u>						
N 022271	001 >A>	8173663	Dec 02, 2025	U-1338		
<u>ALOGLIPTIN BENZOATE - NESINA</u>						
N 022271	002 >A>	8173663	Dec 02, 2025	U-1338		
<u>ALOGLIPTIN BENZOATE - NESINA</u>						
N 022271	003 >A>	8173663	Dec 02, 2025	U-1338		
<u>ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE - KAZANO</u>						
N 203414	001 >A>	8288539	Jun 24, 2025	DS		
<u>ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE - KAZANO</u>						
N 203414	002 >A>	8288539	Jun 24, 2025	DS		
<u>ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI</u>						
N 022426	005 >A>	6329404	Jun 19, 2021	DP U-1334		
<u>ARIPIRAZOLE LAUROXIL - ARISTADA</u>						
N 207533	001 >A>	9526726	Mar 19, 2035	DP		
<u>ARIPIRAZOLE LAUROXIL - ARISTADA</u>						
N 207533	002 >A>	9526726	Mar 19, 2035	DP		
<u>ARIPIRAZOLE LAUROXIL - ARISTADA</u>						
N 207533	003 >A>	9526726	Mar 19, 2035	DP		
<u>ASENAPINE MALEATE - SAPHRIS</u>						
N 022117	001				>A> D-166 >A> I-597	Jan 13, 2020 Jan 13, 2020
<u>ASENAPINE MALEATE - SAPHRIS</u>						
N 022117	002				>A> D-166 >A> I-597	Jan 13, 2020 Jan 13, 2020
<u>ASENAPINE MALEATE - SAPHRIS</u>						
N 022117	003				>A> D-166 >A> I-597	Jan 13, 2020 Jan 13, 2020
<u>ASPIRIN; OMEPRAZOLE - YOSPRALA</u>						
N 205103	001 >A>	9539214	Mar 13, 2033	U-1902		
<u>ASPIRIN; OMEPRAZOLE - YOSPRALA</u>						
N 205103	002 >A>	9539214	Mar 13, 2033	U-1902		

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2017

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>BENDAMUSTINE HYDROCHLORIDE - TREANDA</u>						
N 022249 001	>A> 9533955	Mar 26, 2029	DP U-1949			
	>A> 9533955	Mar 26, 2029	DP U-1952			
<u>BENDAMUSTINE HYDROCHLORIDE - TREANDA</u>						
N 022249 002	>A> 9533955	Mar 26, 2029	DP U-1949			
	>A> 9533955	Mar 26, 2029	DP U-1952			
<u>BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE - ONEXTON</u>						
N 050819 002	>A> 9561208	Jun 03, 2029	DP U-916			
<u>BROMFENAC SODIUM - PROLENSA</u>						
N 203168 001	>A> 9517220	Nov 11, 2033	U-1933			
<u>BROMOCRIPTINE MESYLATE - CYCLOSET</u>						
N 020866 001	>A> 9522117	Apr 30, 2032	DP U-976			
	>A> 9522117	Apr 30, 2032	DP U-1939			
<u>BUDESONIDE - UCERIS</u>						
N 203634 001	>A> 9532954	Jun 09, 2020	DP U-1325			
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
N 021929 001	>A> 6123924	Sep 26, 2017	DP		>A> NPP	Jan 27, 2020
	>A> 6123924*PED	Mar 26, 2018			>A> PED	Jul 27, 2020
	>A> 7367333	Nov 11, 2018	DP			
	>A> 7367333*PED	May 11, 2019				
	>A> 7587988	Apr 10, 2026	DP			
	>A> 7587988*PED	Oct 10, 2026				
	>A> 7759328	Jan 29, 2023	DP U-1073			
	>A> 7759328*PED	Jul 29, 2023				
	>A> 7967011	Aug 11, 2021	DP			
	>A> 7967011*PED	Feb 11, 2022				
	>A> 8143239	Jan 29, 2023	DP U-1073			
	>A> 8143239*PED	Jul 29, 2023				
	>A> 8387615	Nov 10, 2024	DP			
	>A> 8387615*PED	May 10, 2025				
	>A> 8575137	Jan 29, 2023	DP U-1073			
	>A> 8575137*PED	Jul 29, 2023				
	>A> 8616196	Apr 07, 2029	DP			
	>A> 8616196*PED	Oct 07, 2029				
	>A> 8875699	Nov 10, 2024	DP			
	>A> 8875699*PED	May 10, 2025				
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
N 021929 002	>A> 6123924	Sep 26, 2017	DP			
	>A> 6123924*PED	Mar 26, 2018				
	>A> 7367333	Nov 11, 2018	DP			
	>A> 7367333*PED	May 11, 2019				
	>A> 7587988	Apr 10, 2026	DP			
	>A> 7587988*PED	Oct 10, 2026				
	>A> 7759328	Jan 29, 2023	DP U-1073			
	>A> 7759328*PED	Jul 29, 2023				
	>A> 7897646	Sep 09, 2018	U-1118			
	>A> 7897646*PED	Mar 09, 2019				
	>A> 7967011	Aug 11, 2021	DP			
	>A> 7967011*PED	Feb 11, 2022				
	>A> 8143239	Jan 29, 2023	DP U-1073			
	>A> 8143239*PED	Jul 29, 2023				
	>A> 8387615	Nov 10, 2024	DP			
	>A> 8387615*PED	May 10, 2025				
	>A> 8461211	Sep 09, 2018	U-1118			
	>A> 8461211*PED	Mar 09, 2019				
	>A> 8575137	Jan 29, 2023	DP U-1073			
	>A> 8575137*PED	Jul 29, 2023				
	>A> 8616196	Apr 07, 2029	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2017

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
N 021929 002	>A> 8616196*PED	Oct 07, 2029				
	>A> 8875699	Nov 10, 2024	DP			
	>A> 8875699*PED	May 10, 2025				
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 001	>A> 9533046	Dec 26, 2028	DP U-219			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 002	>A> 9533046	Dec 26, 2028	DP U-219			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 003	>A> 9533046	Dec 26, 2028	DP U-219			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 004	>A> 9533046	Dec 26, 2028	DP U-219			
<u>COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - STRIBILD</u>						
N 203100 001				>A> NPP		Jan 27, 2020
<u>CRISABOROLE - EUCRISA</u>						
N 207695 001	>A> 8039451	Jun 11, 2026	DS DP			
	>A> 8168614	Jan 20, 2030		U-1932		
	>A> 8501712	Feb 16, 2027		U-1932		
<u>DEOXYCHOLIC ACID - KYBELLA</u>						
N 206333 001	>A> 9522155	Feb 21, 2028	DP U-1940			
<u>DICLOFENAC POTASSIUM - ZIPSOR</u>						
N 022202 001	>A> 9561200	Feb 24, 2029		U-1482		
<u>DOXEPIN HYDROCHLORIDE - SILENOR</u>						
N 022036 001	>A> 9532971	Jun 01, 2029	DP			
<u>DOXEPIN HYDROCHLORIDE - SILENOR</u>						
N 022036 002	>A> 9532971	Jun 01, 2029	DP			
<u>FLUTICASONE PROPIONATE - ARMONAIR RESPICLICK</u>						
N 208798 001	>A> 6446627	Dec 18, 2017	DP		>A> NP	Jan 27, 2020
	>A> 6701917	Jun 23, 2021	DP			
	>A> 6718972	Jun 23, 2021	DP			
	>A> 6748947	Jun 23, 2021	DP			
	>A> 6871646	Jun 23, 2021	DP			
	>A> 7540282	May 06, 2023	DP			
	>A> 8006690	Jun 23, 2021	DP			
	>A> 8651103	Mar 26, 2028	DP			
	>A> 8714149	Feb 25, 2032	DP			
	>A> 8978966	Jan 13, 2032	DP			
	>A> 9216260	Jun 28, 2031	DP			
	>A> 9463288	May 19, 2025	DP			
<u>FLUTICASONE PROPIONATE - ARMONAIR RESPICLICK</u>						
N 208798 002	>A> 6446627	Dec 18, 2017	DP		>A> NP	Jan 27, 2020
	>A> 6701917	Jun 23, 2021	DP			
	>A> 6718972	Jun 23, 2021	DP			
	>A> 6748947	Jun 23, 2021	DP			
	>A> 6871646	Jun 23, 2021	DP			
	>A> 7540282	May 06, 2023	DP			
	>A> 8006690	Jun 23, 2021	DP			
	>A> 8651103	Mar 26, 2028	DP			
	>A> 8714149	Feb 25, 2032	DP			
	>A> 8978966	Jan 13, 2032	DP			
	>A> 9216260	Jun 28, 2031	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2017

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>FLUTICASONE PROPIONATE - ARMONAIR RESPICLICK</u>						
N 208798 002	>A> 9463288	May 19, 2025	DP			
<u>FLUTICASONE PROPIONATE - ARMONAIR RESPICLICK</u>						
N 208798 003	>A> 6446627	Dec 18, 2017	DP		>A> NP	Jan 27, 2020
	>A> 6701917	Jun 23, 2021	DP			
	>A> 6718972	Jun 23, 2021	DP			
	>A> 6748947	Jun 23, 2021	DP			
	>A> 6871646	Jun 23, 2021	DP			
	>A> 7540282	May 06, 2023	DP			
	>A> 8006690	Jun 23, 2021	DP			
	>A> 8651103	Mar 26, 2028	DP			
	>A> 8714149	Feb 25, 2032	DP			
	>A> 8978966	Jan 13, 2032	DP			
	>A> 9216260	Jun 28, 2031	DP			
	>A> 9463288	May 19, 2025	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - AIRDUO RESPICLICK</u>						
N 208799 001	>A> 6446627	Dec 18, 2017	DP		>A> NP	Jan 27, 2020
	>A> 6701917	Jun 23, 2021	DP			
	>A> 6718972	Jun 23, 2021	DP			
	>A> 6748947	Jun 23, 2021	DP			
	>A> 6871646	Jun 23, 2021	DP			
	>A> 7540282	May 06, 2023	DP			
	>A> 8006690	Jun 23, 2021	DP			
	>A> 8651103	Mar 26, 2028	DP			
	>A> 8714149	Feb 25, 2032	DP			
	>A> 8978966	Jan 13, 2032	DP			
	>A> 9066957	Oct 06, 2034	DP U-645			
	>A> 9216260	Jun 28, 2031	DP			
	>A> 9415008	Oct 06, 2034	DP U-645			
	>A> 9463288	May 19, 2025	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - AIRDUO RESPICLICK</u>						
N 208799 002	>A> 6446627	Dec 18, 2017	DP		>A> NP	Jan 27, 2020
	>A> 6701917	Jun 23, 2021	DP			
	>A> 6718972	Jun 23, 2021	DP			
	>A> 6748947	Jun 23, 2021	DP			
	>A> 6871646	Jun 23, 2021	DP			
	>A> 7540282	May 06, 2023	DP			
	>A> 8006690	Jun 23, 2021	DP			
	>A> 8651103	Mar 26, 2028	DP			
	>A> 8714149	Feb 25, 2032	DP			
	>A> 8978966	Jan 13, 2032	DP			
	>A> 9066957	Oct 06, 2034	DP U-645			
	>A> 9216260	Jun 28, 2031	DP			
	>A> 9463288	May 19, 2025	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - AIRDUO RESPICLICK</u>						
N 208799 003	>A> 6446627	Dec 18, 2017	DP		>A> NP	Jan 27, 2020
	>A> 6701917	Jun 23, 2021	DP			
	>A> 6718972	Jun 23, 2021	DP			
	>A> 6748947	Jun 23, 2021	DP			
	>A> 6871646	Jun 23, 2021	DP			
	>A> 7540282	May 06, 2023	DP			
	>A> 8006690	Jun 23, 2021	DP			
	>A> 8651103	Mar 26, 2028	DP			
	>A> 8714149	Feb 25, 2032	DP			
	>A> 8978966	Jan 13, 2032	DP			
	>A> 9066957	Oct 06, 2034	DP U-645			
	>A> 9216260	Jun 28, 2031	DP			
	>A> 9463288	May 19, 2025	DP			

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<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 001	>A> 9486451	Sep 12, 2034	U-55			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 002	>A> 9486451	Sep 12, 2034	U-55			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 003	>A> 9486451	Sep 12, 2034	U-55			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 004	>A> 9486451	Sep 12, 2034	U-55			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 005	>A> 9486451	Sep 12, 2034	U-55			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 006	>A> 9486451	Sep 12, 2034	U-55			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 001	>A> 9517236	Oct 30, 2021	DP			
	>A> 9545380	Aug 24, 2027	U-1556			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 002	>A> 9517236	Oct 30, 2021	DP			
	>A> 9545380	Aug 24, 2027	U-1556			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 003	>A> 9517236	Oct 30, 2021	DP			
	>A> 9545380	Aug 24, 2027	U-1556			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 004	>A> 9517236	Oct 30, 2021	DP			
	>A> 9545380	Aug 24, 2027	U-1556			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 005	>A> 9517236	Oct 30, 2021	DP			
	>A> 9545380	Aug 24, 2027	U-1556			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 006	>A> 9517236	Oct 30, 2021	DP			
	>A> 9545380	Aug 24, 2027	U-1556			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 007	>A> 9517236	Oct 30, 2021	DP			
	>A> 9545380	Aug 24, 2027	U-1556			
<u>HYDROCODONE BITARTRATE - VANTRELA ER</u>						
N 207975 001	>A> 8445018	Jul 31, 2029	DP			
	>A> 9216176	Sep 13, 2027	DP			
<u>HYDROCODONE BITARTRATE - VANTRELA ER</u>						
N 207975 002	>A> 8445018	Jul 31, 2029	DP			
	>A> 9216176	Sep 13, 2027	DP			
<u>HYDROCODONE BITARTRATE - VANTRELA ER</u>						
N 207975 003	>A> 8445018	Jul 31, 2029	DP			
	>A> 9216176	Sep 13, 2027	DP			
<u>HYDROCODONE BITARTRATE - VANTRELA ER</u>						
N 207975 004	>A> 8445018	Jul 31, 2029	DP			
	>A> 9216176	Sep 13, 2027	DP			

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<u>HYDROCODONE BITARTRATE - VANTRELA ER</u>						
N 207975 004	>A> 8445018	Jul 31, 2029	DP			
	>A> 9216176	Sep 13, 2027	DP			
<u>HYDROCODONE BITARTRATE - VANTRELA ER</u>						
N 207975 005	>A> 8445018	Jul 31, 2029	DP			
	>A> 9216176	Sep 13, 2027	DP			
<u>IBRUTINIB - IMBRUVICA</u>						
N 205552 001	>A> 9540382	Aug 18, 2033	U-1456		>A> I-741	Jan 18, 2020
	>A> 9540382	Aug 18, 2033	U-1650		>A> ODE	Jan 18, 2024
	>A> 9540382	Aug 18, 2033	U-1684			
	>A> 9540382	Aug 18, 2033	U-1946			
	>A> 9540382	Aug 18, 2033	U-1947			
<u>INSULIN GLARGINE RECOMBINANT - LANTUS SOLOSTAR</u>						
N 021081 002	>A> 9561331	Aug 28, 2024	DP			
<u>INSULIN GLARGINE RECOMBINANT - TOUJEO SOLOSTAR</u>						
N 206538 001	>A> 9561331	Aug 28, 2024	DP			
<u>INSULIN GLARGINE; LIXISENATIDE - SOLIQUA 100/33</u>						
N 208673 001	>A> 9561331	Aug 28, 2024	DP			
<u>INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR</u>						
N 021629 003	>A> 9561331	Aug 28, 2024	DP			
<u>LEUPROLIDE ACETATE - ELIGARD</u>						
N 021343 001	>A> 9254307	Oct 28, 2018	DS DP			
<u>LEUPROLIDE ACETATE - ELIGARD</u>						
N 021379 001	>A> 8470359	Oct 15, 2023	DS DP U-621			
	>A> 8486455	Oct 28, 2018	DS DP			
	>A> 8840916	Nov 13, 2020	DP			
	>A> 9539333	Nov 13, 2020	DS DP U-621			
<u>LEUPROLIDE ACETATE - ELIGARD</u>						
N 021488 001	>A> 8470359	Oct 15, 2023	DS DP U-621			
	>A> 8486455	Oct 28, 2018	DS DP			
	>A> 8840916	Nov 13, 2020	DP			
	>A> 9539333	Nov 13, 2020	DS DP U-621			
<u>LEUPROLIDE ACETATE - ELIGARD</u>						
N 021731 001	>A> 8470359	Oct 15, 2023	DS DP U-621			
	>A> 8486455	Oct 28, 2018	DS DP			
	>A> 8840916	Nov 13, 2020	DP			
	>A> 9539333	Nov 13, 2020	DS DP U-621			
<u>LINACLOTIDE - LINZESS</u>						
N 202811 003					>A> NCE	Aug 30, 2017
					>A> NS	Jan 25, 2020
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N 208510 001					>A> I-703	Jan 30, 2018
					>A> M-188	Oct 14, 2019
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N 208510 002					>A> I-703	Jan 30, 2018
					>A> M-188	Oct 14, 2019

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<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N 208510	003				>A> I-703 >A> M-188	Jan 30, 2018 Oct 14, 2019
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N 208510	004				>A> I-703 >A> M-188	Jan 30, 2018 Oct 14, 2019
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N 208510	005				>A> I-703 >A> M-188	Jan 30, 2018 Oct 14, 2019
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N 208510	006				>A> I-703 >A> M-188	Jan 30, 2018 Oct 14, 2019
<u>LURASIDONE HYDROCHLORIDE - LATUDA</u>						
N 200603	001				>A> M-195 >A> NPP >A> PED >A> PED	Jan 27, 2020 Jan 27, 2020 Jul 27, 2020 Jul 27, 2020
<u>LURASIDONE HYDROCHLORIDE - LATUDA</u>						
N 200603	002				>A> NPP >A> PED	Jan 27, 2020 Jul 27, 2020
<u>LURASIDONE HYDROCHLORIDE - LATUDA</u>						
N 200603	003				>A> M-195 >A> NPP >A> PED >A> PED	Jan 27, 2020 Jan 27, 2020 Jul 27, 2020 Jul 27, 2020
<u>LURASIDONE HYDROCHLORIDE - LATUDA</u>						
N 200603	005				>A> M-195 >A> NPP >A> PED >A> PED	Jan 27, 2020 Jan 27, 2020 Jul 27, 2020 Jul 27, 2020
<u>MARAVIROC - SELZENTRY</u>						
N 022128	001				>A> NPP >A> NS	Nov 04, 2019 Nov 04, 2019
<u>MARAVIROC - SELZENTRY</u>						
N 022128	002				>A> NPP >A> NS	Nov 04, 2019 Nov 04, 2019
<u>MARAVIROC - SELZENTRY</u>						
N 022128	003				>A> 6586430 >A> 6667314 >A> 7368460 >A> 7576097	Dec 01, 2019 Aug 06, 2021 Nov 25, 2022 May 25, 2021
			DS DP U-824 DS DP U-824 U-824 DS		>A> NPP >A> NS	Nov 04, 2019 Nov 04, 2019
<u>MARAVIROC - SELZENTRY</u>						
N 022128	004				>A> 6586430 >A> 6667314 >A> 7368460 >A> 7576097	Dec 01, 2019 Aug 06, 2021 Nov 25, 2022 May 25, 2021
			DS DP U-824 DS DP U-824 U-824 DS		>A> NPP >A> NS	Nov 04, 2019 Nov 04, 2019
<u>MARAVIROC - SELZENTRY</u>						
N 208984	001				>A> NP	Nov 04, 2019



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<u>METHOTREXATE - OTREXUP</u>						
N 204824 001	>A> 9533102	Jan 24, 2026	DP			
<u>METHOTREXATE - OTREXUP</u>						
N 204824 002	>A> 9533102	Jan 24, 2026	DP			
<u>METHOTREXATE - OTREXUP</u>						
N 204824 003	>A> 9533102	Jan 24, 2026	DP			
<u>METHOTREXATE - OTREXUP</u>						
N 204824 004	>A> 9533102	Jan 24, 2026	DP			
<u>METHOTREXATE - OTREXUP</u>						
N 204824 005	>A> 9533102	Jan 24, 2026	DP			
<u>METHOTREXATE - OTREXUP</u>						
N 204824 006	>A> 9533102	Jan 24, 2026	DP			
<u>METHOTREXATE - OTREXUP</u>						
N 204824 007	>A> 9533102	Jan 24, 2026	DP			
<u>METHOTREXATE - OTREXUP</u>						
N 204824 008	>A> 9533102	Jan 24, 2026	DP			
<u>METHYLPHENIDATE HYDROCHLORIDE - QUILLICHEW ER</u>						
N 207960 001	>A> 9545399	Aug 14, 2033	DP U-1827			
<u>METHYLPHENIDATE HYDROCHLORIDE - QUILLICHEW ER</u>						
N 207960 002	>A> 9545399	Aug 14, 2033	DP U-1827			
<u>METHYLPHENIDATE HYDROCHLORIDE - QUILLICHEW ER</u>						
N 207960 003	>A> 9545399	Aug 14, 2033	DP U-1827			
<u>MORPHINE SULFATE - ARYMO ER</u>						
N 208603 001	>A> 9044402	Jul 01, 2033	DP U-1556			
<u>MORPHINE SULFATE - ARYMO ER</u>						
N 208603 002	>A> 9044402	Jul 01, 2033	DP U-1556			
<u>MORPHINE SULFATE - ARYMO ER</u>						
N 208603 003	>A> 9044402	Jul 01, 2033	DP U-1556			
<u>NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE - TARGINIQ</u>						
N 205777 001	>A> 9555000	Apr 04, 2023	DP U-1556			
<u>NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE - TARGINIQ</u>						
N 205777 002	>A> 9555000	Apr 04, 2023	DP U-1556			
<u>NUSINERSEN SODIUM - SPINRAZA</u>						
N 209531 001	>A> 6166197	Dec 26, 2017	DS		>A> ODE	Dec 23, 2023
	>A> 6210892	Oct 07, 2018				
	>A> 7101993	Sep 05, 2023	DS			
	>A> 7838657	Jul 11, 2027	DS			
	>A> 8110560	Dec 05, 2025				U-1942
	>A> 8110560	Dec 05, 2025				U-1943
	>A> 8110560	Dec 05, 2025				U-1944
	>A> 8361977	May 27, 2030	DS DP			
	>A> 8980853	Nov 24, 2030				U-1941

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<u>OLOPATADINE HYDROCHLORIDE - PAZEO</u>						
N 206276 001	>A> 9533053	May 19, 2032	DP			
<u>OXYCODONE HYDROCHLORIDE - OXAYDO</u>						
N 202080 001	>A> 9492443	May 26, 2024	DS DP			
<u>OXYCODONE HYDROCHLORIDE - OXAYDO</u>						
N 202080 002	>A> 9492443	May 26, 2024	DP			
<u>OXYMETAZOLINE HYDROCHLORIDE - RHOFADÉ</u>						
N 208552 001	>A> 7812049	May 02, 2028	U-1959		>A> NP	Jan 18, 2020
	>A> 8420688	Aug 02, 2024	U-1959			
	>A> 8883838	Dec 01, 2031	DP			
<u>PIRFENIDONE - ESBRIET</u>						
N 208780 001					>A> NCE >A> ODE	Oct 16, 2019 Oct 15, 2021
<u>PIRFENIDONE - ESBRIET</u>						
N 208780 002					>A> NCE >A> ODE	Oct 16, 2019 Oct 15, 2021
<u>PIRFENIDONE - ESBRIET</u>						
N 208780 003					>A> NCE >A> ODE	Oct 16, 2019 Oct 15, 2021
<u>PLECANATIDE - TRULANCE</u>						
N 208745 001	>A> 7041786	Mar 25, 2023	DS		>A> NCE	Jan 19, 2022
	>A> 7799897	Jun 09, 2022	DS			
	>A> 8637451	Mar 28, 2022	U-1964			
<u>PREDNISONE - RAYOS</u>						
N 202020 001	>A> 9504699	Aug 03, 2027	U-1362			
<u>PREDNISONE - RAYOS</u>						
N 202020 002	>A> 9504699	Aug 03, 2027	U-1362			
<u>REGADENOSON - LEXISCAN</u>						
N 022161 001					>A> M-194	Jan 17, 2020
<u>RIVAROXABAN - XARELTO</u>						
N 022406 001	>A> 9539218	Feb 17, 2034	U-1953			
	>A> 9539218	Feb 17, 2034	U-1954			
	>A> 9539218	Feb 17, 2034	U-1955			
	>A> 9539218	Feb 17, 2034	U-1956			
	>A> 9539218	Feb 17, 2034	U-1957			
<u>RIVAROXABAN - XARELTO</u>						
N 022406 002	>A> 9539218	Feb 17, 2034	U-1953			
	>A> 9539218	Feb 17, 2034	U-1954			
	>A> 9539218	Feb 17, 2034	U-1955			
	>A> 9539218	Feb 17, 2034	U-1956			
	>A> 9539218	Feb 17, 2034	U-1957			
<u>RIVAROXABAN - XARELTO</u>						
N 022406 003	>A> 9539218	Feb 17, 2034	U-1953			
	>A> 9539218	Feb 17, 2034	U-1954			
	>A> 9539218	Feb 17, 2034	U-1955			
	>A> 9539218	Feb 17, 2034	U-1957			

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<u>RUCAPARIB CAMSYLATE - RUBRACA</u>						
N 209115	001				>A> ODE	Dec 19, 2023
<u>RUCAPARIB CAMSYLATE - RUBRACA</u>						
N 209115	002				>A> ODE	Dec 19, 2023
<u>SACROSIDASE - SUCRAID</u>						
N 020772	001	>A> 9469847	Feb 07, 2034	DS DP		
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N 021995	001	>A> 7459428	Feb 02, 2019	U-1945		
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N 021995	002	>A> 7459428	Feb 02, 2019	U-1945		
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N 021995	003	>A> 7459428	Feb 02, 2019	U-1945		
<u>SODIUM OXYBATE - XYREM</u>						
N 021196	001	>A> 9539330	Dec 22, 2019	DP		
<u>SOFOSBUVIR - SOVALDI</u>						
N 204671	001	>A> 9549941	Mar 26, 2029	U-1958		
<u>TASIMELTEON - HETLIOZ</u>						
N 205677	001	>A> 9539234	Jan 25, 2033	U-1934		
		>A> 9549913	Jan 25, 2033	U-1486		
<u>TAVABOROLE - KERYDIN</u>						
N 204427	001	>A> 9549938	Feb 16, 2026	U-1951		
<u>TEDUGLUTIDE RECOMBINANT - GATTEX KIT</u>						
N 203441	001	>A> 9539310	Nov 01, 2025	U-1320		
		>A> 9545434	Nov 01, 2025	U-1320		
		>A> 9545435	Nov 01, 2025	U-1320		
		>A> 9555079	Nov 01, 2025	U-1320		
<u>THIOTEPA - TEPADINA</u>						
N 208264	001				>A> ODE	Jan 26, 2024
<u>THIOTEPA - TEPADINA</u>						
N 208264	002				>A> ODE	Jan 26, 2024
<u>TICAGRELOR - BRILINTA</u>						
N 022433	001	6525060	Dec 02, 2019	DS DP U-1171	Y	
		6525060	Dec 02, 2019	DS DP U-1860	Y	
		6525060	Dec 02, 2019	DS DP U-1862	Y	
		6525060	Dec 02, 2019	DS DP U-1863	Y	
	>A>	RE46276	Dec 02, 2019	DS DP U-1935		
	>A>	RE46276	Dec 02, 2019	DS DP U-1936		
	>A>	RE46276	Dec 02, 2019	DS DP U-1937		
	>A>	RE46276	Dec 02, 2019	DS DP U-1938		
<u>TICAGRELOR - BRILINTA</u>						
N 022433	002	>A> 6525060	Dec 02, 2019	DS DP U-1171	Y	
	>A>	6525060	Dec 02, 2019	DS DP U-1860	Y	
	>A>	6525060	Dec 02, 2019	DS DP U-1862	Y	
	>A>	6525060	Dec 02, 2019	DS DP U-1863	Y	
	>A>	RE46276	Dec 02, 2019	DS DP U-1935		
	>A>	RE46276	Dec 02, 2019	DS DP U-1936		
	>A>	RE46276	Dec 02, 2019	DS DP U-1937		
	>A>	RE46276	Dec 02, 2019	DS DP U-1938		

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<u>TICAGRELOR - BRILINTA</u>						
N 022433 002	>A> 6525060	Dec 02, 2019	DS DP U-1171	Y		
	>A> 6525060	Dec 02, 2019	DS DP U-1860	Y		
	>A> 6525060	Dec 02, 2019	DS DP U-1862	Y		
	>A> 6525060	Dec 02, 2019	DS DP U-1863	Y		
	>A> RE46276	Dec 02, 2019	DS DP U-1935			
	>A> RE46276	Dec 02, 2019	DS DP U-1936			
	>A> RE46276	Dec 02, 2019	DS DP U-1937			
	>A> RE46276	Dec 02, 2019	DS DP U-1938			
<u>TIOTROPIUM BROMIDE - SPIRIVA</u>						
N 021395 001	>A> 6777423	Sep 24, 2021	DS DP			
	>A> 6777423*PED	Mar 24, 2022				
	>A> 6908928	Sep 24, 2021	DS DP U-566			
	>A> 6908928	Sep 24, 2021	DS DP U-762			
	>A> 6908928*PED	Mar 24, 2022				
	>A> 7070800	Jan 22, 2022	DP U-566			
	>A> 7070800*PED	Jul 22, 2022				
	>A> 7309707	Sep 24, 2021	DS DP			
	>A> 7309707*PED	Mar 24, 2022				
	>A> 7642268	Sep 24, 2021	DS DP			
	>A> 7642268*PED	Mar 24, 2022				
	>A> 7694676	Mar 12, 2027	DP			
	>A> 7694676*PED	Sep 12, 2027				
	>A> 8022082	Jan 19, 2026	DP U-1186			
	>A> 8022082*PED	Jul 19, 2026				
	>A> RE38912	Oct 11, 2021	DP			
	>A> RE38912*PED	Apr 11, 2022				
	>A> RE39820	Jan 30, 2018	DS DP U-566			
	>A> RE39820*PED	Jul 30, 2018				
<u>TIOTROPIUM BROMIDE - SPIRIVA RESPIMAT</u>						
N 021936 001	>A> 5964416	Oct 04, 2016	DP			
	>A> 5964416*PED	Apr 04, 2017				
	>A> 6149054	Dec 16, 2016	DP			
	>A> 6149054*PED	Jun 16, 2017				
	>A> 6176442*PED	Dec 01, 2016				
	>A> 6453795	Dec 05, 2016	DP			
	>A> 6453795*PED	Jun 05, 2017				
	>A> 6726124	Oct 04, 2016	DP			
	>A> 6726124*PED	Apr 04, 2017				
	>A> 6846413	Aug 28, 2018	DP			
	>A> 6846413*PED	Feb 28, 2019				
	>A> 6977042	Aug 28, 2018	DP			
	>A> 6977042*PED	Feb 28, 2019				
	>A> 6988496	Feb 23, 2020	DP			
	>A> 6988496*PED	Aug 23, 2020				
	>A> 7104470	Oct 04, 2016	DP			
	>A> 7104470*PED	Apr 04, 2017				
	>A> 7246615*PED	Dec 01, 2016				
	>A> 7284474	Aug 26, 2024	DP			
	>A> 7284474*PED	Feb 26, 2025				
	>A> 7396341	Oct 10, 2026	DP			
	>A> 7396341*PED	Apr 10, 2027				
	>A> 7802568	Feb 26, 2019	DP			
	>A> 7802568*PED	Aug 26, 2019				
	>A> 7837235	Mar 13, 2028	DP			
	>A> 7837235*PED	Sep 13, 2028				
	>A> 7896264	May 26, 2025	DP			
	>A> 7896264*PED	Nov 26, 2025				
	>A> 7988001	Aug 04, 2021	DP			
	>A> 7988001*PED	Feb 04, 2022				
	>A> RE39820	Jan 30, 2018	DS DP U-1593			
	>A> RE39820*PED	Jul 30, 2018				

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>TIOTROPIUM BROMIDE - SPIRIVA RESPIMAT</u>						
N 021936 002	>A> 6149054	Dec 16, 2016	DP			
	>A> 6846413	Aug 28, 2018	DP			
	>A> 6846413*PED	Feb 28, 2019				
	>A> 6977042	Aug 28, 2018	DP			
	>A> 6977042*PED	Feb 28, 2019				
	>A> 6988496	Feb 23, 2020	DP			
	>A> 6988496*PED	Aug 23, 2020				
	>A> 7284474	Aug 26, 2024	DP			
	>A> 7284474*PED	Feb 26, 2025				
	>A> 7396341	Oct 10, 2026	DP			
	>A> 7396341*PED	Apr 10, 2027				
	>A> 7802568	Feb 26, 2019	DP			
	>A> 7802568*PED	Aug 26, 2019				
	>A> 7837235	Mar 13, 2028	DP			
	>A> 7837235*PED	Sep 13, 2028				
	>A> 7896264	May 26, 2025	DP			
	>A> 7896264*PED	Nov 26, 2025				
	>A> 7988001	Aug 04, 2021	DP			
	>A> 7988001*PED	Feb 04, 2022				
	>A> 8733341	Dec 16, 2029	DP			
	>A> 8733341*PED	Jun 16, 2030				
	>A> RE39820	Jan 30, 2018	DS DP			
	>A> RE39820*PED	Jul 30, 2018				
<u>TIPIRACIL HYDROCHLORIDE; TRIFLURIDINE - LONSURF</u>						
N 207981 001	>A> 9527833	Jun 17, 2034	DS DP			
<u>TIPIRACIL HYDROCHLORIDE; TRIFLURIDINE - LONSURF</u>						
N 207981 002	>A> 9527833	Jun 17, 2034	DS DP			
<u>TOPIRAMATE - TROKENDI XR</u>						
N 201635 001	>A> 9549940	Nov 16, 2027	DP U-1675			
	>A> 9555004	Nov 16, 2027	DP U-1675			
<u>TOPIRAMATE - TROKENDI XR</u>						
N 201635 002	>A> 9549940	Nov 16, 2027	DP U-1675			
	>A> 9555004	Nov 16, 2027	DP U-1675			
<u>TOPIRAMATE - TROKENDI XR</u>						
N 201635 003	>A> 9549940	Nov 16, 2027	DP U-1675			
	>A> 9555004	Nov 16, 2027	DP U-1675			
<u>TOPIRAMATE - TROKENDI XR</u>						
N 201635 004	>A> 9549940	Nov 16, 2027	DP U-1675			
	>A> 9555004	Nov 16, 2027	DP U-1675			
<u>TOPIRAMATE - OUDEXY XR</u>						
N 205122 001	>A> 9555005	Mar 19, 2033	DP			
<u>TOPIRAMATE - OUDEXY XR</u>						
N 205122 002	>A> 9555005	Mar 19, 2033	DP			
<u>TOPIRAMATE - OUDEXY XR</u>						
N 205122 003	>A> 9555005	Mar 19, 2033	DP			
<u>TOPIRAMATE - OUDEXY XR</u>						
N 205122 004	>A> 9555005	Mar 19, 2033	DP			
<u>TOPIRAMATE - OUDEXY XR</u>						
N 205122 005	>A> 9555005	Mar 19, 2033	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2017

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>TREPROSTINIL DIOLAMINE - ORENITRAM</u>						
N 203496 005	>A> 6765117	Oct 24, 2017	DS			
	>A> 7417070	Jul 30, 2026	DS			
	>A> 7544713	Jul 14, 2024			U-1475	
	>A> 8252839	May 24, 2024	DP			
	>A> 8349892	Jan 22, 2031	DP			
	>A> 8410169	Feb 13, 2030	DP			
	>A> 8497393	Dec 15, 2028	DS			
	>A> 8747897	Oct 08, 2029	DP			
	>A> 9050311	May 24, 2024	DS DP			
	>A> 9278901	May 24, 2024			U-1475	
	>A> 9393203	Apr 27, 2026	DP		U-1877	
	>A> 9422223	May 24, 2024	DP			

## Footnote:

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

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

## PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 37<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/results\\_patent.cfm](http://www.accessdata.fda.gov/scripts/cder/ob/results_patent.cfm)

The current complete list of exclusivity terms is available at [http://www.accessdata.fda.gov/scripts/cder/ob/results\\_exclusivity.cfm](http://www.accessdata.fda.gov/scripts/cder/ob/results_exclusivity.cfm)