

APPROVED DRUG PRODUCTS

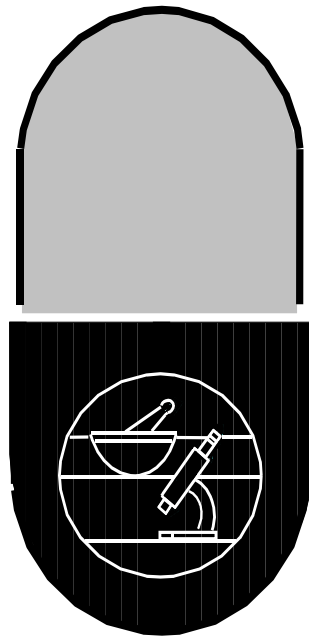
With Therapeutic Equivalence Evaluations



The "Orange Book"

FDA data supplied by [DrugPatentWatch.com](https://www.drugpatentwatch.com)

**CUMULATIVE
SUPPLEMENT 2
FEBRUARY 2018**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

38th 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**

2018

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

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

38th EDITION

**Cumulative Supplement 2
February 2018**

CONTENTS

	<i>PAGE</i>
1.0 INTRODUCTION.....	v
1.1 How to use the Cumulative Supplement.....	v
1.2 Cumulative Supplement Content	vi
1.3 Applicant Name Changes	vii
1.4 Levothyroxine Sodium.....	vii
1.5 Availability of the Edition	viii
1.6 Report of Counts for the Prescription Drug Product List.....	ix
1.7 Cumulative Supplement Legend	x
 DRUG PRODUCT LISTS	
Prescription Drug Product List	1-1
OTC Drug Product List	2-1
Drug Products with Approval under Section 505 of the Act	
Administered by the Center for Biologics Evaluation and Research List	3-1
Orphan Product Designations and Approvals List	4-1
Drug Products Which Must Demonstrate in vivo Bioavailability	
Only if Product Fails to Achieve Adequate Dissolution	5-1
 PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Patent and Exclusivity Lists	A-1
B. Patent and Exclusivity Terms	B-1

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

38th EDITION

**CUMULATIVE SUPPLEMENT 2
February 2018**

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, 38th 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 12th Cumulative Supplement of this Edition List will then be added to the "Discontinued Drug Product List" appearing in the

next Edition. The current Annual Edition Section 2.1, How To Use The Drug Product Lists, describes the layout and usage of the List.

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

- New Drug Application (NDA) approvals appear in the CS month they were approved.
- Patent information, also updated daily in the EOB, is current to the date of publication.
- Exclusivity information is updated monthly and current to the date of publication.

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at 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>
SAGENT AGILA LLC (SAGENT AGILA)	MYLAN ASI LLC (MYLAN ASI)
SAGENT AGILA LLC (SAGENT AGILA LLC)	MYLAN ASI LLC (MYLAN ASI)
SAGENT STRIDES LLC (SAGENT STRIDESC)	MYLAN ASI LLC (MYLAN ASI)

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 2017</u>	<u>MAR 2018</u>	<u>JUN 2018</u>	<u>SEP 2018</u>	<u>DEC 2018</u>
DRUG PRODUCTS LISTED SINGLE SOURCE	19294				
	2758				
	(14.3%)				
MULTISOURCE	16536				
	(85.7%)				
THERAPEUTICALLY EQUIVALENT	16431				
	(85.2%)				
NOT THERAPEUTICALLY EQUIVALENT	105				
	(0.5%)				
EXCEPTIONS ¹	73				
	(0.4%)				
NEW MOLECULAR ENTITIES APPROVED	25				
NUMBER OF APPLICANTS	1075				

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

1.7 CUMULATIVE SUPPLEMENT LEGEND

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

ABACAVIR SULFATE

SOLUTION;ORAL
ABACAVIR SULFATE

>A> AA	AUROBINDO PHARMA LTD	EQ 20MG BASE/ML	A077950	001	Mar 14, 2018	Feb NEWA
--------	----------------------	-----------------	---------	-----	--------------	----------

ABIRATERONE ACETATE

TABLET;ORAL
ZYTIGA

>D>	+	JANSSEN BIOTECH	250MG	N202379	001	Apr 28, 2011	Feb CHRS
>A>	+		250MG	N202379	001	Apr 28, 2011	Feb CHRS
>D>	+		500MG	N202379	002	Apr 14, 2017	Feb CHRS
>A>	+		500MG	N202379	002	Apr 14, 2017	Feb CHRS

ACETAMINOPHEN; BENZHYDROCODONE HYDROCHLORIDE

TABLET;ORAL
APADAZ

>A>	+	KEMPHARM	325MG;EQ 6.12MG BASE	N208653	001	Feb 23, 2018	Feb NEWA
-----	---	----------	----------------------	---------	-----	--------------	----------

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET;ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
@ FOSUN PHARMA 300MG;30MG
@ 300MG;60MG

A081250	001	Jul 16, 1992	Jan CAHN
A081249	001	Jul 16, 1992	Jan CAHN

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

SOLUTION;ORAL
OXYCODONE AND ACETAMINOPHEN
@ SPECGX LLC 325MG/5ML;5MG/5ML
OXYCODONE HYDROCHLORIDE AND ACETAMINOPHEN
@ VINTAGE PHARMS 325MG/5ML;5MG/5ML
TABLET;ORAL
OXYCODONE AND ACETAMINOPHEN

A040680	001	Sep 29, 2006	Jan DISC
A203573	001	Dec 18, 2014	Jan DISC

AA	ABHAI LLC	325MG;2.5MG	A210644	001	Feb 09, 2018	Jan NEWA
AA		325MG;5MG	A210644	002	Feb 09, 2018	Jan NEWA
AA		325MG;7.5MG	A210644	003	Feb 09, 2018	Jan NEWA
AA		325MG;10MG	A210644	004	Feb 09, 2018	Jan NEWA

ACETIC ACID, GLACIAL

SOLUTION/DROPS;OTIC
ACETIC ACID

>A> AT	RISING PHARMS INC	2%	A207280	001	Mar 09, 2018	Feb NEWA
--------	-------------------	----	---------	-----	--------------	----------

ACYCLOVIR

TABLET;ORAL
ACYCLOVIR

>A> AB	YILING PHARM LTD	400MG	A210401	001	Mar 07, 2018	Feb NEWA
>A> AB		800MG	A210401	002	Mar 07, 2018	Feb NEWA

ADAPALENE; BENZOYL PEROXIDE

GEL;TOPICAL
ADAPALENE AND BENZOYL PEROXIDE

AB	PERRIGO ISRAEL	0.1%;2.5%	A205033	001	Jan 23, 2018	Jan NEWA
AB	TARO	0.1%;2.5%	A206959	001	Jan 24, 2018	Jan NEWA

ADENOSINE

INJECTABLE;INJECTION
ADENOSINE

>A> AP	GLAND PHARMA LTD	3MG/ML	A206778	001	Feb 16, 2018	Feb NEWA
--------	------------------	--------	---------	-----	--------------	----------

ALBUTEROL SULFATE

TABLET;ORAL
ALBUTEROL SULFATE
@ YAOPHARMA CO LTD EQ 2MG BASE
@ EQ 4MG BASE

A072151	001	Dec 05, 1989	Jan CAHN
A072152	001	Dec 05, 1989	Jan CAHN

ALBUTEROL SULFATE; IPRATROPIUM BROMIDE

SOLUTION; INHALATION

ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE

@ FOSUN PHARMA	EQ 0.083% BASE; 0.017%	A076867	001	Dec 21, 2006	Jan CAHN
----------------	------------------------	---------	-----	--------------	----------

ALENDRONATE SODIUM

TABLET; ORAL

ALENDRONATE SODIUM

AB	HANGZHOU BINJIANG	EQ 5MG BASE	A090258	001	Sep 24, 2009	Jan CAHN
AB		EQ 10MG BASE	A090258	002	Sep 24, 2009	Jan CAHN
AB		EQ 35MG BASE	A090258	003	Sep 24, 2009	Jan CAHN
AB		EQ 70MG BASE	A090258	004	Sep 24, 2009	Jan CAHN

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL

@ FOSUN PHARMA	100MG	A070268	001	Dec 31, 1985	Jan CAHN
----------------	-------	---------	-----	--------------	----------

ALOSETRON HYDROCHLORIDE

TABLET; ORAL

ALOSETRON HYDROCHLORIDE

>A> AB	PAR PHARM INC	EQ 0.5MG BASE	A206113	001	Feb 23, 2018	Feb NEWA
>A> AB		EQ 1MG BASE	A206113	002	Feb 23, 2018	Feb NEWA

AMANTADINE HYDROCHLORIDE

TABLET; ORAL

AMANTADINE HYDROCHLORIDE

AB	JUBILANT GENERICS	100MG	A210403	001	Feb 07, 2018	Jan NEWA	
>A>	TABLET, EXTENDED RELEASE; ORAL						
>A>	OSMOLEX ER						
>A>	+	OSMOTICA PHARM	EQ 129MG BASE	N209410	001	Feb 16, 2018	Feb NEWA
>A>	+		EQ 193MG BASE	N209410	002	Feb 16, 2018	Feb NEWA
>A>	+	!	EQ 258MG BASE	N209410	003	Feb 16, 2018	Feb NEWA

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMILORIDE HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

@ YAOPHARMA CO LTD	EQ 5MG ANHYDROUS; 50MG	A073357	001	Nov 27, 1991	Jan CAHN
--------------------	------------------------	---------	-----	--------------	----------

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HYDROCHLORIDE

AB	SUN PHARM INDS INC	10MG	A089399	002	Jul 14, 1987	Jan CMFD
AB		25MG	A089399	001	Jul 14, 1987	Jan CMFD
AB		50MG	A089399	003	Jul 14, 1987	Jan CMFD
AB		75MG	A089399	004	Jul 14, 1987	Jan CMFD
AB		100MG	A089399	005	Jul 14, 1987	Jan CMFD
AB		150MG	A089399	006	Jul 14, 1987	Jan CMFD

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HYDROCHLORIDE

@ FOSUN PHARMA	10MG; 2MG	A071062	001	Nov 27, 1987	Jan CAHN
@	10MG; 4MG	A071862	001	Dec 21, 1987	Jan CAHN
@	25MG; 4MG	A071064	001	Nov 27, 1987	Jan CAHN
@	50MG; 4MG	A071863	001	Dec 21, 1987	Jan CAHN
@ SANDOZ INC	25MG; 2MG	A071063	001	Nov 27, 1987	Jan CAHN

AMLODIPINE BESYLATE

TABLET; ORAL

AMLODIPINE BESYLATE

@ YAOPHARMA CO LTD	EQ 2.5MG BASE	A076859	001	Sep 10, 2007	Jan CAHN
@	EQ 5MG BASE	A076859	002	Sep 10, 2007	Jan CAHN
@	EQ 10MG BASE	A076859	003	Sep 10, 2007	Jan CAHN

AMMONIA N-13

INJECTABLE; INTRAVENOUS

AMMONIA N 13

>D> AP	IBA MOLECULAR N AM	18.8mCi-188mCi/5ML (3.75-37.5mCi/ML)	A204667	001	Apr 22, 2015	Feb CAHN
>A> AP	SOFIE	18.8mCi-188mCi/5ML (3.75-37.5	A204667	001	Apr 22, 2015	Feb CAHN

INJECTABLE; INTRAVENOUS
AMMONIA N 13

mCi/ML)

AMMONIUM LACTATE

CREAM; TOPICAL
LAC-HYDRIN

>D>	@ RANBAXY	EQ 12% BASE	N020508	001	Aug 29, 1996	Feb CAHN
>A>	@ SUN PHARM INDS INC	EQ 12% BASE	N020508	001	Aug 29, 1996	Feb CAHN
	LOTION; TOPICAL LAC-HYDRIN					
>D>	+ @ RANBAXY	EQ 12% BASE	N019155	001	Apr 24, 1985	Feb CAHN
>A>	+ @ SUN PHARM INDS INC	EQ 12% BASE	N019155	001	Apr 24, 1985	Feb CAHN

ANASTROZOLE

TABLET; ORAL
ARIMIDEX

AB	+! ANI PHARMS INC	1MG	N020541	001	Dec 27, 1995	Jan CAHN
----	-------------------	-----	---------	-----	--------------	----------

ANGIOTENSIN II ACETATE

SOLUTION; IV (INFUSION)
GIAPREZA

	+! LA JOLLA PHARM CO	EQ 2.5MG BASE/ML (EQ 2.5MG BASE/ML)	N209360	001	Dec 21, 2017	Jan CAIN
	+!	EQ 5MG BASE/2ML (EQ 2.5MG BASE/ML)	N209360	002	Dec 21, 2017	Jan CAIN

>A> APALUTAMIDE

TABLET; ORAL
ERLEADA

>A>	+! JANSSEN BIOTECH	60MG	N210951	001	Feb 14, 2018	Feb NEWA
-----	--------------------	------	---------	-----	--------------	----------

APREPITANT

CAPSULE; ORAL
APREPITANT

AB	GLENMARK PHARMS SA	40MG	A207777	001	Oct 12, 2017	Jan CAHN
AB		80MG	A207777	002	Oct 12, 2017	Jan CAHN
AB		125MG	A207777	003	Oct 12, 2017	Jan CAHN

ARGATROBAN

INJECTABLE; INJECTION
ARGATROBAN

AP	AMNEAL PHARMS CO	250MG/2.5ML (100MG/ML)	A206698	001	Jan 26, 2018	Jan NEWA
----	------------------	------------------------	---------	-----	--------------	----------

ARMODAFINIL

TABLET; ORAL
ARMODAFINIL

>A> AB	AUROBINDO PHARMA LTD	50MG	A206069	001	Mar 06, 2018	Feb NEWA
>A> AB		150MG	A206069	002	Mar 06, 2018	Feb NEWA
>A> AB		250MG	A206069	003	Mar 06, 2018	Feb NEWA

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL, ASPIRIN AND CAFFEINE

	@ FOSUN PHARMA	325MG; 50MG; 40MG	A086398	002	Apr 06, 1984	Jan CAHN
--	----------------	-------------------	---------	-----	--------------	----------

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
ORPHENGESIC

>A>	@ GALT PHARMS	385MG; 30MG; 25MG	A075141	001	May 29, 1998	Feb CAHN
>D>	@ PRINSTON INC	385MG; 30MG; 25MG	A075141	001	May 29, 1998	Feb CAHN
	ORPHENGESIC FORTE					
>A>	@ GALT PHARMS	770MG; 60MG; 50MG	A075141	002	May 29, 1998	Feb CAHN
>D>	@ PRINSTON INC	770MG; 60MG; 50MG	A075141	002	May 29, 1998	Feb CAHN

ASPIRIN; CARISOPRODOL

TABLET; ORAL
CARISOPRODOL AND ASPIRIN

	@ OXFORD PHARMS	325MG; 200MG	A040252	001	Dec 10, 1997	Jan DISC
--	-----------------	--------------	---------	-----	--------------	----------

ATOMOXETINE HYDROCHLORIDE

CAPSULE;ORAL

ATOMOXETINE HYDROCHLORIDE

>A>	AB	DR REDDYS LABS LTD	10MG	A090609	001	Feb 23, 2018	Feb NEWA
>A>	AB		18MG	A090609	002	Feb 23, 2018	Feb NEWA
>A>	AB		25MG	A090609	003	Feb 23, 2018	Feb NEWA
>A>	AB		40MG	A090609	004	Feb 23, 2018	Feb NEWA
>A>	AB		60MG	A090609	005	Feb 23, 2018	Feb NEWA
>A>	AB		80MG	A090609	006	Feb 23, 2018	Feb NEWA
>A>	AB		100MG	A090609	007	Feb 23, 2018	Feb NEWA

ATROPINE SULFATE

SOLUTION;IV (INFUSION), INTRAMUSCULAR, SUBCUTANEOUS, INTRAOSSEOUS, ENDOTRACHEAL

ATROPINE SULFATE

+! FRESSENIUS KABI USA 8MG/20ML (0.4MG/ML)

N209260 001 Jan 26, 2018 Jan NEWA

SOLUTION/DROPS;OPHTHALMIC

ISOPTO ATROPINE

>A>		ALCON LABS INC	1%	N208151	001	Dec 01, 2016	Feb CAHN
>D>		NOVARTIS PHARMS CORP	1%	N208151	001	Dec 01, 2016	Feb CAHN

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET;ORAL

DIPHENOXYLATE HYDROCHLORIDE AND ATROPINE SULFATE

@ FOSUN PHARMA 0.025MG;2.5MG

A086173 001 Jan CAHN

LONOX

@ FOSUN PHARMA 0.025MG;2.5MG

A085311 002 Jan CAHN

AVIBACTAM SODIUM; CEFTAZIDIME

POWDER;IV (INFUSION)

AVYCAZ

+! ALLERGAN SALES LLC EQ 0.5GM BASE;2GM/VIAL

N206494 001 Feb 25, 2015 Jan CAHN

BACITRACIN

INJECTABLE;INJECTION

BACITRACIN

@ MYLAN ASI 50,000 UNITS/VIAL

A090211 001 May 11, 2010 Jan DISC

BACLOFEN

INJECTABLE;INTRATHECAL

>A>		BACLOFEN					
>A>	AP	MYLAN LABS LTD	1MG/ML	A209594	001	Mar 06, 2018	Feb NEWA
		GABLOFEN					
>D>		+! PIRAMAL CRITICAL	1MG/ML	N022462	004	Jun 22, 2012	Feb CFTG
>A>	AP	+!	1MG/ML	N022462	004	Jun 22, 2012	Feb CFTG

BARIUM SULFATE

SUSPENSION;ORAL

VARIBAR THIN HONEY

+! BRACCO 40% (100GM/250ML)

N208143 006 Jan 23, 2018 Jan NEWA

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED;INHALATION

QVAR REDHALER

+! NORTON WATERFORD 0.04MG/INH

N207921 001 Aug 03, 2017 Jan CHRS

BENZTROPINE MESYLATE

TABLET;ORAL

BENZTROPINE MESYLATE

@ CHARTWELL RX 1MG

A081264 001 Jan 23, 1992 Jan CAHN

@ 2MG

A081265 001 Jan 23, 1992 Jan CAHN

BETAMETHASONE DIPROPIONATE

LOTION;TOPICAL

BETAMETHASONE DIPROPIONATE

AB		HI-TECH PHARMACAL	EQ 0.05% BASE	A209896	001	Feb 06, 2018	Jan NEWA
----	--	-------------------	---------------	---------	-----	--------------	----------

LOTION, AUGMENTED;TOPICAL

BETAMETHASONE DIPROPIONATE

AB		TELLIGENT PHARMA INC	EQ 0.05% BASE	A206389	001	Feb 13, 2018	Jan NEWA
----	--	----------------------	---------------	---------	-----	--------------	----------

BETAMETHASONE VALERATE

LOTION;TOPICAL
BETA-VAL

@ G AND W LABS INC EQ 0.1% BASE A070072 001 Jun 27, 1985 Jan DISC

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC
BETOPTIC

AT +! SANDOZ INC EQ 0.5% BASE N019270 001 Aug 30, 1985 Jan CAHN

BICALUTAMIDE

TABLET;ORAL
CASODEX

AB +! ANI PHARMS INC 50MG N020498 001 Oct 04, 1995 Jan CAHN

>A> BICTEGRAVIR SODIUM; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE

>A> TABLET;ORAL

>A> BIKTARVY

>A> +! GILEAD SCIENCES INC EQ 50MG BASE;200MG;EQ 25MG BASE N210251 001 Feb 07, 2018 Feb NEWA

BISMUTH SUBCITRATE POTASSIUM; METRONIDAZOLE; TETRACYCLINE

CAPSULE;ORAL
PYLERA

+! ALLERGAN SALES LLC 140MG;125MG;125MG N050786 001 Sep 28, 2006 Jan CAHN

BIVALIRUDIN

SOLUTION;IV (INFUSION)
BIVALIRUDIN IN 0.9% SODIUM CHLORIDE

+! BAXTER HLTHCARE CORP 250MG/50ML (5MG/ML) N208374 001 Dec 21, 2017 Jan CAHN

+! 500MG/100ML (5MG/ML) N208374 002 Dec 21, 2017 Jan CAHN

BUMETANIDE

TABLET;ORAL
BUMETANIDE

AB UPSHER-SMITH LABS 0.5MG A209916 001 Jan 23, 2018 Jan NEWA

AB 1MG A209916 002 Jan 23, 2018 Jan NEWA

AB 2MG A209916 003 Jan 23, 2018 Jan NEWA

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
BUPROPION HYDROCHLORIDE

AB2 SCIEGEN PHARMS INC 150MG A206122 001 Aug 17, 2016 Jan CAHN

BUSPIRONE HYDROCHLORIDE

TABLET;ORAL
BUSPIRONE HYDROCHLORIDE

>A> AB AUROBINDO PHARMA LTD 5MG A078246 001 Feb 27, 2009 Feb CAHN

>A> AB 10MG A078246 002 Feb 27, 2009 Feb CAHN

>A> AB 15MG A078246 003 Feb 27, 2009 Feb CAHN

>A> AB 30MG A078246 004 Feb 27, 2009 Feb CAHN

>D> AB DR REDDYS LABS LTD 5MG A078246 001 Feb 27, 2009 Feb CAHN

>D> AB 10MG A078246 002 Feb 27, 2009 Feb CAHN

>D> AB 15MG A078246 003 Feb 27, 2009 Feb CAHN

>D> AB 30MG A078246 004 Feb 27, 2009 Feb CAHN

@ FOSUN PHARMA 5MG A075413 001 Mar 19, 2002 Jan CAHN

@ 10MG A075413 002 Mar 19, 2002 Jan CAHN

@ 15MG A075413 003 Mar 19, 2002 Jan CAHN

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE;INJECTION

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

+ @ ICU MEDICAL INC 20MG/100ML;5GM/100ML;104MG/100ML;6 00MG/100ML;310MG/100ML N019685 005 Oct 17, 1988 Jan CRLD

+ @ 20MG/100ML;5GM/100ML;179MG/100ML;6 00MG/100ML;310MG/100ML N019685 006 Oct 17, 1988 Jan CRLD

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

+ @ ICU MEDICAL INC 20MG/100ML;5GM/100ML;254MG/100ML;6 00MG/100ML;310MG/100ML N019685 007 Oct 17, 1988 Jan CRLD

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

AP + ICU MEDICAL INC 20MG/100ML;5GM/100ML;179MG/100ML;6 00MG/100ML;310MG/100ML N019685 002 Oct 17, 1988 Jan CRLD

+ @ 20MG/100ML;5GM/100ML;328MG/100ML; N019685 008 Oct 17, 1988 Jan DISC

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER		600MG/100ML; 310MG/100ML				
POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER						
+ @	ICU MEDICAL INC	20MG/100ML; 5GM/100ML; 254MG/100ML; 600MG/100ML; 310MG/100ML	N019685	003	Oct 17, 1988	Jan CRLD
POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER						
+ @	ICU MEDICAL INC	20MG/100ML; 5GM/100ML; 328MG/100ML; 600MG/100ML; 310MG/100ML	N019685	004	Oct 17, 1988	Jan DISC
POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER						
+ @	ICU MEDICAL INC	20MG/100ML; 5GM/100ML; 104MG/100ML; 600MG/100ML; 310MG/100ML	N019685	001	Oct 17, 1988	Jan CRLD

CANDESARTAN CILEXETIL

TABLET; ORAL

ATACAND

AB	+	ANI PHARMS INC	4MG	N020838	001	Jun 04, 1998	Jan CAHN
AB	+		8MG	N020838	002	Jun 04, 1998	Jan CAHN
AB	+		16MG	N020838	003	Jun 04, 1998	Jan CAHN
AB	+	!	32MG	N020838	004	Jun 04, 1998	Jan CAHN

CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL

ATACAND HCT

>A>	AB	+	ANI PHARMS INC	16MG; 12.5MG	N021093	001	Sep 05, 2000	Feb CAHN
>A>	AB	+		32MG; 12.5MG	N021093	002	Sep 05, 2000	Feb CAHN
>A>	AB	+	!	32MG; 25MG	N021093	003	May 16, 2008	Feb CAHN
>D>	AB	+	ASTRAZENECA	16MG; 12.5MG	N021093	001	Sep 05, 2000	Feb CAHN
>D>	AB	+		32MG; 12.5MG	N021093	002	Sep 05, 2000	Feb CAHN
>D>	AB	+	!	32MG; 25MG	N021093	003	May 16, 2008	Feb CAHN

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

@	YAOPHARMA CO LTD	12.5MG	A074363	001	Nov 09, 1995	Jan CAHN
@		12.5MG	A074519	001	Feb 13, 1996	Jan CAHN
@		25MG	A074363	002	Nov 09, 1995	Jan CAHN
@		25MG	A074519	002	Feb 13, 1996	Jan CAHN
@		50MG	A074363	003	Nov 09, 1995	Jan CAHN
@		50MG	A074519	003	Feb 13, 1996	Jan CAHN
@		100MG	A074363	004	Nov 09, 1995	Jan CAHN
@		100MG	A074519	004	Feb 13, 1996	Jan CAHN

CAPTOPRIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL

CAPTOPRIL AND HYDROCHLOROTHIAZIDE

@	G AND W LABS INC	25MG; 15MG	A074827	001	Dec 29, 1997	Jan DISC
@		25MG; 25MG	A074827	002	Dec 29, 1997	Jan DISC
@		50MG; 15MG	A074827	004	Dec 29, 1997	Jan DISC
@		50MG; 25MG	A074827	003	Dec 29, 1997	Jan DISC
	MYLAN	25MG; 15MG	A074896	001	Dec 29, 1997	Jan CTEC
!		25MG; 25MG	A074896	002	Dec 29, 1997	Jan CTEC
!		50MG; 15MG	A074896	004	Dec 29, 1997	Jan CTEC
		50MG; 25MG	A074896	003	Dec 29, 1997	Jan CTEC

CARIPRAZINE HYDROCHLORIDE

CAPSULE; ORAL

VRAYLAR

+	ALLERGAN SALES LLC	EQ 1.5MG BASE	N204370	001	Sep 17, 2015	Jan CAHN
+		EQ 3MG BASE	N204370	002	Sep 17, 2015	Jan CAHN
+		EQ 4.5MG BASE	N204370	003	Sep 17, 2015	Jan CAHN
+	!	EQ 6MG BASE	N204370	004	Sep 17, 2015	Jan CAHN

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

@	FOSUN PHARMA	350MG	A081025	001	Apr 13, 1989	Jan CAHN
---	--------------	-------	---------	-----	--------------	----------

CEFEPIME HYDROCHLORIDE

INJECTABLE;INJECTION
CEFEPIME HYDROCHLORIDE

@ FOSUN PHARMA	EQ 500MG BASE/VIAL	A090291	001	Dec 21, 2010	Jan CAHN
@	EQ 1GM BASE/VIAL	A090291	002	Dec 21, 2010	Jan CAHN
@	EQ 2GM BASE/VIAL	A090291	003	Dec 21, 2010	Jan CAHN

CEFOTAXIME SODIUM

INJECTABLE;INJECTION
CEFOTAXIME SODIUM

>D> AP	LUPIN	EQ 500MG BASE/VIAL	A065124	001	Sep 24, 2003	Feb DISC
>A>	@	EQ 500MG BASE/VIAL	A065124	001	Sep 24, 2003	Feb DISC
>D> AP		EQ 1GM BASE/VIAL	A065124	002	Sep 24, 2003	Feb DISC
>A>	@	EQ 1GM BASE/VIAL	A065124	002	Sep 24, 2003	Feb DISC
>D> AP		EQ 2GM BASE/VIAL	A065124	003	Sep 24, 2003	Feb DISC
>A>	@	EQ 2GM BASE/VIAL	A065124	003	Sep 24, 2003	Feb DISC

CEFTAROLINE FOSAMIL

POWDER;IV (INFUSION)
TEFLARO

+ ALLERGAN SALES LLC	400MG/VIAL	N200327	001	Oct 29, 2010	Jan CAHN
+!	600MG/VIAL	N200327	002	Oct 29, 2010	Jan CAHN

CEFTIBUTEN DIHYDRATE

CAPSULE;ORAL
CEDAX

@ SI PHARMS	EQ 400MG BASE	N050685	002	Dec 20, 1995	Jan CAHN
FOR SUSPENSION;ORAL					
CEDAX					
+ @ SI PHARMS	EQ 90MG BASE/5ML	N050686	001	Dec 20, 1995	Jan CAHN
+ @	EQ 180MG BASE/5ML	N050686	002	Dec 20, 1995	Jan CAHN

CEFTRIAXONE SODIUM

INJECTABLE;INJECTION
CEFTRIAXONE

>D> AP	LUPIN	EQ 10GM BASE/VIAL	A065263	001	Sep 12, 2006	Feb DISC
>A>	@	EQ 10GM BASE/VIAL	A065263	001	Sep 12, 2006	Feb DISC

CEFUROXIME AXETIL

TABLET;ORAL
CEFUROXIME AXETIL

@ SANDOZ INC	EQ 250MG BASE	A065126	001	Oct 28, 2003	Jan CAHN
@	EQ 500MG BASE	A065126	002	Oct 28, 2003	Jan CAHN

CELECOXIB

CAPSULE;ORAL
CELECOXIB

AB	CSPC OUYI PHARM CO	50MG	A210071	001	Jan 23, 2018	Jan NEWA
AB		100MG	A210071	002	Jan 23, 2018	Jan NEWA
AB		200MG	A210071	003	Jan 23, 2018	Jan NEWA

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE;ORAL
SONAZINE

@ FOSUN PHARMA	30MG/ML	A080983	004		Jan CAHN
@	100MG/ML	A080983	005		Jan CAHN

SYRUP;ORAL

@ FOSUN PHARMA	10MG/5ML	A083040	001		Jan CAHN
----------------	----------	---------	-----	--	----------

CICLOPIROX

SOLUTION;TOPICAL
CICLOPIROX

AT	INGENUS PHARMS LLC	8%	A078124	001	Sep 18, 2007	Jan CAHN
----	--------------------	----	---------	-----	--------------	----------

CIMETIDINETABLET;ORAL
CIMETIDINE

@	CHARTWELL MOLECULES	200MG	A074329	002	May 17, 1994	Jan CMS1
@		300MG	A074329	003	May 17, 1994	Jan CMS1
@		400MG	A074329	004	May 17, 1994	Jan CMS1
@	YAOPHARMA CO LTD	200MG	A074100	001	Jan 31, 1995	Jan CAHN
@		300MG	A074100	002	Jan 31, 1995	Jan CAHN
@		400MG	A074100	003	Jan 31, 1995	Jan CAHN
@		800MG	A074100	004	Jan 31, 1995	Jan CAHN

CINACALCET HYDROCHLORIDE

TABLET;ORAL

CINACALCET HYDROCHLORIDE

>A>	AB	AUROBINDO PHARMA LTD	EQ 30MG BASE	A206125	001	Mar 08, 2018	Feb NEWA
>A>	AB		EQ 60MG BASE	A206125	002	Mar 08, 2018	Feb NEWA
>A>	AB		EQ 90MG BASE	A206125	003	Mar 08, 2018	Feb NEWA
>A>	AB	CIPLA LTD	EQ 30MG BASE	A208915	001	Mar 08, 2018	Feb NEWA
>A>	AB		EQ 60MG BASE	A208915	002	Mar 08, 2018	Feb NEWA
>A>	AB		EQ 90MG BASE	A208915	003	Mar 08, 2018	Feb NEWA
		SENSIPAR					
>D>	+	AMGEN	EQ 30MG BASE	N021688	001	Mar 08, 2004	Feb CFTG
>A>	AB	+	EQ 30MG BASE	N021688	001	Mar 08, 2004	Feb CFTG
>D>	+		EQ 60MG BASE	N021688	002	Mar 08, 2004	Feb CFTG
>A>	AB	+	EQ 60MG BASE	N021688	002	Mar 08, 2004	Feb CFTG
>D>	+	+	EQ 90MG BASE	N021688	003	Mar 08, 2004	Feb CFTG
>A>	AB	+	EQ 90MG BASE	N021688	003	Mar 08, 2004	Feb CFTG

CIPROFLOXACIN

INJECTABLE;INJECTION

CIPROFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	INFORLIFE	200MG/100ML	A078252	001	Mar 18, 2008	Jan CAHN
AP		400MG/200ML	A078252	002	Mar 18, 2008	Jan CAHN

CIPROFLOXACIN HYDROCHLORIDE

TABLET;ORAL

CIPROFLOXACIN HYDROCHLORIDE

@	FOSUN PHARMA	EQ 250MG BASE	A076593	002	Jun 09, 2004	Jan CAHN
@		EQ 500MG BASE	A076593	003	Jun 09, 2004	Jan CAHN
@		EQ 750MG BASE	A076593	004	Jun 09, 2004	Jan CAHN

CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

CIPROFLOXACIN EXTENDED RELEASE

@	FOSUN PHARMA	212.6MG;EQ 287.5MG BASE	A078712	001	Dec 11, 2007	Jan CAHN
---	--------------	-------------------------	---------	-----	--------------	----------

CITALOPRAM HYDROBROMIDE

TABLET;ORAL

CELEXA

AB	+	ALLERGAN SALES LLC	EQ 10MG BASE	N020822	001	Apr 27, 2000	Jan CAHN
AB	+		EQ 20MG BASE	N020822	002	Jul 17, 1998	Jan CAHN
AB	+	+	EQ 40MG BASE	N020822	003	Jul 17, 1998	Jan CAHN
		@	EQ 60MG BASE	N020822	004	Jul 17, 1998	Jan CAHN

CITALOPRAM HYDROBROMIDE

@	FOSUN PHARMA	EQ 10MG BASE	A077035	001	Oct 28, 2004	Jan CAHN
@		EQ 10MG BASE	A077040	001	Aug 17, 2005	Jan CAHN
@		EQ 20MG BASE	A077035	002	Oct 28, 2004	Jan CAHN
@		EQ 20MG BASE	A077040	002	Aug 17, 2005	Jan CAHN
@		EQ 40MG BASE	A077035	003	Oct 28, 2004	Jan CAHN
@		EQ 40MG BASE	A077040	003	Aug 17, 2005	Jan CAHN

CLINDAMYCIN PHOSPHATE

SOLUTION;TOPICAL

CLINDAMYCIN PHOSPHATE

AT	GLASSHOUSE PHARMS	EQ 1% BASE	A209846	001	Feb 08, 2018	Jan NEWA
----	-------------------	------------	---------	-----	--------------	----------

CLOBETASOL PROPIONATE

CREAM;TOPICAL

CLOBETASOL PROPIONATE

AB1	LUPIN LTD	0.05%	A210208	001	Jan 30, 2018	Jan NEWA
	IMPOYZ					
	+! ENCORE DERMAT	0.025%	N209483	001	Nov 28, 2017	Jan CAHN

CLONIDINE HYDROCHLORIDE

TABLET;ORAL

CLONIDINE HYDROCHLORIDE

@ AUROLIFE PHARMA LLC 0.1MG

A070886 002 Aug 31, 1988 Jan CMS1

@ 0.3MG

A070886 003 Aug 31, 1988 Jan CMS1

TABLET, EXTENDED RELEASE;ORAL

CLONIDINE HYDROCHLORIDE

AB1	JUBILANT GENERICS	0.1MG	A210338	001	Jan 29, 2018	Jan NEWA
-----	-------------------	-------	---------	-----	--------------	----------

CLOZAPINE

TABLET;ORAL

CLOZAPINE

>D> AB	ZYDUS PHARMS USA INC	25MG	A209480	001	Dec 06, 2017	Feb DISC
>A>	@	25MG	A209480	001	Dec 06, 2017	Feb DISC
>D> AB		50MG	A209480	002	Dec 06, 2017	Feb DISC
>A>	@	50MG	A209480	002	Dec 06, 2017	Feb DISC
>D> AB		100MG	A209480	003	Dec 06, 2017	Feb DISC
>A>	@	100MG	A209480	003	Dec 06, 2017	Feb DISC
>D> AB		200MG	A209480	004	Dec 06, 2017	Feb DISC
>A>	@	200MG	A209480	004	Dec 06, 2017	Feb DISC

CROMOLYN SODIUM

SOLUTION/DROPS;OPHTHALMIC

CROMOLYN SODIUM

AT	SANDOZ INC	4%	A075282	001	Jun 16, 1999	Jan CAHN
----	------------	----	---------	-----	--------------	----------

CROTAMITON

CREAM;TOPICAL

EURAX

>D>	+! RANBAXY	10%	N006927	001		Feb CAHN
>A>	+! SUN PHARM INDS INC	10%	N006927	001		Feb CAHN

LOTION;TOPICAL

EURAX

>D> AT	+! RANBAXY	10%	N009112	003		Feb CAHN
>A> AT	+! SUN PHARM INDS INC	10%	N009112	003		Feb CAHN

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

CYCLOGYL

>A> AT	! ALCON LABS INC	0.5%	A084109	001		Feb CAHN
>A> AT	!	1%	A084110	001		Feb CAHN
>A>	!	2%	A084108	001		Feb CAHN
>D> AT	! NOVARTIS PHARMS CORP	0.5%	A084109	001		Feb CAHN
>D> AT	!	1%	A084110	001		Feb CAHN
>D>	!	2%	A084108	001		Feb CAHN

CYCLOPENTOLATE HYDROCHLORIDE; PHENYLEPHRINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

CYCLOMYDRIL

>A>	! ALCON LABS INC	0.2%;1%	A084300	001		Feb CAHN
>D>	! NOVARTIS PHARMS CORP	0.2%;1%	A084300	001		Feb CAHN

CYPROHEPTADINE HYDROCHLORIDE

TABLET;ORAL

CYPROHEPTADINE HYDROCHLORIDE

	@ FOSUN PHARMA	4MG	A086808	001		Jan CAHN
AA	MOUNTAIN	4MG	A040537	001	Sep 30, 2003	Jan CAHN

CYTARABINEINJECTABLE; INJECTION
CYTARABINE

AP	MYLAN LABS LTD	20MG/ML	A200916	001	Dec 13, 2011	Jan CAHN
----	----------------	---------	---------	-----	--------------	----------

DAPTOMYCINPOWDER; INTRAVENOUS
DAPTOMYCIN

>D>	AP	TEVA PARENTERAL	500MG/VIAL	A091039	001	Mar 25, 2016	Feb CAHN
>A>	AP	TEVA PHARMS USA	500MG/VIAL	A091039	001	Mar 25, 2016	Feb CAHN

DESFLURANE

LIQUID; INHALATION

>A>		DESFLURANE					
>A>	AN	SHANGHAI HENGRUI	100%	A208234	001	Feb 26, 2018	Feb NEWA
		SUPRANE					
>D>		+! BAXTER HLTHCARE	99.9%	N020118	001	Sep 18, 1992	Feb CFTG
>A>	AN	+!	100%	N020118	001	Sep 18, 1992	Feb CFTG

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HYDROCHLORIDE

>D>	AB	COREPHARMA	10MG	A205153	001	Oct 28, 2016	Feb CAHN
>D>	AB		25MG	A205153	002	Oct 28, 2016	Feb CAHN
>D>	AB		50MG	A205153	003	Oct 28, 2016	Feb CAHN
>D>	AB		75MG	A205153	004	Oct 28, 2016	Feb CAHN
>D>	AB		100MG	A205153	005	Oct 28, 2016	Feb CAHN
>D>	AB		150MG	A205153	006	Oct 28, 2016	Feb CAHN
>A>	AB	MOUNTAIN	10MG	A205153	001	Oct 28, 2016	Feb CAHN
>A>	AB		25MG	A205153	002	Oct 28, 2016	Feb CAHN
>A>	AB		50MG	A205153	003	Oct 28, 2016	Feb CAHN
>A>	AB		75MG	A205153	004	Oct 28, 2016	Feb CAHN
>A>	AB		100MG	A205153	005	Oct 28, 2016	Feb CAHN
>A>	AB		150MG	A205153	006	Oct 28, 2016	Feb CAHN

DEXAMETHASONE

ELIXIR; ORAL

HEXADROL

>A>		@ ASPEN GLOBAL INC	0.5MG/5ML	N012674	001		Feb CAHN
>D>		@ ORGANON USA INC	0.5MG/5ML	N012674	001		Feb CAHN
>A>		SUSPENSION; INTRAOCULAR					
>A>		DEXYCU KIT					
>A>		+! ICON BIOSCIENCE	9%	N208912	001	Feb 09, 2018	Feb NEWA

TABLET; ORAL

DEXAMETHASONE

BP	FERA PHARMS LLC	0.5MG	A088148	001	Apr 28, 1983	Jan CAHN
BP		0.75MG	A088160	001	Apr 28, 1983	Jan CAHN
BP		4MG	A088238	001	Apr 28, 1983	Jan CAHN
BP		6MG	A088481	001	Nov 28, 1983	Jan CAHN

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

HEXADROL

>A>		+ @ ASPEN GLOBAL INC	EQ 4MG PHOSPHATE/ML	N014694	002		Feb CAHN
>A>		+ @	EQ 10MG PHOSPHATE/ML	N014694	003		Feb CAHN
>A>		@	EQ 20MG PHOSPHATE/ML	N014694	004		Feb CAHN
>D>		+ @ ORGANON USA INC	EQ 4MG PHOSPHATE/ML	N014694	002		Feb CAHN
>D>		+ @	EQ 10MG PHOSPHATE/ML	N014694	003		Feb CAHN
>D>		@	EQ 20MG PHOSPHATE/ML	N014694	004		Feb CAHN

DEXMEDETOMIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

DEXMEDETOMIDINE HYDROCHLORIDE

>A>	AP	ZYDUS PHARMS USA INC	EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML)	A206798	001	Feb 27, 2018	Feb NEWA
-----	----	----------------------	--	---------	-----	--------------	----------

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP;ORAL

PROMETH W/ DEXTROMETHORPHAN

@ G AND W LABS INC	15MG/5ML;6.25MG/5ML	A088762	001	Oct 31, 1984	Jan DISC
--------------------	---------------------	---------	-----	--------------	----------

DEXTROSE

INJECTABLE;INJECTION

DEXTROSE 5% IN PLASTIC CONTAINER

>D> AP	+	!	HOSPIRA	50MG/ML	N019222	001	Jul 13, 1984	Feb CAHN
>A> AP	+	!	ICU MEDICAL INC	50MG/ML	N019222	001	Jul 13, 1984	Feb CAHN
DEXTROSE 70% IN PLASTIC CONTAINER								
>A> AP	+	!	B BRAUN	70GM/100ML	N019626	005	Feb 18, 2015	Feb NEWA

DEXTROSE; SODIUM CHLORIDE

INJECTABLE;INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	+		ICU MEDICAL INC	5GM/100ML;450MG/100ML	N017607	001		Jan CRLD
----	---	--	-----------------	-----------------------	---------	-----	--	----------

DICYCLOMINE HYDROCHLORIDE

CAPSULE;ORAL

BENTYL

AB	+	!	ALLERGAN SALES LLC	10MG	N007409	003	Oct 15, 1984	Jan CAHN
----	---	---	--------------------	------	---------	-----	--------------	----------

INJECTABLE;INJECTION

BENTYL

AP	+	!	ALLERGAN SALES LLC	10MG/ML	N008370	001	Oct 15, 1984	Jan CAHN
----	---	---	--------------------	---------	---------	-----	--------------	----------

BENTYL PRESERVATIVE FREE

AP	+	!	ALLERGAN SALES LLC	10MG/ML	N008370	002	Oct 15, 1984	Jan CAHN
----	---	---	--------------------	---------	---------	-----	--------------	----------

TABLET;ORAL

BENTYL

AB	+	!	ALLERGAN SALES LLC	20MG	N007409	001	Oct 15, 1984	Jan CAHN
----	---	---	--------------------	------	---------	-----	--------------	----------

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE;ORAL

DIPHENHYDRAMINE HYDROCHLORIDE

@ FOSUN PHARMA	25MG	A080832	001		Jan CAHN
@	25MG	A080845	002		Jan CAHN
@	50MG	A080832	002		Jan CAHN
@	50MG	A080845	001		Jan CAHN

DOCETAXEL

INJECTABLE;INJECTION

DOCETAXEL

AP		AMNEAL PHARMS CO	20MG/ML (20MG/ML)	A209640	001	Jan 19, 2018	Jan NEWA
AP			80MG/4ML (20MG/ML)	A209640	002	Jan 19, 2018	Jan NEWA
AP			160MG/8ML (20MG/ML)	A209640	003	Jan 19, 2018	Jan NEWA

DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC

DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE

@ ZAMBON SPA	EQ 2% BASE;EQ 0.5% BASE	A091180	001	Dec 04, 2013	Jan DISC
--------------	-------------------------	---------	-----	--------------	----------

DOXAZOSIN MESYLATE

TABLET;ORAL

DOXAZOSIN MESYLATE

AB		HERITAGE PHARMA	EQ 1MG BASE	A205210	001	Feb 13, 2018	Jan NEWA
AB			EQ 2MG BASE	A205210	002	Feb 13, 2018	Jan NEWA
AB			EQ 4MG BASE	A205210	003	Feb 13, 2018	Jan NEWA
AB			EQ 8MG BASE	A205210	004	Feb 13, 2018	Jan NEWA
AB		IDT AUSTRALIA LTD	EQ 1MG BASE	A075432	001	Oct 18, 2000	Jan CMFD
AB			EQ 2MG BASE	A075432	002	Oct 18, 2000	Jan CMFD
AB			EQ 4MG BASE	A075432	003	Oct 18, 2000	Jan CMFD
AB			EQ 8MG BASE	A075432	004	Oct 18, 2000	Jan CMFD
		@ YAOPHARMA CO LTD	EQ 1MG BASE	A075646	001	Oct 18, 2000	Jan CAHN
		@	EQ 2MG BASE	A075646	002	Oct 18, 2000	Jan CAHN
		@	EQ 4MG BASE	A075646	003	Oct 18, 2000	Jan CAHN
		@	EQ 8MG BASE	A075646	004	Oct 18, 2000	Jan CAHN

DOXEPIN HYDROCHLORIDE

TABLET;ORAL

DOXEPIN HYDROCHLORIDE

@ ACTAVIS ELIZABETH EQ 3MG BASE

A201951 001 Jul 26, 2013 Jan DISC

@ EQ 6MG BASE

A201951 002 Jul 26, 2013 Jan DISC

SILENOR

+ PERNIX THERAPS LLC EQ 3MG BASE

N022036 001 Mar 17, 2010 Jan CTEC

+! EQ 6MG BASE

N022036 002 Mar 17, 2010 Jan CTEC

DROSPIRENONE; ETHINYL ESTRADIOL

TABLET;ORAL

LO-ZUMANDIMINE

>A> AB AUROBINDO PHARMA LTD 3MG;0.02MG

A209632 001 Feb 27, 2018 Feb NEWA

EFAVIRENZ

TABLET;ORAL

EFAVIRENZ

>A> AB STRIDES PHARMA 600MG

A204869 001 Mar 12, 2018 Feb NEWA

>A> EFAVIRENZ; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE

>A> TABLET;ORAL

>A> SYMFI LO

>A> +! MYLAN PHARMS INC 400MG;300MG;300MG

N208255 001 Feb 05, 2018 Feb NEWA

EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL

EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE

AB AUROBINDO PHARMA LTD 200MG;300MG

A090513 001 Jan 26, 2018 Jan NEWA

EPTIFIBATIDE

INJECTABLE;INJECTION

EPTIFIBATIDE

>A> AP SAGENT PHARMS 2MG/ML

A204693 001 Mar 07, 2018 Feb NEWA

>A> AP 75MG/100ML

A204693 002 Mar 07, 2018 Feb NEWA

ERTUGLIFLOZIN; SITAGLIPTIN PHOSPHATE

TABLET;ORAL

STEGLUJAN

+ MERCK SHARP DOHME 5MG;EQ 100MG BASE

N209805 001 Dec 19, 2017 Jan CMS1

+! 15MG;EQ 100MG BASE

N209805 002 Dec 19, 2017 Jan CMS1

ERYTHROMYCIN

TABLET;ORAL

ERYTHROMYCIN

>A> AB AMNEAL PHARMS CO 250MG

A209720 001 Mar 09, 2018 Feb NEWA

>A> AB 500MG

A209720 002 Mar 09, 2018 Feb NEWA

>D> ARBOR PHARMS LLC 250MG

A061621 001 Feb CTEC

>A> AB 250MG

A061621 001 Feb CTEC

>D> ! 500MG

A061621 002 Feb CTEC

>A> AB ! 500MG

A061621 002 Feb CTEC

ESCITALOPRAM OXALATE

SOLUTION;ORAL

LEXAPRO

AA +! ALLERGAN SALES LLC EQ 5MG BASE/5ML

N021365 001 Nov 27, 2002 Jan CAHN

TABLET;ORAL

LEXAPRO

AB + ALLERGAN SALES LLC EQ 5MG BASE

N021323 001 Aug 14, 2002 Jan CAHN

AB + EQ 10MG BASE

N021323 002 Aug 14, 2002 Jan CAHN

AB +! EQ 20MG BASE

N021323 003 Aug 14, 2002 Jan CAHN

ESTRADIOL

CREAM;VAGINAL

ESTRADIOL

>A> AB ALVOGEN PINE BROOK 0.01%

A209767 001 Mar 05, 2018 Feb NEWA

AB PERRIGO UK FINCO 0.01%

A210194 001 Jan 22, 2018 Jan NEWA

ESTRADIOL VALERATEINJECTABLE; INJECTION
ESTRADIOL VALERATE

@ FOSUN PHARMA	10MG/ML	A040628	001	Oct 04, 2007	Jan CAHN
@	20MG/ML	A040628	002	Oct 04, 2007	Jan CAHN
@	40MG/ML	A040628	003	Oct 04, 2007	Jan CAHN

ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

ESTRADIOL AND NORETHINDRONE ACETATE

>A> AB	ACCORD HLTHCARE	1MG;0.5MG	A210233	001	Feb 28, 2018	Feb NEWA
--------	-----------------	-----------	---------	-----	--------------	----------

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL

BALCOLTRA

>A>	AVION PHARMS	0.02MG;0.1MG	N208612	001	Jan 09, 2018	Feb CAHN
>D>	NEUVOSYN LABS LLC	0.02MG;0.1MG	N208612	001	Jan 09, 2018	Feb CAHN
		0.02MG;0.1MG	N208612	001	Jan 09, 2018	Jan NEWA

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

MODICON 28

>D> AB	+! JANSSEN PHARMS	0.035MG;0.5MG	N017735	001		Feb DISC
>A>	+ @	0.035MG;0.5MG	N017735	001		Feb DISC

WERA

>D> AB	NOVAST LABS LTD	0.035MG;0.5MG	A091204	001	Mar 27, 2012	Feb CHRS
>A> AB	!	0.035MG;0.5MG	A091204	001	Mar 27, 2012	Feb CHRS

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET, CHEWABLE, TABLET; ORAL

LO MINASTRIN FE

+ @ APIL	0.01MG,0.01MG,N/A;1MG,N/A,N/A	N204654	001	Jul 24, 2013	Jan DISC
----------	-------------------------------	---------	-----	--------------	----------

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

>A>	@ PLD ACQUISITIONS	20MG	A075302	001	Apr 16, 2001	Feb CAHN
>A>	@	40MG	A075302	002	Apr 16, 2001	Feb CAHN
>D>	@ SANDOZ	20MG	A075302	001	Apr 16, 2001	Feb CAHN
>D>	@	40MG	A075302	002	Apr 16, 2001	Feb CAHN

FENOFIBRATE

TABLET; ORAL

FENOFIBRATE

AB	AMNEAL PHARMS LLC	48MG	A209951	001	Feb 09, 2018	Jan NEWA
AB		145MG	A209951	002	Feb 09, 2018	Jan NEWA

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL

DURAGESIC-37

+ JANSSEN PHARMS	37.5MCG/HR	N019813	006	Jan 24, 2018	Jan NEWA
------------------	------------	---------	-----	--------------	----------

FLUCONAZOLE

INJECTABLE; INJECTION

FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	! INFORLIFE	200MG/100ML (2MG/ML)	A079104	001	Jul 30, 2009	Jan CAHN
AP	!	400MG/200ML (2MG/ML)	A079104	002	Jul 30, 2009	Jan CAHN

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

FLUOCINOLONE ACETONIDE

@ G AND W LABS	0.025%	A089525	001	Jul 26, 1988	Jan DISC
----------------	--------	---------	-----	--------------	----------

SOLUTION; TOPICAL

FLUOCINOLONE ACETONIDE

@ G AND W LABS INC	0.01%	A207441	001	Sep 28, 2016	Jan DISC
--------------------	-------	---------	-----	--------------	----------

FLUORESCEIN SODIUMINJECTABLE;INTRAVENOUS
FLUORESCITE

>A>	AP	+	ALCON LABS INC	EQ 500MG BASE/5ML (EQ 100MG BASE/ML)	N021980	001	Mar 28, 2006	Feb CAHN
>D>	AP	+	NOVARTIS PHARMS CORP	EQ 500MG BASE/5ML (EQ 100MG BASE/ML)	N021980	001	Mar 28, 2006	Feb CAHN

FLUOXETINE HYDROCHLORIDETABLET;ORAL
FLUOXETINE HYDROCHLORIDE
@ FOSUN PHARMA

EQ 10MG BASE

A076024 001 Jan 29, 2002 Jan CAHN

FLUTAMIDECAPSULE;ORAL
FLUTAMIDE

@ YAOPHARMA CO LTD

125MG

A075818 001 Sep 18, 2001 Jan CAHN

FLUTICASONE PROPIONATESPRAY, METERED;NASAL
XHANCE

+! OPTINOSE US INC 0.093MG

N209022 001 Sep 18, 2017 Jan CMS1

FOSINOPRIL SODIUM; HYDROCHLOROTHIAZIDE

TABLET;ORAL

FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE

AB			EMCURE PHARMS LTD	10MG;12.5MG	A079025	001	Sep 17, 2010	Jan CAHN
AB	!			20MG;12.5MG	A079025	002	Sep 17, 2010	Jan CAHN

GEMFIBROZILTABLET;ORAL
GEMFIBROZIL

@ YAOPHARMA CO LTD

600MG

A074615 001 Sep 29, 1995 Jan CAHN

GENTAMICIN SULFATE

OINTMENT;TOPICAL

GENTAMICIN SULFATE

AT			G AND W LABS INC	EQ 0.1% BASE	A064054	001	Apr 29, 1994	Jan CMFD
----	--	--	------------------	--------------	---------	-----	--------------	----------

GLATIRAMER ACETATEINJECTABLE;SUBCUTANEOUS
GLATOPIA

AP			SANDOZ INC	40MG/ML	A206921	001	Feb 12, 2018	Jan NEWA
----	--	--	------------	---------	---------	-----	--------------	----------

GLYBURIDETABLET;ORAL
GLYBURIDE (MICRONIZED)

@ YAOPHARMA CO LTD

1.5MG

A075174 001 Jun 22, 1998 Jan CAHN

@

3MG

A075174 002 Jun 22, 1998 Jan CAHN

GRANISETRON HYDROCHLORIDE

INJECTABLE;INJECTION

GRANISETRON HYDROCHLORIDE

>D>	AP	!	TEVA PHARMS USA	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A077963	001	Jan 03, 2008	Feb DISC
>A>		@		EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A077963	001	Jan 03, 2008	Feb DISC

GRISEOFULVIN, ULTRAMICROSIZE

TABLET;ORAL

GRISEOFULVIN, ULTRAMICROSIZE

AB			MOUNTAIN	125MG	A204371	001	Jan 09, 2014	Jan CAHN
AB				250MG	A204371	002	Jan 09, 2014	Jan CAHN

GUANABENZ ACETATE

TABLET;ORAL

GUANABENZ ACETATE

@ YAOPHARMA CO LTD

EQ 4MG BASE

A074517 001 Sep 30, 1998 Jan CAHN

@

EQ 8MG BASE

A074517 002 Sep 30, 1998 Jan CAHN

HALCINONIDECREAM; TOPICAL
HALOG

>D>	+	!	RANBAXY	0.1%	N017556	001		Feb	CAHN
>A>	+	!	SUN PHARM INDS INC	0.1%	N017556	001		Feb	CAHN

HALOBETASOL PROPIONATECREAM; TOPICAL
ULTRAVATE

>A>	AB	+	SUN PHARM INDS INC	0.05%	N019967	001	Dec 27, 1990	Feb	CAHN
>D>	AB	+	SUN PHARM INDS LTD	0.05%	N019967	001	Dec 27, 1990	Feb	CAHN

OINTMENT; TOPICAL
ULTRAVATE

>D>	AB	+	RANBAXY	0.05%	N019968	001	Dec 17, 1990	Feb	CAHN
>A>	AB	+	SUN PHARM INDS INC	0.05%	N019968	001	Dec 17, 1990	Feb	CAHN

HALOPERIDOL LACTATEINJECTABLE; INJECTION
HALOPERIDOL

@	FOSUN PHARMA	EQ 5MG BASE/ML	A076464	001	Sep 29, 2004	Jan	CAHN
---	--------------	----------------	---------	-----	--------------	-----	------

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

>A>	AA		SCIEGEN PHARMS INC	10MG	A205236	001	May 26, 2017	Feb	CAHN
>A>	AA			25MG	A205236	002	May 26, 2017	Feb	CAHN
>A>	AA			50MG	A205236	003	May 26, 2017	Feb	CAHN
>A>	AA			100MG	A205236	004	May 26, 2017	Feb	CAHN
>D>	AA		TECH ORGANIZED	10MG	A205236	001	May 26, 2017	Feb	CAHN
>D>	AA			25MG	A205236	002	May 26, 2017	Feb	CAHN
>D>	AA			50MG	A205236	003	May 26, 2017	Feb	CAHN
>D>	AA			100MG	A205236	004	May 26, 2017	Feb	CAHN

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

AB			SCIEGEN PHARMS INC	25MG	A203018	001	Jul 23, 2014	Jan	CAHN
AB				50MG	A203018	002	Jul 23, 2014	Jan	CAHN
		@	YAOPHARMA CO LTD	25MG	A087565	001	Mar 09, 1982	Jan	CAHN
		@		50MG	A084912	001		Jan	CAHN

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

@	YAOPHARMA CO LTD	15MG; 250MG	A070182	001	Jan 15, 1986	Jan	CAHN
@		25MG; 250MG	A070183	001	Jan 15, 1986	Jan	CAHN
@		30MG; 500MG	A070543	001	Jan 15, 1986	Jan	CAHN
@		50MG; 500MG	A070544	001	Jan 15, 1986	Jan	CAHN

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

@	YAOPHARMA CO LTD	25MG; 40MG	A071060	001	Aug 26, 1987	Jan	CAHN
@		25MG; 80MG	A071061	001	Aug 26, 1987	Jan	CAHN

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

@	YAOPHARMA CO LTD	25MG; 25MG	A086881	001		Jan	CAHN
---	------------------	------------	---------	-----	--	-----	------

HYDROCODONE BITARTRATE

TABLET, EXTENDED RELEASE; ORAL

VANTRELA ER

+	@	TEVA BRANDED PHARM	15MG	N207975	001	Jan 17, 2017	Jan	DISC
+	@		30MG	N207975	002	Jan 17, 2017	Jan	DISC
+	@		45MG	N207975	003	Jan 17, 2017	Jan	DISC
+	@		60MG	N207975	004	Jan 17, 2017	Jan	DISC
+	@		90MG	N207975	005	Jan 17, 2017	Jan	DISC

HYDROCORTISONE VALERATEOINTMENT;TOPICAL
WESTCORT

>D>	+ @ RANBAXY	0.2%	N018726	001	Aug 08, 1983	Feb CAHN
>A>	+ @ SUN PHARM INDS INC	0.2%	N018726	001	Aug 08, 1983	Feb CAHN

HYDROMORPHONE HYDROCHLORIDETABLET;ORAL
HYDROMORPHONE HYDROCHLORIDE

AB	ASCENT PHARMS INC	2MG	A210506	001	Jan 17, 2018	Jan NEWA
AB		4MG	A210506	002	Jan 17, 2018	Jan NEWA
AB		8MG	A210506	003	Jan 17, 2018	Jan NEWA

HYDROXYPROGESTERONE CAPROATESOLUTION;SUBCUTANEOUS
MAKENA (AUTOINJECTOR)

>A>	+! AMAG PHARMA USA	275MG/1.1ML (250MG/ML)	N021945	004	Feb 14, 2018	Feb NEWA
-----	--------------------	------------------------	---------	-----	--------------	----------

HYDROXYZINE HYDROCHLORIDETABLET;ORAL
ATARAX

>D>	@ PFIZER	10MG	N010392	001		Feb CRLD
>A>	+ @	10MG	N010392	001		Feb CRLD
>D>	@	25MG	N010392	004		Feb CRLD
>A>	+ @	25MG	N010392	004		Feb CRLD
>D>	@	50MG	N010392	006		Feb CRLD
>A>	+ @	50MG	N010392	006		Feb CRLD
>D>	@	100MG	N010392	005		Feb CRLD
>A>	+ @	100MG	N010392	005		Feb CRLD

IBRUTINIB

>A>	TABLET;ORAL					
>A>	IMBRUVICA					
>A>	+ PHARMACYCLICS INC	140MG	N210563	001	Feb 16, 2018	Feb NEWA
>A>	+	280MG	N210563	002	Feb 16, 2018	Feb NEWA
>A>	+	420MG	N210563	003	Feb 16, 2018	Feb NEWA
>A>	+!	560MG	N210563	004	Feb 16, 2018	Feb NEWA

IBUPROFENSUSPENSION;ORAL
IBUPROFEN

>A>	AUROBINDO PHARMA LTD	100MG/5ML	A209178	001	Feb 16, 2018	Feb NEWA
-----	----------------------	-----------	---------	-----	--------------	----------

IBUTILIDE FUMARATEINJECTABLE;INJECTION
IBUTILIDE FUMARATE

@ MYLAN INSTITUTIONAL	0.1MG/ML	A090924	001	Jan 11, 2010	Jan DISC
-----------------------	----------	---------	-----	--------------	----------

IMIQUIMODCREAM;TOPICAL
IMIQUIMOD

@ G AND W LABS INC	5%	A200481	001	Apr 18, 2011	Jan DISC
--------------------	----	---------	-----	--------------	----------

INDAPAMIDETABLET;ORAL
INDAPAMIDE

@ YAOPHARMA CO LTD	1.25MG	A074594	001	May 23, 1996	Jan CAHN
@	2.5MG	A074594	002	May 23, 1996	Jan CAHN

IPRATROPIUM BROMIDESPRAY, METERED;NASAL
ATROVENT

+ @ BOEHRINGER INGELHEIM	0.021MG/SPRAY	N020393	001	Oct 20, 1995	Jan DISC
+ @	0.042MG/SPRAY	N020394	001	Oct 20, 1995	Jan DISC
IPRATROPIUM BROMIDE					
AB ! WEST-WARD PHARMS INT	0.021MG/SPRAY	A076664	001	Nov 05, 2003	Jan CHRS
AB !	0.042MG/SPRAY	A076598	001	Nov 05, 2003	Jan CHRS

>A>	<u>IVACAFITOR; IVACAFITOR, TEZACAFITOR</u>							
>A>	TABLET, TABLET;ORAL							
>A>	SYMDEKO (COPACKAGED)							
>A>	+	VERTEX PHARMS INC	150MG,N/A;150MG, 100MG		N210491	001	Feb 12, 2018	Feb NEWA
	<u>KETOROLAC TROMETHAMINE</u>							
	SOLUTION/DROPS;OPHTHALMIC							
	KETOROLAC TROMETHAMINE							
AT		SANDOZ INC	0.4%		A078721	001	Nov 05, 2009	Jan CAHN
>A>	<u>LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE</u>							
>A>	TABLET;ORAL							
>A>	CIMDUO							
>A>	+	MYLAN LABS LTD	300MG;300MG		N022141	001	Feb 28, 2018	Feb NEWA
	<u>LEFLUNOMIDE</u>							
	TABLET;ORAL							
	LEFLUNOMIDE							
	@	FOSUN PHARMA	10MG		A077087	001	Sep 13, 2005	Jan CAHN
	@		20MG		A077087	002	Sep 13, 2005	Jan CAHN
	<u>LEUPROLIDE ACETATE</u>							
	INJECTABLE;INJECTION							
	LUPRON							
>D>	@	ABBVIE ENDOCRINE INC	1MG/0.2ML		N019010	001	Apr 09, 1985	Feb CRLD
>A>	+	@	1MG/0.2ML		N019010	001	Apr 09, 1985	Feb CRLD
	<u>LEVETIRACETAM</u>							
	TABLET;ORAL							
	LEVETIRACETAM							
	@	FOSUN PHARMA	250MG		A077324	001	Jan 15, 2009	Jan CAHN
	@		500MG		A077324	002	Jan 15, 2009	Jan CAHN
	@		750MG		A077324	003	Jan 15, 2009	Jan CAHN
	@		1GM		A077324	004	Jan 15, 2009	Jan CAHN
	<u>LEVOCETIRIZINE DIHYDROCHLORIDE</u>							
	TABLET;ORAL							
	LEVOCETIRIZINE DIHYDROCHLORIDE							
	@	FOSUN PHARMA	5MG		A090486	001	Mar 26, 2013	Jan CAHN
	<u>LEVOFLOXACIN</u>							
	INJECTABLE;INJECTION							
>D>	LEVAQUIN							
>D> AP	+	JANSSSEN PHARMS	EQ 500MG/20ML (EQ 25MG/ML)		N020635	001	Dec 20, 1996	Feb DISC
>A>	+	@	EQ 500MG/20ML (EQ 25MG/ML)		N020635	001	Dec 20, 1996	Feb DISC
>D> AP	+		EQ 750MG/30ML (EQ 25MG/ML)		N020635	004	Dec 20, 1996	Feb DISC
>A>	+	@	EQ 750MG/30ML (EQ 25MG/ML)		N020635	004	Dec 20, 1996	Feb DISC
	LEVOFLOXACIN							
>D> AP		ZYDUS PHARMS USA INC	EQ 500MG/20ML (EQ 25MG/ML)		A205968	001	Jun 01, 2017	Feb DISC
>A>	@		EQ 500MG/20ML (EQ 25MG/ML)		A205968	001	Jun 01, 2017	Feb DISC
>D> AP			EQ 750MG/30ML (EQ 25MG/ML)		A205968	002	Jun 01, 2017	Feb DISC
>A>	@		EQ 750MG/30ML (EQ 25MG/ML)		A205968	002	Jun 01, 2017	Feb DISC
	LEVOFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER							
AP	!	INFORLIFE	EQ 250MG/50ML (EQ 5MG/ML)		A090343	001	Jul 07, 2011	Jan CAHN
AP	!		EQ 500MG/100ML (EQ 5MG/ML)		A090343	002	Jul 07, 2011	Jan CAHN
AP	!		EQ 750MG/150ML (EQ 5MG/ML)		A090343	003	Jul 07, 2011	Jan CAHN
	TABLET;ORAL							
>D>	LEVAQUIN							
>D> AB	+	JANSSSEN PHARMS	250MG		N020634	001	Dec 20, 1996	Feb DISC
>A>	+	@	250MG		N020634	001	Dec 20, 1996	Feb DISC
>D> AB	+		500MG		N020634	002	Dec 20, 1996	Feb DISC
>A>	+	@	500MG		N020634	002	Dec 20, 1996	Feb DISC
>D> AB	+	!	750MG		N020634	003	Sep 08, 2000	Feb DISC
>A>	+	@	750MG		N020634	003	Sep 08, 2000	Feb DISC
	LEVOFLOXACIN							
>D> AB		AUROBINDO PHARMA LTD	750MG		A201043	003	Jun 20, 2011	Feb CHRS
>A> AB	!		750MG		A201043	003	Jun 20, 2011	Feb CHRS

LEVOMILNACIPRAN HYDROCHLORIDECAPSULE, EXTENDED RELEASE;ORAL
FETZIMA

+	ALLERGAN SALES LLC	EQ 20MG BASE	N204168	001	Jul 25, 2013	Jan CAHN
+		EQ 40MG BASE	N204168	002	Jul 25, 2013	Jan CAHN
+		EQ 80MG BASE	N204168	003	Jul 25, 2013	Jan CAHN
+	!	EQ 120MG BASE	N204168	004	Jul 25, 2013	Jan CAHN

LEVOTHYROXINE SODIUMPOWDER;INTRAVENOUS
LEVOTHYROXINE SODIUM

AP	PIRAMAL CRITICAL	100MCG/VIAL	A206163	001	Jun 29, 2016	Jan CAHN
AP		500MCG/VIAL	A206163	002	Jun 29, 2016	Jan CAHN

LIDOCAINEOINTMENT;TOPICAL
LIDOCAINE

AT	TEVA PHARMS USA	5%	A210256	001	Jan 16, 2018	Jan NEWA
----	-----------------	----	---------	-----	--------------	----------

PATCH;TOPICAL

>A> ZTLIDO

>A>	+	!	SCILEX PHARMS INC	1.8%	N207962	001	Feb 28, 2018	Feb NEWA
-----	---	---	-------------------	------	---------	-----	--------------	----------

LINACLOTIDECAPSULE;ORAL
LINZESS

+	ALLERGAN SALES LLC	72MCG	N202811	003	Jan 25, 2017	Jan CAHN
+		145MCG	N202811	001	Aug 30, 2012	Jan CAHN
+	!	290MCG	N202811	002	Aug 30, 2012	Jan CAHN

LOPERAMIDE HYDROCHLORIDECAPSULE;ORAL
LOPERAMIDE HYDROCHLORIDE
@ YAOPHARMA CO LTD

2MG

A072993	001	Aug 28, 1992	Jan CAHN
---------	-----	--------------	----------

LORAZEPAMTABLET;ORAL
LORAZEPAM@ MYLAN 0.5MG
@ 1MG

A071591	002	Oct 13, 1987	Jan CMS1
A071591	003	Oct 13, 1987	Jan CMS1

LUTETIUM DOTATATE LU-177SOLUTION;IV (INFUSION)
LUTATHERA

+	!	AAA USA INC	10mCi/ML	N208700	001	Jan 26, 2018	Jan NEWA
---	---	-------------	----------	---------	-----	--------------	----------

MACIMORELIN ACETATEFOR SOLUTION;ORAL
MACRILEN

+	!	STRONGBRIDGE IRELAND	EQ 60MG BASE/POUCH	N205598	001	Dec 21, 2017	Jan CAHN
---	---	----------------------	--------------------	---------	-----	--------------	----------

MEBENDAZOLETABLET, CHEWABLE;ORAL
VERMOX

>D>								
>D>	+	!	JANSSEN PHARMS	500MG	N208398	001	Oct 19, 2016	Feb DISC
>A>	+	@		500MG	N208398	001	Oct 19, 2016	Feb DISC

MECLOFENAMATE SODIUMCAPSULE;ORAL
MECLOFENAMATE SODIUM@ FOSUN PHARMA EQ 50MG BASE
@ EQ 100MG BASE

A072262	001	Nov 29, 1988	Jan CAHN
A072263	001	Nov 29, 1988	Jan CAHN

MEFENAMIC ACIDCAPSULE;ORAL
MEFENAMIC ACID

>A>	AB		MICRO LABS	250MG	A090562	001	Nov 19, 2010	Feb CAHN
>D>	AB		VIVA HLTHCARE	250MG	A090562	001	Nov 19, 2010	Feb CAHN

MEMANTINE HYDROCHLORIDE

SOLUTION;ORAL

MEMANTINE HYDROCHLORIDE

AA	APOTEX INC	2MG/ML	A209955	001	Feb 09, 2018	Jan NEWA
	NAMENDA					
AA	+! ALLERGAN SALES LLC	2MG/ML	N021627	001	Apr 18, 2005	Jan CAHN
	TABLET;ORAL					
	NAMENDA					
AB	+ ALLERGAN SALES LLC	5MG	N021487	001	Oct 16, 2003	Jan CAHN
AB	+!	10MG	N021487	002	Oct 16, 2003	Jan CAHN

MEROPENEM; VABORBACTAM

POWDER;IV (INFUSION)

VABOMERE

	+! REMPEX PHARMS	1GM/VIAL;1GM/VIAL	N209776	001	Aug 29, 2017	Jan CAHN
--	------------------	-------------------	---------	-----	--------------	----------

MESALAMINE

ENEMA;RECTAL

MESALAMINE

@ G AND W LABS INC

4GM/60ML

A076841 001 Sep 30, 2004 Jan DISC

SUPPOSITORY;RECTAL

CANASA

@ ALLERGAN SALES LLC

500MG

N021252 001 Jan 05, 2001 Jan CAHN

AB	+!	1GM	N021252	002	Nov 05, 2004	Jan CAHN
----	----	-----	---------	-----	--------------	----------

MESNA

INJECTABLE;INTRAVENOUS

MESNA

@ MYLAN INSTITUTIONAL

100MG/ML

A076488 001 Mar 08, 2012 Jan DISC

>D> METARAMINOL BITARTRATE

>D> INJECTABLE;INJECTION

>D> METARAMINOL BITARTRATE

>D> ! FRESENIUS KABI USA EQ 10MG BASE/ML A080722 001 Feb DISC

>A> @ EQ 10MG BASE/ML A080722 001 Feb DISC

METAXALONE

TABLET;ORAL

METAXALONE

MOUNTAIN

400MG

A040486 001 Feb 27, 2015 Jan CAHN

@ PRIMUS PHARMS

640MG

N022503 001 Jun 01, 2015 Jan CAHN

METHOCARBAMOL

TABLET;ORAL

METHOCARBAMOL

>A> AA ALLIED PHARMA INC 500MG A203550 001 Feb 08, 2017 Feb CAHN

>A> AA 750MG A203550 002 Feb 08, 2017 Feb CAHN

>D> AA ATLAS PHARMS LLC 500MG A203550 001 Feb 08, 2017 Feb CAHN

>D> AA 750MG A203550 002 Feb 08, 2017 Feb CAHN

@ FOSUN PHARMA 500MG A084616 001 Jan CAHN

@ 750MG A084615 001 Jan CAHN

METHYCLOTHIAZIDE

TABLET;ORAL

METHYCLOTHIAZIDE

@ YAOPHARMA CO LTD

2.5MG

A089835 001 Aug 18, 1988 Jan CAHN

@ 5MG A089837 001 Aug 18, 1988 Jan CAHN

METHYLDOPA

TABLET;ORAL

METHYLDOPA

@ YAOPHARMA CO LTD

125MG

A071700 001 Mar 02, 1988 Jan CAHN

@ 250MG N018934 001 Jun 29, 1984 Jan CAHN

@ 500MG N018934 002 Jun 29, 1984 Jan CAHN

METHYLPHENIDATE HYDROCHLORIDECAPSULE, EXTENDED RELEASE;ORAL
METHYLPHENIDATE HYDROCHLORIDE

>A>	AB1	MAYNE PHARMA	10MG	A200886	001	Feb 26, 2018	Feb	NEWA
		TABLET;ORAL						
		METHYLPHENIDATE HYDROCHLORIDE						
>A>	AB	BIONPHARMA INC	5MG	A209753	001	Mar 02, 2018	Feb	NEWA
>A>	AB		10MG	A209753	002	Mar 02, 2018	Feb	NEWA
>A>	AB		20MG	A209753	003	Mar 02, 2018	Feb	NEWA
	AB	MOUNTAIN	5MG	A091159	001	Mar 12, 2014	Jan	CAHN
	AB		10MG	A091159	002	Mar 12, 2014	Jan	CAHN
	AB		20MG	A091159	003	Mar 12, 2014	Jan	CAHN
		TABLET, EXTENDED RELEASE;ORAL						
		METHYLPHENIDATE HYDROCHLORIDE						
	AB	AMNEAL PHARMS	18MG	A207515	001	Feb 01, 2018	Jan	NEWA
	AB		27MG	A207515	002	Feb 01, 2018	Jan	NEWA
	AB		36MG	A207515	003	Feb 01, 2018	Jan	NEWA
	AB		54MG	A207515	004	Feb 01, 2018	Jan	NEWA
	AB	MOUNTAIN	18MG	A208607	001	Jul 14, 2017	Jan	CAHN
	AB		27MG	A208607	002	Jul 14, 2017	Jan	CAHN
	AB		36MG	A208607	003	Jul 14, 2017	Jan	CAHN
	AB		54MG	A208607	004	Jul 14, 2017	Jan	CAHN
	!	OSMOTICA	72MG	A205327	005	Jul 28, 2017	Jan	CHRS

METOCLOPRAMIDE HYDROCHLORIDE

TABLET;ORAL

METOCLOPRAMIDE HYDROCHLORIDE

@ YAOPHARMA CO LTD EQ 5MG BASE
 @ EQ 10MG BASE
 @ EQ 10MG BASE

A074478 001 Oct 05, 1995 Jan CAHN
 A072215 001 Jan 30, 1990 Jan CAHN
 A074478 002 Oct 05, 1995 Jan CAHN

METOPROLOL SUCCINATE

CAPSULE, EXTENDED RELEASE;ORAL

METOPROLOL SUCCINATE

+ SPIL EQ 25MG TARTRATE
 + EQ 50MG TARTRATE
 + EQ 100MG TARTRATE
 +! EQ 200MG TARTRATE

N210428 001 Jan 26, 2018 Jan NEWA
 N210428 002 Jan 26, 2018 Jan NEWA
 N210428 003 Jan 26, 2018 Jan NEWA
 N210428 004 Jan 26, 2018 Jan NEWA

TABLET, EXTENDED RELEASE;ORAL

METOPROLOL SUCCINATE

AB NOVAST LABS LTD EQ 25MG TARTRATE
 AB EQ 50MG TARTRATE
 AB EQ 100MG TARTRATE
 AB EQ 200MG TARTRATE

A204106 001 Feb 06, 2018 Jan NEWA
 A204106 002 Feb 06, 2018 Jan NEWA
 A204106 003 Feb 06, 2018 Jan NEWA
 A204106 004 Feb 06, 2018 Jan NEWA

METOPROLOL TARTRATE

TABLET;ORAL

METOPROLOL TARTRATE

@ RENATA 50MG
 @ 100MG
 @ YAOPHARMA CO LTD 50MG
 @ 100MG

A074453 001 Apr 27, 1995 Jan CAHN
 A074453 002 Apr 27, 1995 Jan CAHN
 A073288 001 Mar 25, 1994 Jan CAHN
 A073289 001 Mar 25, 1994 Jan CAHN

METRONIDAZOLE

TABLET;ORAL

METRONIDAZOLE

@ FOSUN PHARMA 250MG
 @ 250MG
 @ 500MG
 @ 500MG

N018620 001 Mar 04, 1982 Jan CAHN
 N018740 001 Oct 22, 1982 Jan CAHN
 N018620 002 Jun 02, 1983 Jan CAHN
 N018740 002 Oct 22, 1982 Jan CAHN

MIDODRINE HYDROCHLORIDE

TABLET;ORAL

MIDODRINE HYDROCHLORIDE

>D>	BX	APOTEX INC	2.5MG	A077746	001	Sep 12, 2006	Feb	CTEC
>A>	AB		2.5MG	A077746	001	Sep 12, 2006	Feb	CTEC
>D>	BX		5MG	A077746	002	Sep 12, 2006	Feb	CTEC
>A>	AB		5MG	A077746	002	Sep 12, 2006	Feb	CTEC
>D>	BX		10MG	A077746	003	Sep 12, 2006	Feb	CTEC
>A>	AB		10MG	A077746	003	Sep 12, 2006	Feb	CTEC

MINOCYCLINE HYDROCHLORIDE

INJECTABLE;INJECTION

MINOCIN

+! REMPEX PHARMS EQ 100MG BASE/VIAL

N050444 001

Jan CAHN

TABLET, EXTENDED RELEASE;ORAL

MINOCYCLINE HYDROCHLORIDE

AB BARR LABS INC EQ 65MG BASE

A065485 004 May 18, 2012 Jan CMFD

AB EQ 115MG BASE

A065485 005 May 18, 2012 Jan CMFD

NALTREXONE HYDROCHLORIDE

TABLET;ORAL

NALTREXONE HYDROCHLORIDE

@ FOSUN PHARMA 50MG

A075434 001 Mar 08, 2000 Jan CAHN

NAPROXEN

TABLET;ORAL

NAPROXEN

@ FOSUN PHARMA 250MG

A074140 001 Dec 21, 1993 Jan CAHN

@ 375MG

A074140 002 Dec 21, 1993 Jan CAHN

@ 500MG

A074140 003 Dec 21, 1993 Jan CAHN

TABLET, DELAYED RELEASE;ORAL

NAPROXEN

@ FOSUN PHARMA 375MG

A075061 001 Feb 18, 1998 Jan CAHN

@ 500MG

A075061 002 Feb 18, 1998 Jan CAHN

NAPROXEN SODIUM; SUMATRIPTAN SUCCINATE

TABLET;ORAL

>A> SUMATRIPTAN AND NAPROXEN SODIUM

>A> AB AUROBINDO PHARMA LTD 500MG;EQ 85MG BASE
TREXIMET

A207457 001 Feb 15, 2018 Feb NEWA

>D> +! PERNIX IRELAND LTD 500MG;EQ 85MG BASE

N021926 001 Apr 15, 2008 Feb CFTG

>A> AB +! 500MG;EQ 85MG BASE

N021926 001 Apr 15, 2008 Feb CFTG

NEBIVOLOL HYDROCHLORIDE

TABLET;ORAL

BYSTOLIC

>D> + ALLERGAN SALES LLC EQ 2.5MG BASE

N021742 002 Dec 17, 2007 Feb CFTG

>A> AB + EQ 2.5MG BASE

N021742 002 Dec 17, 2007 Feb CFTG

+ EQ 2.5MG BASE

N021742 002 Dec 17, 2007 Jan CAHN

>D> + EQ 5MG BASE

N021742 003 Dec 17, 2007 Feb CFTG

>A> AB + EQ 5MG BASE

N021742 003 Dec 17, 2007 Feb CFTG

+ EQ 5MG BASE

N021742 003 Dec 17, 2007 Jan CAHN

>D> + EQ 10MG BASE

N021742 004 Dec 17, 2007 Feb CFTG

>A> AB + EQ 10MG BASE

N021742 004 Dec 17, 2007 Feb CFTG

+ EQ 10MG BASE

N021742 004 Dec 17, 2007 Jan CAHN

>D> +! EQ 20MG BASE

N021742 005 Oct 08, 2008 Feb CFTG

>A> AB +! EQ 20MG BASE

N021742 005 Oct 08, 2008 Feb CFTG

+! EQ 20MG BASE

N021742 005 Oct 08, 2008 Jan CAHN

>A> NEBIVOLOL HYDROCHLORIDE

>A> AB TORRENT PHARMS LTD EQ 2.5MG BASE

A203966 001 Mar 02, 2018 Feb NEWA

>A> AB EQ 5MG BASE

A203966 002 Mar 02, 2018 Feb NEWA

>A> AB EQ 10MG BASE

A203966 003 Mar 02, 2018 Feb NEWA

>A> AB EQ 20MG BASE

A203966 004 Mar 02, 2018 Feb NEWA

NEBIVOLOL HYDROCHLORIDE; VALSARTAN

TABLET;ORAL

BYVALSON

+! ALLERGAN SALES LLC EQ 5MG BASE;80MG

N206302 001 Jun 03, 2016 Jan CAHN

NEFAZODONE HYDROCHLORIDE

TABLET;ORAL

NEFAZODONE HYDROCHLORIDE

@ FOSUN PHARMA 50MG

A076302 001 Sep 16, 2003 Jan CAHN

@ 100MG

A076302 002 Sep 16, 2003 Jan CAHN

@ 150MG

A076302 003 Sep 16, 2003 Jan CAHN

@ 200MG

A076302 004 Sep 16, 2003 Jan CAHN

@ 250MG

A076302 005 Sep 16, 2003 Jan CAHN

NEOSTIGMINE METHYLSULFATESOLUTION; INTRAVENOUS
BLOXIVERZ

>A>	AP	+	!	AVADEL LEGACY	5MG/10ML (0.5MG/ML)	N204078	001	May 31, 2013	Feb CAHN
>A>	AP	+	!		10MG/10ML (1MG/ML)	N204078	002	May 31, 2013	Feb CAHN
>D>	AP	+	!	ECLAT PHARMS LLC	5MG/10ML (0.5MG/ML)	N204078	001	May 31, 2013	Feb CAHN
>D>	AP	+	!		10MG/10ML (1MG/ML)	N204078	002	May 31, 2013	Feb CAHN

NEVIRAPINETABLET; ORAL
NEVIRAPINE

@ TECH ORGANIZED 200MG

A203176 001 May 22, 2012 Jan DISC

TABLET, EXTENDED RELEASE; ORAL

NEVIRAPINE

@ APOTEX INC 400MG

A205258 001 Apr 03, 2014 Jan DISC

NIACINTABLET, EXTENDED RELEASE; ORAL
NIACIN

AB		AUROBINDO PHARMA LTD	500MG
AB			750MG
AB			1GM

A209236	001	Feb 01, 2018	Jan NEWA
A209236	002	Feb 01, 2018	Jan NEWA
A209236	003	Feb 01, 2018	Jan NEWA

NITROGLYCERINOINTMENT; INTRA-ANAL
RECTIV

+! ALLERGAN SALES LLC 0.4%

N021359 001 Jun 21, 2011 Jan CAHN

TABLET; SUBLINGUAL

NITROGLYCERIN

AB		GLENMARK PHARMS SA	0.3MG
AB			0.4MG
AB			0.6MG

A206391	001	Sep 19, 2017	Jan CAHN
A206391	002	Sep 19, 2017	Jan CAHN
A206391	003	Sep 19, 2017	Jan CAHN

NYSTATIN

OINTMENT; TOPICAL

NYSTATIN

@ G AND W LABS INC 100,000 UNITS/GM

A209114 001 Oct 06, 2017 Jan DISC

SUSPENSION; ORAL

NYSTATIN

@ G AND W LABS INC 100,000 UNITS/ML

A062349 001 Jul 14, 1982 Jan DISC

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

NYSTATIN AND TRIAMCINOLONE ACETONIDE

>A> AT AMNEAL PHARMS LLC 100,000 UNITS/GM; 0.1%

A209990 001 Feb 15, 2018 Feb NEWA

OINTMENT; TOPICAL

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AT STRIDES PHARMA 100,000 UNITS/GM; 0.1%

A210077 001 Jan 29, 2018 Jan NEWA

ORITAVANCIN DIPHOSPHATE

POWDER; IV (INFUSION)

ORBACTIV

+! MELINTA EQ 400MG BASE/VIAL

N206334 001 Aug 06, 2014 Jan CAHN

OSELTAMIVIR PHOSPHATE

CAPSULE; ORAL

OSELTAMIVIR PHOSPHATE

>A>	AB		HETERO LABS LTD III	EQ 30MG BASE
>A>	AB			EQ 45MG BASE
>A>	AB			EQ 75MG BASE

A209438	001	Feb 23, 2018	Feb NEWA
A209438	002	Feb 23, 2018	Feb NEWA
A209438	003	Feb 23, 2018	Feb NEWA

FOR SUSPENSION; ORAL

OSELTAMIVIR PHOSPHATE

>A> AB LUPIN ATLANTIS EQ 6MG BASE/ML

A208347 001 Feb 20, 2018 Feb NEWA

OXALIPLATIN

INJECTABLE; IV (INFUSION)

OXALIPLATIN

>A>	AP		ACTAVIS LLC	50MG/10ML (5MG/ML)
>A>	AP			100MG/20ML (5MG/ML)

A204880	001	Mar 05, 2018	Feb NEWA
A204880	002	Mar 05, 2018	Feb NEWA

OXYBUTYNIN CHLORIDE

TABLET, EXTENDED RELEASE;ORAL									
>D>	DITROPAN XL								
>D>	AB	+	JANSSEN PHARMS	5MG	N020897	001	Dec 16, 1998	Feb	DISC
>A>		+	@	5MG	N020897	001	Dec 16, 1998	Feb	DISC
>D>	AB	+		10MG	N020897	002	Dec 16, 1998	Feb	DISC
>A>		+	@	10MG	N020897	002	Dec 16, 1998	Feb	DISC
>D>	AB	+	!	15MG	N020897	003	Jun 22, 1999	Feb	DISC
>A>		+	@	15MG	N020897	003	Jun 22, 1999	Feb	DISC
OXYBUTYNIN CHLORIDE									
>D>	AB		MYLAN PHARMS INC	15MG	A076644	002	May 10, 2007	Feb	CHRS
>A>	AB	!		15MG	A076644	002	May 10, 2007	Feb	CHRS

OXYMORPHONE HYDROCHLORIDE

TABLET;ORAL									
OXYMORPHONE HYDROCHLORIDE									
AB			ASCENT PHARMS INC	5MG	A210175	001	Feb 02, 2018	Jan	NEWA
AB				10MG	A210175	002	Feb 02, 2018	Jan	NEWA

OXYTETRACYCLINE HYDROCHLORIDE; POLYMYXIN B SULFATE

OINTMENT;OPHTHALMIC									
TERRAMYCIN W/ POLYMYXIN B SULFATE									
>D>		!	CASPER PHARMA LLC	EQ 5MG BASE/GM;10,000 UNITS/GM	A061015	001		Feb	CMS2
>A>		!		EQ 5MG BASE/GM;10,000 UNITS/GM	N061015	001		Feb	CMS2

PEMOLINE

TABLET;ORAL									
PEMOLINE									
		@	FOSUN PHARMA	18.75MG	A075286	001	Dec 27, 1999	Jan	CAHN
		@		37.5MG	A075286	002	Jun 30, 1999	Jan	CAHN
		@		75MG	A075286	003	Jun 30, 1999	Jan	CAHN

PENICILLIN G BENZATHINE

INJECTABLE;INJECTION									
PERMAPEN									
>D>	BC		CASPER PHARMA LLC	600,000 UNITS/ML	A060014	001		Feb	CMS2
>A>	BC			600,000 UNITS/ML	N060014	001		Feb	CMS2

PERINDOPRIL ERBUMINE

TABLET;ORAL									
PERINDOPRIL ERBUMINE									
		@	APOTEX	2MG	A090463	001	Aug 30, 2010	Jan	DISC
		@		4MG	A090463	002	Aug 30, 2010	Jan	DISC
		@		8MG	A090463	003	Aug 30, 2010	Jan	DISC

PHENTERMINE HYDROCHLORIDE

CAPSULE;ORAL									
PHENTERMINE HYDROCHLORIDE									
		@	ELITE LABS INC	15MG	A040460	001	Jan 14, 2003	Jan	CAHN

PHENYLBUTAZONE

CAPSULE;ORAL									
PHENYLBUTAZONE									
		@	FOSUN PHARMA	100MG	A087774	001	Jun 16, 1982	Jan	CAHN
TABLET;ORAL									
PHENYLBUTAZONE									
		@	FOSUN PHARMA	100MG	A084339	001		Jan	CAHN

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP;ORAL									
PHENYLEPHRINE HYDROCHLORIDE AND PROMETHAZINE HYDROCHLORIDE									
AA	!		VINTAGE	5MG/5ML;6.25MG/5ML	A040654	001	Dec 07, 2006	Jan	CHRS
			PROMETH VC PLAIN						
		@	G AND W LABS INC	5MG/5ML;6.25MG/5ML	A088761	001	Nov 08, 1984	Jan	DISC

PHENYTOINSUSPENSION;ORAL
PHENYTOIN

AB	WOCKHARDT BIO AG	125MG/5ML	A040420	001	Apr 19, 2002	Jan CAHN
----	------------------	-----------	---------	-----	--------------	----------

PIPERACILLIN SODIUM; TAZOBACTAM SODIUMINJECTABLE;INJECTION
PIPERACILLIN AND TAZOBACTAM

AP	WOCKHARDT BIO AG	EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A207146	001	Mar 17, 2017	Jan CPOT
----	------------------	--------------------------------------	---------	-----	--------------	----------

PIROXICAMCAPSULE;ORAL
PIROXICAM

>A>	AB	LABORATORIOS CINFA	10MG	A208991	001	Feb 21, 2018	Feb NEWA
>A>	AB		20MG	A208991	002	Feb 21, 2018	Feb NEWA
>D>	AB	+ MICRO LABS	10MG	A206152	001	Dec 29, 2017	Feb CRLD
>A>	AB		10MG	A206152	001	Dec 29, 2017	Feb CRLD
>D>	AB	+	20MG	A206152	002	Dec 29, 2017	Feb CRLD
>A>	AB		20MG	A206152	002	Dec 29, 2017	Feb CRLD
	AB	STRIDES PHARMA	10MG	A210347	001	Jan 26, 2018	Jan NEWA
	AB		20MG	A210347	002	Jan 26, 2018	Jan NEWA

POLIDOCANOLSOLUTION;INTRAVENOUS
VARITHENA

+	!	PROVENSIS	77.5MG/7.75ML (10MG/ML)	N205098	002	Dec 21, 2017	Jan CDFR
---	---	-----------	-------------------------	---------	-----	--------------	----------

POTASSIUM CHLORIDETABLET, EXTENDED RELEASE;ORAL
K-TAB

AB3	+	ABBVIE	10MEQ	N018279	001		Jan CTEC
AB2	+	!	20MEQ	N018279	003	Nov 25, 2013	Jan CTEC
		POTASSIUM CHLORIDE					
AB3		PADDOCK LLC	10MEQ	A209688	001	Jan 12, 2018	Jan NEWA
AB2			20MEQ	A209688	002	Jan 12, 2018	Jan NEWA

POTASSIUM CITRATETABLET, EXTENDED RELEASE;ORAL
POTASSIUM CITRATE

AB		MOUNTAIN	5MEQ	A077440	001	Jun 09, 2006	Jan CAHN
AB			10MEQ	A077440	002	Jun 09, 2006	Jan CAHN
>A>	AB	TEVA PHARMS USA INC	5MEQ	A209758	001	Mar 05, 2018	Feb NEWA
>A>	AB		10MEQ	A209758	002	Mar 05, 2018	Feb NEWA
>A>	AB		15MEQ	A209758	003	Mar 05, 2018	Feb NEWA

PRASUGREL HYDROCHLORIDETABLET;ORAL
PRASUGREL

AB		ACCORD HLTHCARE	EQ 5MG BASE	A205987	001	Feb 02, 2018	Jan NEWA
AB			EQ 10MG BASE	A205987	002	Feb 02, 2018	Jan NEWA
AB		USPHARMA WINDLAS	EQ 5MG BASE	A205790	001	Oct 16, 2017	Jan CAHN
AB			EQ 10MG BASE	A205790	002	Oct 16, 2017	Jan CAHN

PREDNISOLONETABLET;ORAL
PREDNISOLONE
@ FOSUN PHARMA

5MG

A080339	001		Jan CAHN
---------	-----	--	----------

PREDNISOLONE SODIUM PHOSPHATESOLUTION;ORAL
PREDNISOLONE SODIUM PHOSPHATE

AA	!	WOCKHARDT BIO AG	EQ 15MG BASE/5ML	A076895	001	Oct 04, 2004	Jan CAHN
----	---	------------------	------------------	---------	-----	--------------	----------

PROPARACAINE HYDROCHLORIDESOLUTION/DROPS;OPHTHALMIC
ALCAINE

>A>	AT	!	ALCON LABS INC	0.5%	A080027	001	Feb CAHN
>D>	AT	!	NOVARTIS PHARMS CORP	0.5%	A080027	001	Feb CAHN

PROPRANOLOL HYDROCHLORIDE

INJECTABLE;INJECTION

PROPRANOLOL HYDROCHLORIDE

@ FOSUN PHARMA 1MG/ML

A076400 001 Feb 26, 2003 Jan CAHN

TABLET;ORAL

PROPRANOLOL HYDROCHLORIDE

@ YAOPHARMA CO LTD 10MG

A070663 001 Jun 13, 1986 Jan CAHN

@ 20MG

A070664 001 Jun 13, 1986 Jan CAHN

@ 40MG

A070665 001 Jun 13, 1986 Jan CAHN

@ 60MG

A070666 001 Oct 10, 1986 Jan CAHN

@ 80MG

A070667 001 Jun 13, 1986 Jan CAHN

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET;ORAL

CORPHED

@ FOSUN PHARMA 60MG;2.5MG

A088602 001 Apr 11, 1985 Jan CAHN

PYRIMETHAMINE

TABLET;ORAL

DARAPRIM

+! VYERA PHARMS LLC 25MG

N008578 001 Jan CAHN

QUAZEPAM

TABLET;ORAL

DORAL

>D> @ CUTIS HEALTH LLC 7.5MG

N018708 003 Feb 26, 1987 Feb CAHN

>D> +! 15MG

N018708 001 Dec 27, 1985 Feb CAHN

>A> @ GALT PHARMS 7.5MG

N018708 003 Feb 26, 1987 Feb CAHN

>A> +! 15MG

N018708 001 Dec 27, 1985 Feb CAHN

QUINAPRIL HYDROCHLORIDE

TABLET;ORAL

QUINAPRIL HYDROCHLORIDE

@ YAOPHARMA CO LTD EQ 5MG BASE

A076803 001 Mar 02, 2005 Jan CAHN

@ EQ 10MG BASE

A076803 002 Mar 02, 2005 Jan CAHN

@ EQ 20MG BASE

A076803 003 Mar 02, 2005 Jan CAHN

@ EQ 40MG BASE

A076803 004 Mar 02, 2005 Jan CAHN

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE;ORAL

QUINIDINE SULFATE

@ G AND W LABS INC 300MG

A040045 001 Jun 30, 1994 Jan DISC

RABEPRAZOLE SODIUM

CAPSULE, DELAYED RELEASE;ORAL

ACIPHEX SPRINKLE

>D> + AVADEL PHARMS 5MG

N204736 001 Mar 26, 2013 Feb CAHN

>D> +! 10MG

N204736 002 Mar 26, 2013 Feb CAHN

>A> + CERECOR INC 5MG

N204736 001 Mar 26, 2013 Feb CAHN

>A> +! 10MG

N204736 002 Mar 26, 2013 Feb CAHN

RAMIPRIL

CAPSULE;ORAL

RAMIPRIL

@ YAOPHARMA CO LTD 1.25MG

A077514 001 Jun 18, 2008 Jan CAHN

@ 2.5MG

A077514 002 Jun 18, 2008 Jan CAHN

@ 5MG

A077514 003 Jun 18, 2008 Jan CAHN

@ 10MG

A077514 004 Jun 18, 2008 Jan CAHN

REMIFENTANIL HYDROCHLORIDE

INJECTABLE;INJECTION

REMIFENTANIL HYDROCHLORIDE

AP FRESENIUS KABI USA EQ 1MG BASE/VIAL

A206223 001 Jan 16, 2018 Jan NEWA

AP EQ 2MG BASE/VIAL

A206223 002 Jan 16, 2018 Jan NEWA

AP EQ 5MG BASE/VIAL

A206223 003 Jan 16, 2018 Jan NEWA

ULTIVA

AP + MYLAN INSTITUTIONAL EQ 1MG BASE/VIAL

N020630 001 Jul 12, 1996 Jan CFTG

AP + EQ 2MG BASE/VIAL

N020630 002 Jul 12, 1996 Jan CFTG

AP +! EQ 5MG BASE/VIAL

N020630 003 Jul 12, 1996 Jan CFTG

RISPERIDONE

TABLET;ORAL

RISPERIDONE

AB	RENATA	0.25MG	A078707	001	Dec 29, 2008	Jan CAHN
AB		0.5MG	A078707	002	Dec 29, 2008	Jan CAHN
AB		1MG	A078707	003	Dec 29, 2008	Jan CAHN
AB		2MG	A078707	004	Dec 29, 2008	Jan CAHN
AB		3MG	A078707	005	Dec 29, 2008	Jan CAHN
AB		4MG	A078707	006	Dec 29, 2008	Jan CAHN

ROFLUMILAST

TABLET;ORAL

DALIRESP

+	ASTRAZENECA PHARMS	250MCG	N022522	002	Jan 23, 2018	Jan NEWA
---	--------------------	--------	---------	-----	--------------	----------

ROPINIROLE HYDROCHLORIDE

TABLET;ORAL

ROPINIROLE HYDROCHLORIDE

@	G AND W LABS INC	EQ 0.25MG BASE	A077460	001	May 05, 2008	Jan DISC
@		EQ 0.5MG BASE	A077460	002	May 05, 2008	Jan DISC
@		EQ 1MG BASE	A077460	003	May 05, 2008	Jan DISC
@		EQ 2MG BASE	A077460	004	May 05, 2008	Jan DISC
@		EQ 3MG BASE	A077460	005	May 05, 2008	Jan DISC
@		EQ 4MG BASE	A077460	006	May 05, 2008	Jan DISC
@		EQ 5MG BASE	A077460	007	May 19, 2008	Jan DISC

SERTRALINE HYDROCHLORIDE

TABLET;ORAL

SERTRALINE HYDROCHLORIDE

@	FOSUN PHARMA	EQ 25MG BASE	A077713	001	Feb 06, 2007	Jan CAHN
@		EQ 50MG BASE	A077713	002	Feb 06, 2007	Jan CAHN
@		EQ 100MG BASE	A077713	003	Feb 06, 2007	Jan CAHN

SIMVASTATIN

TABLET;ORAL

SIMVASTATIN

@	YAOPHARMA CO LTD	5MG	A077766	001	Dec 20, 2006	Jan CAHN
@		10MG	A077766	002	Dec 20, 2006	Jan CAHN
@		20MG	A077766	003	Dec 20, 2006	Jan CAHN
@		40MG	A077766	004	Dec 20, 2006	Jan CAHN
@		80MG	A077766	005	Dec 20, 2006	Jan CAHN

SINECATECHINS

OINTMENT;TOPICAL

VEREGEN

+	FOUGERA PHARMS INC	15%	N021902	001	Oct 31, 2006	Jan CAHN
---	--------------------	-----	---------	-----	--------------	----------

SODIUM CHLORIDE

INJECTABLE;INJECTION

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

>D>	AP	+	HOSPIRA	9MG/ML	N019217	001	Jul 13, 1984	Feb CAHN
>A>	AP	+	ICU MEDICAL INC	9MG/ML	N019217	001	Jul 13, 1984	Feb CAHN

SODIUM FLUORIDE F-18

INJECTABLE;INTRAVENOUS

SODIUM FLUORIDE F-18

>A>	AP		SOFIE	10-200mCi/ML	A203592	001	Aug 18, 2015	Feb CAHN
>D>	AP		ZEVACOR PHARMA INC	10-200mCi/ML	A203592	001	Aug 18, 2015	Feb CAHN

>A> SOMATROPIN

>A> INJECTABLE;INJECTION

>A> BIO-TROPIN

>A>		@	FERRING	4.8MG/VIAL	N019774	001	May 25, 1995	Feb CAIN
>A>			ZOMACTON					
>A>	BX	+	FERRING	5MG/VIAL	N019774	002	Jan 04, 2002	Feb CAIN
>A>		+		10MG/VIAL	N019774	003	Mar 07, 2012	Feb CAIN

>D>	<u>SOMATROPIN RECOMBINANT</u>								
>D>	INJECTABLE; INJECTION								
>D>	BIO-TROPIN								
>D>	@	FERRING	4.8MG/VIAL		N019774	001	May 25, 1995	Feb	CAIN
>D>	ZOMACTON								
>D> BX	+	FERRING	5MG/VIAL		N019774	002	Jan 04, 2002	Feb	CAIN
>D>	+		10MG/VIAL		N019774	003	Mar 07, 2012	Feb	CAIN
<u>SUCRALFATE</u>									
SUSPENSION; ORAL									
CARAFATE									
	+	ALLERGAN SALES LLC	1GM/10ML		N019183	001	Dec 16, 1993	Jan	CAHN
TABLET; ORAL									
CARAFATE									
AB	+	ALLERGAN SALES LLC	1GM		N018333	001		Jan	CAHN
<u>SULFAMETHOXAZOLE; TRIMETHOPRIM</u>									
TABLET; ORAL									
SULFAMETHOXAZOLE AND TRIMETHOPRIM									
	@	FOSUN PHARMA	400MG; 80MG		A070889	001	Nov 13, 1986	Jan	CAHN
	@		400MG; 80MG		N018598	003	May 19, 1982	Jan	CAHN
	@		800MG; 160MG		A070890	001	Nov 13, 1986	Jan	CAHN
SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH									
	@	FOSUN PHARMA	800MG; 160MG		N018598	004	May 19, 1982	Jan	CAHN
<u>SULINDAC</u>									
TABLET; ORAL									
SULINDAC									
	@	FOSUN PHARMA	150MG		A072712	001	Aug 30, 1991	Jan	CAHN
	@		200MG		A072713	001	Aug 30, 1991	Jan	CAHN
<u>SUMATRIPTAN SUCCINATE</u>									
TABLET; ORAL									
SUMATRIPTAN SUCCINATE									
	@	FOSUN PHARMA	EQ 25MG BASE		A076976	001	Aug 10, 2009	Jan	CAHN
	@		EQ 50MG BASE		A076976	002	Aug 10, 2009	Jan	CAHN
	@		EQ 100MG BASE		A076976	003	Aug 10, 2009	Jan	CAHN
<u>TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT</u>									
INJECTABLE; INJECTION									
>D>	PULMOLITE								
>D> BS	+	JUBILANT DRAXIMAGE	N/A		N017776	001		Feb	DISC
>A>	+	@	N/A		N017776	001		Feb	DISC
<u>TECHNETIUM TC-99M MEDRONATE KIT</u>									
INJECTABLE; INJECTION									
CIS-MDP									
		PHARMALUCENCE	N/A		N018124	001		Jan	CTEC
MDP-BRACCO									
	@	CARDINAL HEALTH 414	N/A		N018107	001		Jan	DISC
<u>TECHNETIUM TC-99M PENTETATE KIT</u>									
INJECTABLE; INJECTION									
DTPA									
	+	JUBILANT DRAXIMAGE	N/A		N018511	001	Dec 29, 1989	Jan	CAHN
<u>TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR</u>									
>A>	SOLUTION; INTRAVENOUS, INTRAVESICULAR, OPHTHALMIC								
>A>	RADIOGENIX SYSTEM								
>A>	+	NORTHSTAR MEDICAL	30-1153mCi/GENERATOR		N202158	001	Feb 08, 2018	Feb	NEWA
<u>TENOFOVIR DISOPROXIL FUMARATE</u>									
TABLET; ORAL									
TENOFVIR DISOPROXIL FUMARATE									
AB		AUROBINDO PHARMA LTD	150MG		A090647	001	Jan 26, 2018	Jan	NEWA
AB			200MG		A090647	002	Jan 26, 2018	Jan	NEWA
AB			250MG		A090647	003	Jan 26, 2018	Jan	NEWA
AB			300MG		A090647	004	Jan 26, 2018	Jan	NEWA
AB		CIPLA LTD	300MG		A078800	001	Jan 26, 2018	Jan	NEWA
AB		HETERO LABS LTD III	300MG		A090636	001	Jan 26, 2018	Jan	NEWA
>A> AB		LAURUS LABS PVT	300MG		A209550	001	Feb 26, 2018	Feb	NEWA

TABLET;ORAL

TENOFIVIR DISOPROXIL FUMARATE

AB	MACLEODS PHARMS LTD	300MG	A203232	001	Jan 26, 2018	Jan NEWA
>A> AB	QILU TIANHE	200MG	A209498	001	Mar 02, 2018	Feb NEWA
>A> AB		250MG	A209498	002	Mar 02, 2018	Feb NEWA
>A> AB		300MG	A209498	003	Mar 02, 2018	Feb NEWA
AB	STRIDES PHARMA	300MG	A090742	001	Jan 26, 2018	Jan NEWA
AB	TEVA PHARMS USA	150MG	A091612	002	Jan 26, 2018	Jan NEWA
AB		200MG	A091612	003	Jan 26, 2018	Jan NEWA
AB		250MG	A091612	004	Jan 26, 2018	Jan NEWA
VIREAD						
AB	+ GILEAD SCIENCES INC	150MG	N021356	002	Jan 18, 2012	Jan CFTG
AB	+	200MG	N021356	003	Jan 18, 2012	Jan CFTG
AB	+	250MG	N021356	004	Jan 18, 2012	Jan CFTG

TERCONAZOLE

CREAM;VAGINAL

>D>	TERAZOL 7					
>D> AB	+! JANSSEN PHARMS	0.4%	N019579	001	Dec 31, 1987	Feb DISC
>A>	+ @	0.4%	N019579	001	Dec 31, 1987	Feb DISC
TERCONAZOLE						
>D> AB	TARO	0.4%	A076043	001	Jan 19, 2005	Feb CHRS
>A> AB	!	0.4%	A076043	001	Jan 19, 2005	Feb CHRS
SUPPOSITORY;VAGINAL						
>D>	TERAZOL 3					
>D> AB	+! JANSSEN PHARMS	80MG	N019641	001	May 24, 1988	Feb DISC
>A>	+ @	80MG	N019641	001	May 24, 1988	Feb DISC
TERCONAZOLE						
>D> AB	PERRIGO NEW YORK	80MG	A077149	001	Mar 17, 2006	Feb CHRS
>A> AB	!	80MG	A077149	001	Mar 17, 2006	Feb CHRS

TESTOSTERONE

GEL;TRANSDERMAL

TESTOSTERONE

	@ ANI PHARMS INC	25MG/2.5GM PACKET	N202763	001	Feb 14, 2012	Jan DISC
	@	50MG/5GM PACKET	N202763	002	Feb 14, 2012	Jan DISC
	SOLUTION, METERED;TRANSDERMAL					
	TESTOSTERONE					
AT	CIPLA LTD	30MG/1.5ML ACTUATION	A209533	001	Jan 29, 2018	Jan NEWA

THEOPHYLLINE

TABLET, EXTENDED RELEASE;ORAL

THEOCHRON

AB	NOSTRUM PHARMS LLC	100MG	A087400	003	Feb 21, 1985	Jan CTEC
AB		200MG	A087400	004	Feb 21, 1985	Jan CTEC

THIORIDAZINE HYDROCHLORIDE

TABLET;ORAL

THIORIDAZINE HYDROCHLORIDE

@ FOSUN PHARMA	10MG	A088131	001	Aug 30, 1983	Jan CAHN
@	25MG	A088133	001	Aug 30, 1983	Jan CAHN
@	50MG	A088134	001	Aug 30, 1983	Jan CAHN
@	100MG	A088135	001	Nov 20, 1984	Jan CAHN
@	200MG	A088137	001	Sep 17, 1986	Jan CAHN

THIOTHIXENE

CAPSULE;ORAL

NAVANE

+ @ PFIZER	1MG	N016584	001		Jan CRLD
+ @	2MG	N016584	002		Jan CRLD
+ @	5MG	N016584	003		Jan CRLD
+ @	10MG	N016584	004		Jan CRLD
+ @	20MG	N016584	005		Jan CRLD

TICLOPIDINE HYDROCHLORIDE

TABLET;ORAL

TICLOPIDINE HYDROCHLORIDE

@ YAOPHARMA CO LTD	250MG	A075318	001	Aug 20, 1999	Jan CAHN
@	250MG	A075326	001	Aug 20, 1999	Jan CAHN

TIGECYCLINE

POWDER; IV (INFUSION)

TIGECYCLINE

ACCORD HLTHCARE INC 50MG/VIAL

N208744 001 Jan 18, 2018 Jan NEWA

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

TIMOPTIC

AT + ATON EQ 0.25% BASE
 AT1 + EQ 0.5% BASE

N018086 001 Jan CMFD
 N018086 002 Jan CMFD

TABLET; ORAL

TIMOLOL MALEATE

@ YAOPHARMA CO LTD

5MG

A072550 001 Apr 13, 1989 Jan CAHN

@

10MG

A072551 001 Apr 13, 1989 Jan CAHN

@

20MG

A072552 001 Apr 13, 1989 Jan CAHN

TIZANIDINE HYDROCHLORIDE

TABLET; ORAL

TIZANIDINE HYDROCHLORIDE

>A> AB ZYDUS PHARMS USA INC EQ 2MG BASE
 >A> AB EQ 4MG BASE

A208187 001 Mar 09, 2018 Feb NEWA
 A208187 002 Mar 09, 2018 Feb NEWA

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

@ YAOPHARMA CO LTD

100MG

A071633 001 Dec 09, 1987 Jan CAHN

@

250MG

A070289 001 Mar 13, 1986 Jan CAHN

@

500MG

A070290 001 Mar 13, 1986 Jan CAHN

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

@ YAOPHARMA CO LTD

500MG

A086574 001 Jan CAHN

TOLMETIN SODIUM

CAPSULE; ORAL

TOLMETIN SODIUM

@ FOSUN PHARMA

EQ 400MG BASE

A073462 001 Apr 30, 1992 Jan CAHN

TABLET; ORAL

TOLMETIN SODIUM

@ FOSUN PHARMA

EQ 200MG BASE

A073588 001 Jul 31, 1992 Jan CAHN

@

EQ 600MG BASE

A074002 001 Sep 27, 1993 Jan CAHN

TOPIRAMATE

CAPSULE; ORAL

TOPIRAMATE

@ FOSUN PHARMA

15MG

A079206 001 Oct 14, 2009 Jan CAHN

@

25MG

A079206 002 Oct 14, 2009 Jan CAHN

TRAMADOL HYDROCHLORIDE

TABLET; ORAL

TRAMADOL HYDROCHLORIDE

@ FOSUN PHARMA

50MG

A075968 001 Jun 25, 2002 Jan CAHN

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HYDROCHLORIDE

@ FOSUN PHARMA

100MG

A072483 001 Apr 30, 1990 Jan CAHN

TRIAMCINOLONE ACETONIDE

SPRAY; TOPICAL

KENALOG

>D> AT +! RANBAXY LABS LTD 0.147MG/GM
 >A> AT +! SUN PHARM INDS INC 0.147MG/GM

N012104 001 Feb CAHN
 N012104 001 Feb CAHN

TRIENTINE HYDROCHLORIDECAPSULE;ORAL
SYPRINE

AB	+	ATON	250MG	N019194	001	Nov 08, 1985	Jan CFTG
		TRIENTINE HYDROCHLORIDE					
AB		WATSON LABS TEVA	250MG	A207567	001	Feb 07, 2018	Jan NEWA

TRIFLUOPERAZINE HYDROCHLORIDECONCENTRATE;ORAL
TRIFLUOPERAZINE HYDROCHLORIDE

@	FOSUN PHARMA	EQ 10MG BASE/ML	A085787	001	Apr 15, 1982	Jan CAHN
---	--------------	-----------------	---------	-----	--------------	----------

VANCOMYCIN HYDROCHLORIDECAPSULE;ORAL
VANCOMYCIN HYDROCHLORIDE

>D>	AB	FRESENIUS KABI USA	EQ 125MG BASE	A065453	001	Jun 18, 2012	Feb DISC
>A>		@	EQ 125MG BASE	A065453	001	Jun 18, 2012	Feb DISC
>D>	AB		EQ 250MG BASE	A065453	002	Jun 18, 2012	Feb DISC
>A>		@	EQ 250MG BASE	A065453	002	Jun 18, 2012	Feb DISC

FOR SOLUTION;ORAL
FIRVANQ KIT

+	RXMTM THERAPS LLC	EQ 25MG BASE/ML	N208910	001	Jan 26, 2018	Jan NEWA
+		EQ 50MG BASE/ML	N208910	002	Jan 26, 2018	Jan NEWA

VARENICLINE TARTRATETABLET;ORAL
CHANTIX

>A>	+	PF PRISM CV	EQ 0.5MG BASE	N021928	001	May 10, 2006	Feb CAHN
>A>	+		EQ 1MG BASE	N021928	002	May 10, 2006	Feb CAHN
>D>	+	PFIZER INC	EQ 0.5MG BASE	N021928	001	May 10, 2006	Feb CAHN
>D>	+		EQ 1MG BASE	N021928	002	May 10, 2006	Feb CAHN

VENLAFAXINE HYDROCHLORIDETABLET;ORAL
VENLAFAXINE HYDROCHLORIDE

@	FOSUN PHARMA	EQ 25MG BASE	A077515	001	Jun 13, 2008	Jan CAHN
@		EQ 37.5MG BASE	A077515	002	Jun 13, 2008	Jan CAHN
@		EQ 50MG BASE	A077515	003	Jun 13, 2008	Jan CAHN
@		EQ 75MG BASE	A077515	004	Jun 13, 2008	Jan CAHN
@		EQ 100MG BASE	A077515	005	Jun 13, 2008	Jan CAHN

VERAPAMIL HYDROCHLORIDESOLUTION;INTRAVENOUS
VERAPAMIL HYDROCHLORIDE

AP	!	HOSPIRA	5MG/2ML (2.5MG/ML)	A070738	001	May 06, 1987	Jan CPOT
----	---	---------	--------------------	---------	-----	--------------	----------

TABLET;ORAL
VERAPAMIL HYDROCHLORIDE

@	YAOPHARMA CO LTD	40MG	A073168	001	Jul 31, 1992	Jan CAHN
@		80MG	A071423	001	May 24, 1988	Jan CAHN
@		120MG	A071424	001	May 25, 1988	Jan CAHN

VIGABATRINFOR SOLUTION;ORAL
VIGABATRIN

>A>	AA	AMNEAL PHARMS	500MG/PACKET	A210155	001	Mar 13, 2018	Feb NEWA
-----	----	---------------	--------------	---------	-----	--------------	----------

VILAZODONE HYDROCHLORIDETABLET;ORAL
VIIBRYD

+	ALLERGAN SALES LLC	10MG	N022567	001	Jan 21, 2011	Jan CAHN
+		20MG	N022567	002	Jan 21, 2011	Jan CAHN
+		40MG	N022567	003	Jan 21, 2011	Jan CAHN

WARFARIN SODIUMTABLET;ORAL
WARFARIN SODIUM

@	YAOPHARMA CO LTD	1MG	A040196	001	Sep 30, 1997	Jan CAHN
@		2MG	A040196	002	Sep 30, 1997	Jan CAHN
@		2.5MG	A040196	003	Sep 30, 1997	Jan CAHN
@		3MG	A040196	008	Jul 26, 2000	Jan CAHN
@		4MG	A040196	004	Sep 30, 1997	Jan CAHN

TABLET;ORAL

WARFARIN SODIUM

@	5MG	A040196	005	Sep 30, 1997	Jan CAHN
@	6MG	A040196	009	Jul 26, 2000	Jan CAHN
@	7.5MG	A040196	006	Sep 30, 1997	Jan CAHN
@	10MG	A040196	007	Sep 30, 1997	Jan CAHN

ZOLEDRONIC ACID

INJECTABLE;IV (INFUSION)

ZOLEDRONIC ACID

AP	INFORLIFE	EQ 4MG BASE/100ML	N203231	001	Aug 02, 2013	Jan CAHN
AP		EQ 5MG BASE/100ML	A202828	001	Sep 23, 2013	Jan CAHN
>D> AP	! SUN PHARMA GLOBAL	EQ 4MG BASE/VIAL	A090018	001	Mar 04, 2013	Feb DISC
>A>	@	EQ 4MG BASE/VIAL	A090018	001	Mar 04, 2013	Feb DISC

ZONISAMIDE

CAPSULE;ORAL

ZONISAMIDE

>A>	@ AUROBINDO PHARMA LTD	25MG	A077645	002	Sep 29, 2006	Feb CAHN
>A>	@	50MG	A077645	003	Sep 29, 2006	Feb CAHN
>A>	@	100MG	A077645	001	Dec 22, 2005	Feb CAHN
>D>	@ DR REDDYS LABS LTD	25MG	A077645	002	Sep 29, 2006	Feb CAHN
>D>	@	50MG	A077645	003	Sep 29, 2006	Feb CAHN
>D>	@	100MG	A077645	001	Dec 22, 2005	Feb CAHN

ACETAMINOPHENSUPPOSITORY;RECTAL
ACEPHEN@ G AND W LABS 325MG
@ 650MGN018060 003 Dec 18, 1986 Jan DISC
N018060 002 Jan DISCCETIRIZINE HYDROCHLORIDE

TABLET;ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

>A>	PLD ACQUISITIONS	5MG	A077946	001	Dec 27, 2007	Feb CAHN
>A>		10MG	A077946	002	Dec 27, 2007	Feb CAHN
>D>	SANDOZ	5MG	A077946	001	Dec 27, 2007	Feb CAHN
>D>		10MG	A077946	002	Dec 27, 2007	Feb CAHN

CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

>A>	PLD ACQUISITIONS	5MG;120MG	A077991	001	Mar 05, 2008	Feb CAHN
>D>	SANDOZ	5MG;120MG	A077991	001	Mar 05, 2008	Feb CAHN

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SPONGE;TOPICAL

CHLORAPREP ONE-STEP

>A>	+! BECTON DICKINSON CO	2%;70% (1ML)	N020832	008	Oct 23, 2008	Feb NEWA
-----	------------------------	--------------	---------	-----	--------------	----------

CLEMASTINE FUMARATE

TABLET;ORAL

CLEMASTINE FUMARATE

PLD ACQUISITIONS LLC 1.34MG

A073458 001 Oct 31, 1993 Jan CAHN

CLOTTRIMAZOLE

>D>	CREAM, TABLET;TOPICAL, VAGINAL					
>D>	MYCELEX-7 COMBINATION PACK					
>D>	BAYER HEALTHCARE LLC	1%,100MG	N020389	002	Jun 23, 1994	Feb DISC
>A>	@	1%,100MG	N020389	002	Jun 23, 1994	Feb DISC

IBUPROFEN

TABLET;ORAL

IBUPROFEN

@ P AND L DEV LLC 200MG

A070733 001 Sep 19, 1986 Jan CAHN

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET;ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

DR REDDYS LABS LTD 5MG

A210375 001 Jan 19, 2018 Jan NEWA

LORATADINE

TABLET;ORAL

LORATADINE

PLD ACQUISITIONS LLC 10MG

A075209 001 Jan 21, 2003 Jan CAHN

MICONAZOLE NITRATE

CREAM, SUPPOSITORY;TOPICAL, VAGINAL

MICONAZOLE 7 COMBINATION PACK

@ G AND W LABS 2%,100MG

A076585 001 Mar 26, 2004 Jan DISC

NAPROXEN SODIUM

TABLET;ORAL

NAPROXEN SODIUM

@ PLD ACQUISITIONS LLC EQ 200MG BASE

A074646 001 Jan 13, 1997 Jan CAHN

NICOTINE POLACRILEX

GUM, CHEWING;BUCCAL

THRIVE

>A>	GLAXOSMITHKLINE CONS	EQ 2MG BASE	A077658	001	Jun 19, 2007	Feb CAHN
>A>		EQ 4MG BASE	A077656	001	Jun 19, 2007	Feb CAHN
>D>	NOVARTIS	EQ 2MG BASE	A077658	001	Jun 19, 2007	Feb CAHN
>D>		EQ 4MG BASE	A077656	001	Jun 19, 2007	Feb CAHN

TROCHE/LOZENGE;ORAL

>D> COMMIT

>D>	+	GLAXOSMITHKLINE CONS	EQ 2MG BASE	N021330	001	Oct 31, 2002	Feb CTNA
>D>	+	!	EQ 4MG BASE	N021330	002	Oct 31, 2002	Feb CTNA

>A> NICORETTE

>A>	+	GLAXOSMITHKLINE CONS	EQ 2MG BASE	N021330	001	Oct 31, 2002	Feb CTNA
>A>	+	!	EQ 4MG BASE	N021330	002	Oct 31, 2002	Feb CTNA

RANITIDINE HYDROCHLORIDE

TABLET;ORAL

RANITIDINE HYDROCHLORIDE

>A>		VIVIMED GLOBAL	EQ 75MG BASE	A209160	001	Mar 05, 2018	Feb NEWA
>A>			EQ 150MG BASE	A209161	001	Feb 22, 2018	Feb NEWA

TERBINAFINE

GEL;TOPICAL

LAMISIL AT

>A>	+	!	GLAXOSMITHKLINE CONS	1%	N021958	001	Jul 24, 2006	Feb CAHN
>D>	+	!	NOVARTIS	1%	N021958	001	Jul 24, 2006	Feb CAHN

TERBINAFINE HYDROCHLORIDE

SOLUTION;TOPICAL

LAMISIL AT

>A>	+	!	GLAXOSMITHKLINE CONS	1%	N021124	001	Mar 17, 2000	Feb CAHN
>D>	+	!	NOVARTIS	1%	N021124	001	Mar 17, 2000	Feb CAHN

SPRAY;TOPICAL

LAMISIL AT

>A>	+	!	GLAXOSMITHKLINE CONS	1%	N021124	002	Mar 17, 2000	Feb CAHN
>D>	+	!	NOVARTIS	1%	N021124	002	Mar 17, 2000	Feb CAHN

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

CUMULATIVE SUPPLEMENT NUMBER 2 FEBRUARY 2018

NO FEBRUARY 2018 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 FEBRUARY 2018 ADDITIONS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>ABEMACICLIB - VERZENIO</u>						
N 208716	001				>A> I-768	Feb 26, 2021
<u>ABEMACICLIB - VERZENIO</u>						
N 208716	002				>A> I-768	Feb 26, 2021
<u>ABEMACICLIB - VERZENIO</u>						
N 208716	003				>A> I-768	Feb 26, 2021
<u>ABEMACICLIB - VERZENIO</u>						
N 208716	004				>A> I-768	Feb 26, 2021
<u>ABIRATERONE ACETATE - ZYTIGA</u>						
N 202379	001	>A> 8822438	Aug 24, 2027	U-1579	>A> I-765	Feb 07, 2021
		>A> 8822438	Aug 24, 2027	U-1580		
		>A> 8822438	Aug 24, 2027	U-2235		
<u>ABIRATERONE ACETATE - ZYTIGA</u>						
N 202379	002	>A> 8822438	Aug 24, 2027	U-1579	>A> I-765	Feb 07, 2021
		>A> 8822438	Aug 24, 2027	U-1580		
		>A> 8822438	Aug 24, 2027	U-2235		
<u>AFATINIB DIMALEATE - GILOTREF</u>						
N 201292	001				I-763	Jan 12, 2021
<u>AFATINIB DIMALEATE - GILOTREF</u>						
N 201292	002				I-763	Jan 12, 2021
<u>AFATINIB DIMALEATE - GILOTREF</u>						
N 201292	003				I-763	Jan 12, 2021
<u>AMANTADINE HYDROCHLORIDE - GOCOVRI</u>						
N 208944	001	9867791	Dec 02, 2030	U-2106		
		9867792	Dec 02, 2030	U-2106		
		9867793	Dec 02, 2030	U-2106		
		9877933	Dec 02, 2030	U-2224		
<u>AMANTADINE HYDROCHLORIDE - GOCOVRI</u>						
N 208944	002	9867791	Dec 02, 2030	U-2106		
		9867792	Dec 02, 2030	U-2106		
		9867793	Dec 02, 2030	U-2106		
		9877933	Dec 02, 2030	U-2224		
<u>AMANTADINE HYDROCHLORIDE - OSMOLEX ER</u>						
N 209410	001	>A> 8252331	Mar 13, 2030	DP		
		>A> 8574626	Nov 28, 2025	DP U-20		
		>A> RE39069	May 29, 2018	DP		
<u>AMANTADINE HYDROCHLORIDE - OSMOLEX ER</u>						
N 209410	002	>A> 8252331	Mar 13, 2030	DP		
		>A> 8574626	Nov 28, 2025	DP U-20		
		>A> RE39069	May 29, 2018	DP		
<u>AMANTADINE HYDROCHLORIDE - OSMOLEX ER</u>						
N 209410	003	>A> 8252331	Mar 13, 2030	DP		
		>A> 8574626	Nov 28, 2025	DP U-20		
		>A> RE39069	May 29, 2018	DP		

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>ANGIOTENSIN II ACETATE - GIAPREZA</u>						
N 209360 001	9220745	Dec 18, 2034	U-2217		NCE	Dec 21, 2022
	9220745	Dec 18, 2034	U-2218			
	9572856	Sep 20, 2030	U-2221			
>A>	9867863	Dec 16, 2029	U-2231			
<u>ANGIOTENSIN II ACETATE - GIAPREZA</u>						
N 209360 002	9220745	Dec 18, 2034	U-2217		NCE	Dec 21, 2022
	9220745	Dec 18, 2034	U-2218			
	9572856	Sep 20, 2030	U-2221			
>A>	9867863	Dec 16, 2029	U-2231			
<u>APALUTAMIDE - ERLEADA</u>						
N 210951 001	>A> 8445507	Sep 15, 2030	DS DP U-2237		>A> NCE	Feb 14, 2023
	>A> 8802689	Mar 27, 2027	U-2237			
	>A> 9388159	Mar 27, 2027	DS DP			
	>A> 9481663	Jun 04, 2033	DS DP U-2237			
	>A> 9884054	Sep 23, 2033	U-2237			
<u>APREMILAST - OTEZLA</u>						
N 205437 001	>A> 9872854	May 29, 2034	U-2232			
	>A> 9872854	May 29, 2034	U-2233			
<u>APREMILAST - OTEZLA</u>						
N 205437 002	>A> 9872854	May 29, 2034	U-2232			
	>A> 9872854	May 29, 2034	U-2233			
<u>APREMILAST - OTEZLA</u>						
N 205437 003	>A> 9872854	May 29, 2034	U-2232			
	>A> 9872854	May 29, 2034	U-2233			
<u>ARSENIC TRIOXIDE - TRISENOX</u>						
N 021248 001	>A> 6723351	Nov 10, 2018	U-2204			
	>A> 6723351	Nov 10, 2018	U-2229			
	>A> 6723351	Nov 10, 2018	U-573			
	>A> 6855339	Nov 10, 2018	U-2204			
	>A> 6855339	Nov 10, 2018	U-2229			
	>A> 6855339	Nov 10, 2018	U-617			
	>A> 6861076	Nov 10, 2018	U-2204			
	>A> 6861076	Nov 10, 2018	U-2229			
	>A> 6861076	Nov 10, 2018	U-617			
	>A> 6884439	Nov 10, 2018	U-2204			
	>A> 6884439	Nov 10, 2018	U-2229			
	>A> 6884439	Nov 10, 2018	U-651			
	>A> 6982096	Nov 10, 2018	U-2204			
	>A> 6982096	Nov 10, 2018	U-2229			
	>A> 6982096	Nov 10, 2018	U-651			
	8273379	Nov 10, 2018	U-1291			
	8273379	Nov 10, 2018	U-2204			
	8273379	Nov 10, 2018	U-2229			
<u>ARSENIC TRIOXIDE - TRISENOX</u>						
N 021248 002	>A> 6723351	Nov 10, 2018	U-2204			
	>A> 6723351	Nov 10, 2018	U-2229			
	>A> 6723351	Nov 10, 2018	U-573			
	>A> 6855339	Nov 10, 2018	U-2204			
	>A> 6855339	Nov 10, 2018	U-2229			
	>A> 6855339	Nov 10, 2018	U-617			
	>A> 6861076	Nov 10, 2018	U-2204			
	>A> 6861076	Nov 10, 2018	U-2229			
	>A> 6861076	Nov 10, 2018	U-617			
	>A> 6884439	Nov 10, 2018	U-2204			
	>A> 6884439	Nov 10, 2018	U-2229			
	>A> 6884439	Nov 10, 2018	U-651			
	>A> 6982096	Nov 10, 2018	U-2204			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>ARSENIC TRIOXIDE - TRISENOX</u>						
N 021248 002	>A> 6982096	Nov 10, 2018	U-2229			
	>A> 6982096	Nov 10, 2018	U-651			
	>A> 8273379	Nov 10, 2018	U-2204			
	>A> 8273379	Nov 10, 2018	U-2229			
<u>ASENAPINE MALEATE - SAPHRIS</u>						
N 022117 001					M-158	Mar 12, 2018
					NPP	Mar 12, 2018
					PED	Sep 12, 2018
					PED	Sep 12, 2018
<u>ASENAPINE MALEATE - SAPHRIS</u>						
N 022117 002					M-158	Mar 12, 2018
					NPP	Mar 12, 2018
					PED	Sep 12, 2018
					PED	Sep 12, 2018
<u>AVIBACTAM SODIUM; CEFTAZIDIME - AVYCAZ</u>						
N 206494 001	>A> 7112592	Feb 24, 2022	DS DP U-2244			
	>A> 7112592	Feb 24, 2022	DS DP U-282			
	>A> 8178554	Jul 24, 2021	DS DP U-2245			
	>A> 8178554	Jul 24, 2021	DS DP U-282			
<u>BAZEDOXIFENE ACETATE; ESTROGENS, CONJUGATED - DUAVEE</u>						
N 022247 001	>A> 5998402	Apr 04, 2019	DS DP U-594			
<u>BENDAMUSTINE HYDROCHLORIDE - BENDEKA</u>						
N 208194 001	8791270	Jan 12, 2026	DP U-1790			
<u>BETAMETHASONE DIPROPIONATE - SERNIVO</u>						
N 208079 001	>A> 9877974	Aug 31, 2030	DP U-1858			
<u>BICTEGRAVIR SODIUM; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - BIKTARVY</u>						
N 210251 001	>A> 6642245	Nov 04, 2020	U-257		>A> NCE	Feb 07, 2023
	>A> 6703396	Mar 09, 2021	DS DP			
	>A> 7390791	May 07, 2022	DS DP			
	>A> 7803788	Feb 02, 2022	U-257			
	>A> 8754065	Aug 15, 2032	DS DP U-257			
	>A> 9216996	Dec 19, 2033	DS DP			
	>A> 9296769	Aug 15, 2032	DS DP U-257			
	>A> 9708342	Jun 19, 2035	DS DP			
	>A> 9732092	Dec 19, 2033	DS DP			
<u>BOSUTINIB MONOHYDRATE - BOSULIF</u>						
N 203341 001					>A> ODE-163	Dec 19, 2024
<u>BOSUTINIB MONOHYDRATE - BOSULIF</u>						
N 203341 002					>A> ODE-163	Dec 19, 2024
<u>BOSUTINIB MONOHYDRATE - BOSULIF</u>						
N 203341 003					>A> ODE-163	Dec 19, 2024
<u>BRIMONIDINE TARTRATE - MIRVASO</u>						
N 204708 001	9861631	Mar 25, 2031	U-1428			
	9861632	Mar 25, 2031	U-1428			
<u>BRIMONIDINE TARTRATE - LUMIFY</u>						
N 208144 001	8293742	Jul 14, 2030	U-2222			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>BRIMONIDINE TARTRATE; TIMOLOL MALEATE - COMBIGAN</u>						
N 021398 001	>A> 9907801	Apr 19, 2022	DP U-2239			
	>A> 9907802	Apr 19, 2022	DP U-2240			
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
N 021929 001	>A> 8387615	Mar 26, 2027	DP			
	>A> 8387615*PED	Sep 26, 2027				
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
N 021929 002	>A> 8387615	Mar 26, 2027	DP			
	>A> 8387615*PED	Sep 26, 2027				
<u>BUPRENORPHINE - SUBLOCADE</u>						
N 209819 001					NP	Nov 30, 2020
<u>BUPRENORPHINE - SUBLOCADE</u>						
N 209819 002					NP	Nov 30, 2020
<u>CALCIFEDIOL - RAYALDEE</u>						
N 208010 001	9861644	Mar 14, 2034	DP			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 001	>A> 7094427	May 29, 2022	DP U-1645	Y		
	>A> 9901640	Dec 26, 2028	DP U-219			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 002	>A> 7094427	May 29, 2022	DP U-1645	Y		
	>A> 9901640	Dec 26, 2028	DP U-219			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 003	>A> 7094427	May 29, 2022	DP U-1645	Y		
	>A> 9901640	Dec 26, 2028	DP U-219			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 004	>A> 7094427	May 29, 2022	DP U-1645	Y		
	>A> 9901640	Dec 26, 2028	DP U-219			
<u>CEFTOLOZANE SULFATE; TAZOBACTAM SODIUM - ZERBAXA</u>						
N 206829 001	9872906	Mar 14, 2034	DP			
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - PREVANTICS SWAB</u>						
N 021524 001					>A> M-221	Feb 14, 2021
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - PREVANTICS SWABSTICK</u>						
N 021524 002					>A> M-221	Feb 14, 2021
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - PREVANTICS MAXI SWABSTICK</u>						
N 021524 003					>A> M-221	Feb 14, 2021
<u>COBICISTAT; DARUNAVIR ETHANOLATE - PREZCOBIX</u>						
N 205395 001	>A> 9889115	Jun 23, 2019	U-1660			
<u>COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - GENVOYA</u>						
N 207561 001	>A> 9891239	Sep 03, 2029	DP U-257			
<u>COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - STRIBILD</u>						
N 203100 001	>A> 9891239	Sep 03, 2029	DP U-257			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>COCAINE HYDROCHLORIDE - GOPRELTO</u>						
N 209963 001	9867815	Feb 07, 2037	U-2225		NCE	Dec 14, 2022
	9867815	Feb 07, 2037	U-2226			
	9867815	Feb 07, 2037	U-2227			
<u>CYSTEAMINE BITARTRATE - PROCYSBI</u>						
N 203389 001					ODE-162	Dec 22, 2024
<u>CYSTEAMINE BITARTRATE - PROCYSBI</u>						
N 203389 002					ODE-162	Dec 22, 2024
<u>DANTROLENE SODIUM - RYANODEX</u>						
N 205579 001	9884044	Jun 13, 2022	DP U-1546			
<u>DAPAGLIFLOZIN PROPANEDIOL - FARXIGA</u>						
N 202293 001	7456254	Jun 30, 2025	DP U-2139			
	8329648	Aug 18, 2026	U-2139			
	8329648	Aug 18, 2026	U-2212			
	8329648	Aug 18, 2026	U-2213			
	8431685	Apr 13, 2025	DP U-2139			
	8461105	Apr 13, 2025	DP U-2139			
	8906851	Aug 18, 2026	U-2139			
	9238076	Apr 15, 2024	DP U-2139			
<u>DAPAGLIFLOZIN PROPANEDIOL - FARXIGA</u>						
N 202293 002	7456254	Jun 30, 2025	DP U-2139			
	8329648	Aug 18, 2026	U-2139			
	8329648	Aug 18, 2026	U-2212			
	8329648	Aug 18, 2026	U-2213			
	8431685	Apr 13, 2025	DP U-2139			
	8461105	Apr 13, 2025	DP U-2139			
	8906851	Aug 18, 2026	U-2139			
	9238076	Apr 15, 2024	DP U-2139			
<u>DASATINIB - SPRYCEL</u>						
N 021986 001					>A> ODE-164	Nov 09, 2024
<u>DASATINIB - SPRYCEL</u>						
N 021986 002					>A> ODE-164	Nov 09, 2024
<u>DASATINIB - SPRYCEL</u>						
N 021986 003					>A> ODE-164	Nov 09, 2024
<u>DASATINIB - SPRYCEL</u>						
N 021986 004					>A> ODE-164	Nov 09, 2024
<u>DASATINIB - SPRYCEL</u>						
N 021986 005					>A> ODE-164	Nov 09, 2024
<u>DASATINIB - SPRYCEL</u>						
N 021986 006					>A> ODE-164	Nov 09, 2024
<u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>						
N 021992 001					>A> M-222	Feb 06, 2021
<u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>						
N 021992 002					>A> M-222	Feb 06, 2021
<u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>						
N 021992 003					>A> M-222	Feb 06, 2021

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>DEXAMETHASONE - DEXYCU KIT</u>						
N 208912 001	>A> 6960346	Jul 03, 2023	DP		>A> NP	Feb 09, 2021
	>A> 7560120	Sep 05, 2022	DP			
<u>DIMETHYL FUMARATE - TECFIDERA</u>						
N 204063 001	>A> 6509376	Apr 01, 2018	DP			
	>A> 7320999	Oct 20, 2018	U-1384			
	>A> 7619001	Apr 01, 2018	U-1384			
	>A> 7803840	Apr 01, 2018	U-1385			
	>A> 8399514	Feb 07, 2028	U-1384			
<u>DIMETHYL FUMARATE - TECFIDERA</u>						
N 204063 002	>A> 6509376	Apr 01, 2018	DP			
	>A> 7320999	Oct 20, 2018	U-1384			
	>A> 7619001	Apr 01, 2018	U-1384			
	>A> 7803840	Apr 01, 2018	U-1385			
	>A> 8399514	Feb 07, 2028	U-1384			
<u>DOXEPIN HYDROCHLORIDE - SILENOR</u>						
N 022036 001	9861607	May 18, 2027	U-620			
<u>DOXEPIN HYDROCHLORIDE - SILENOR</u>						
N 022036 002	9861607	May 18, 2027	U-620			
<u>EFAVIRENZ - EFAVIRENZ</u>						
A 078064 001					>A> PC	Jun 19, 2018
<u>EFAVIRENZ - EFAVIRENZ</u>						
A 078064 002					>A> PC	Jun 19, 2018
<u>EFAVIRENZ - EFAVIRENZ</u>						
A 078064 003					>A> PC	Jun 19, 2018
<u>EFAVIRENZ - EFAVIRENZ</u>						
A 091471 001					PC	Feb 14, 2018
<u>EFINACONAZOLE - JUBLIA</u>						
N 203567 001	9877955	Jan 03, 2028	U-1969			
<u>ERTUGLIFLOZIN - STEGLATRO</u>						
N 209803 001	8080580	Jul 13, 2030	DS DP U-2214			
<u>ERTUGLIFLOZIN - STEGLATRO</u>						
N 209803 002	8080580	Jul 13, 2030	DS DP U-2214			
<u>ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET</u>						
N 209806 001	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439902	Oct 21, 2030	U-2214			
<u>ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET</u>						
N 209806 002	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439902	Oct 21, 2030	U-2214			
<u>ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET</u>						
N 209806 003	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439902	Oct 21, 2030	U-2214			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET</u>						
N 209806 004	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439902	Oct 21, 2030	U-2214			
<u>ERTUGLIFLOZIN; SITAGLIPTIN PHOSPHATE - STEGLUJAN</u>						
N 209805 001	6699871	Jul 26, 2022	DS DP U-2214			
	6890898	Feb 02, 2019	U-2215			
	7078381	Feb 02, 2019	U-2216			
	7326708	Nov 24, 2026	DS DP U-2214			
	7459428	Feb 02, 2019	U-2215			
	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439901	Oct 21, 2030	U-2214			
<u>ERTUGLIFLOZIN; SITAGLIPTIN PHOSPHATE - STEGLUJAN</u>						
N 209805 002	6699871	Jul 26, 2022	DS DP U-2214			
	6890898	Feb 02, 2019	U-2215			
	7078381	Feb 02, 2019	U-2216			
	7326708	Nov 24, 2026	DS DP U-2214			
	7459428	Feb 02, 2019	U-2215			
	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439901	Oct 21, 2030	U-2214			
<u>EXENATIDE - BYDUREON BCISE</u>						
N 209210 001	>A> 9884092	Aug 18, 2026	U-1313			
	>A> 9884092	Aug 18, 2026	U-2154			
	>A> 9884092	Aug 18, 2026	U-2155			
	>A> 9884092	Aug 18, 2026	U-2156			
<u>EXENATIDE SYNTHETIC - BYDUREON</u>						
N 022200 001	>A> 9884092	Aug 18, 2026	U-1313			
	>A> 9884092	Aug 18, 2026	U-2154			
	>A> 9884092	Aug 18, 2026	U-2155			
	>A> 9884092	Aug 18, 2026	U-2156			
<u>EXENATIDE SYNTHETIC - BYDUREON PEN</u>						
N 022200 002	>A> 9884092	Aug 18, 2026	U-1313			
	>A> 9884092	Aug 18, 2026	U-2154			
	>A> 9884092	Aug 18, 2026	U-2155			
	>A> 9884092	Aug 18, 2026	U-2156			
<u>FENTANYL CITRATE - LAZANDA</u>						
N 022569 001	9814705	Jan 08, 2024	DP			
<u>FENTANYL CITRATE - LAZANDA</u>						
N 022569 002	9814705	Jan 08, 2024	DP			
<u>FENTANYL CITRATE - LAZANDA</u>						
N 022569 003	9814705	Jan 08, 2024	DP			
<u>FERUMOXYTOL - FERAHEME</u>						
N 022180 001				>A> I-767		Feb 02, 2021
<u>FLUTICASONE FUROATE; UMECLIDINIUM BROMIDE; VILANTEROL TRIFENATATE - TRELEGY ELLIPTA</u>						
N 209482 001	9750726	Nov 29, 2030	DP			
<u>FORMOTEROL FUMARATE - PERFOROMIST</u>						
N 022007 001	9730890	Jun 22, 2021	DP			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>HEXAMINOLEVULINATE HYDROCHLORIDE - CYSVIEW KIT</u>						
N 022555 001					>A> M-220	Feb 15, 2021
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 001	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 002	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 003	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 004	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 005	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 006	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 007	9872837	Dec 21, 2031	DP			
<u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID-HP</u>						
N 019034 001	>A> 9248229	Mar 12, 2034	DP			
	>A> 9731082	Apr 23, 2032	DP			
<u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID-HP</u>						
N 019034 002	>A> 9248229	Mar 12, 2034	DP			
	>A> 9731082	Apr 23, 2032	DP			
<u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID</u>						
N 019034 003	>A> 9248229	Mar 12, 2034	DP			
	>A> 9731082	Apr 23, 2032	DP			
<u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID</u>						
N 019034 004	>A> 9248229	Mar 12, 2034	DP			
	>A> 9731082	Apr 23, 2032	DP			
<u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID</u>						
N 019034 005	>A> 9248229	Mar 12, 2034	DP			
	>A> 9731082	Apr 23, 2032	DP			
<u>HYDROXYPROGESTERONE CAPROATE - MAKENA (AUTOINJECTOR)</u>						
N 021945 004	>A> 8021335	Oct 04, 2026	DP			
	>A> 8562564	Jan 24, 2026	DP			
	>A> 9180259	Jan 24, 2026	DP			
	>A> 9533102	Jan 24, 2026	DP			
	>A> 9629959	Jan 24, 2026	DP			
	>A> 9789257	Feb 11, 2034	DP			
	>A> 9844558	May 02, 2036	U-2236			
	>A> RE44846	Aug 10, 2019	DP			
<u>IBRUTINIB - IMBRUVICA</u>						
N 205552 001	8563563	Apr 26, 2027	U-1491			
	8563563	Apr 26, 2027	U-1946			
	8563563	Apr 26, 2027	U-2219			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>IBRUTINIB - IMBRUVICA</u>						
N 205552 002	7514444	Dec 28, 2026	DS DP		>A> NCE	Nov 13, 2018
	8008309	Dec 28, 2026	DS DP			
	8476284	Dec 28, 2026				
	8476284	Dec 28, 2026			U-1456	
	8476284	Dec 28, 2026			U-1650	
	8476284	Dec 28, 2026			U-1946	
	8476284	Dec 28, 2026			U-1947	
	8497277	Dec 28, 2026			U-1456	
	8497277	Dec 28, 2026			U-1491	
	8497277	Dec 28, 2026			U-1650	
	8497277	Dec 28, 2026			U-1946	
	8497277	Dec 28, 2026			U-1947	
	8563563	Apr 26, 2027			U-1491	
	8563563	Apr 26, 2027			U-1946	
	8563563	Apr 26, 2027			U-2219	
	8697711	Dec 28, 2026	DS DP			
	8703780	Dec 28, 2026			U-1491	
	8735403	Dec 28, 2026	DS DP			
	8754090	Jun 03, 2031			U-1456	
	8754091	Dec 28, 2026	DP			
	8952015	Dec 28, 2026			U-1456	
	8952015	Dec 28, 2026			U-1491	
	8952015	Dec 28, 2026			U-1650	
	8952015	Dec 28, 2026			U-1946	
	8952015	Dec 28, 2026			U-1947	
	8957079	Dec 28, 2026	DS DP			
	8999999	Jun 03, 2031			U-1491	
	8999999	Jun 03, 2031			U-1946	
	8999999	Jun 03, 2031			U-2228	
	9125889	Jun 03, 2031			U-1650	
	9181257	Dec 28, 2026	DS			
	9296753	Oct 30, 2033	DS			
	9540382	Aug 18, 2033			U-1456	
	9540382	Aug 18, 2033			U-1491	
	9540382	Aug 18, 2033			U-1650	
	9540382	Aug 18, 2033			U-1946	
	9540382	Aug 18, 2033			U-1947	
	9713617	Jun 03, 2033	DP			
	9725455	Jun 03, 2033	DS			
	9795604	Oct 24, 2034			U-2150	
	9801881	Jun 03, 2031			U-1491	
	9801883	Jun 03, 2031			U-2159	
	9814721	Jun 03, 2031			U-1947	
<u>IBRUTINIB - IMBRUVICA</u>						
N 210563 001	>A> 7514444	Dec 28, 2026	DS DP		>A> NCE	Nov 13, 2018
	>A> 8008309	Dec 28, 2026	DS DP			
	>A> 8476284	Dec 28, 2026			U-1456	
	>A> 8476284	Dec 28, 2026			U-1650	
	>A> 8476284	Dec 28, 2026			U-1946	
	>A> 8476284	Dec 28, 2026			U-1947	
	>A> 8476284	Dec 28, 2026			U-2241	
	>A> 8497277	Dec 28, 2026			U-1456	
	>A> 8497277	Dec 28, 2026			U-1491	
	>A> 8497277	Dec 28, 2026			U-1650	
	>A> 8497277	Dec 28, 2026			U-1946	
	>A> 8497277	Dec 28, 2026			U-1947	
	>A> 8497277	Dec 28, 2026			U-2241	
	>A> 8497277	Dec 28, 2026			U-2242	
	>A> 8563563	Apr 26, 2027			U-1491	
	>A> 8563563	Apr 26, 2027			U-1946	
	>A> 8563563	Apr 26, 2027			U-2241	
	>A> 8563563	Apr 26, 2027			U-2242	
	>A> 8697711	Dec 28, 2026	DS DP			
	>A> 8703780	Dec 28, 2026			U-1491	
	>A> 8703780	Dec 28, 2026			U-2242	
	>A> 8735403	Dec 28, 2026	DS DP			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>IBRUTINIB - IMBRUVICA</u>						
N 210563 001	>A> 8754090	Jun 03, 2031	U-1456			
	>A> 8754091	Dec 28, 2026	DP			
	>A> 8952015	Dec 28, 2026	U-1456			
	>A> 8952015	Dec 28, 2026	U-1491			
	>A> 8952015	Dec 28, 2026	U-1650			
	>A> 8952015	Dec 28, 2026	U-1946			
	>A> 8952015	Dec 28, 2026	U-1947			
	>A> 8952015	Dec 28, 2026	U-2241			
	>A> 8952015	Dec 28, 2026	U-2242			
	>A> 8957079	Dec 28, 2026	DS DP			
	>A> 8999999	Jun 03, 2031	U-1491			
	>A> 8999999	Jun 03, 2031	U-1946			
	>A> 8999999	Jun 03, 2031	U-2241			
	>A> 8999999	Jun 03, 2031	U-2242			
	>A> 9125889	Jun 03, 2031	U-1650			
	>A> 9181257	Dec 28, 2026	DS			
	>A> 9296753	Oct 30, 2033	DS			
	>A> 9655857	Mar 03, 2036	DP			
	>A> 9725455	Jun 03, 2033	DS			
	>A> 9795604	Oct 24, 2034	U-2150			
	>A> 9801881	Jun 03, 2031	U-1491			
	>A> 9801881	Jun 03, 2031	U-2242			
	>A> 9801883	Jun 03, 2031	U-2159			
	>A> 9801883	Jun 03, 2031	U-2243			
	>A> 9814721	Jun 03, 2031	U-1947			
<u>IBRUTINIB - IMBRUVICA</u>						
N 210563 002	>A> 7514444	Dec 28, 2026	DS DP		>A> NCE	Nov 13, 2018
	>A> 8008309	Dec 28, 2026	DS DP			
	>A> 8476284	Dec 28, 2026	U-1456			
	>A> 8476284	Dec 28, 2026	U-1650			
	>A> 8476284	Dec 28, 2026	U-1946			
	>A> 8476284	Dec 28, 2026	U-1947			
	>A> 8476284	Dec 28, 2026	U-2241			
	>A> 8497277	Dec 28, 2026	U-1456			
	>A> 8497277	Dec 28, 2026	U-1491			
	>A> 8497277	Dec 28, 2026	U-1650			
	>A> 8497277	Dec 28, 2026	U-1946			
	>A> 8497277	Dec 28, 2026	U-1947			
	>A> 8497277	Dec 28, 2026	U-2241			
	>A> 8497277	Dec 28, 2026	U-2242			
	>A> 8563563	Apr 26, 2027	U-1491			
	>A> 8563563	Apr 26, 2027	U-1946			
	>A> 8563563	Apr 26, 2027	U-2241			
	>A> 8563563	Apr 26, 2027	U-2242			
	>A> 8697711	Dec 28, 2026	DS DP			
	>A> 8703780	Dec 28, 2026	U-1491			
	>A> 8703780	Dec 28, 2026	U-2242			
	>A> 8735403	Dec 28, 2026	DS DP			
	>A> 8754090	Jun 03, 2031	U-1456			
	>A> 8754091	Dec 28, 2026	DP			
	>A> 8952015	Dec 28, 2026	U-1456			
	>A> 8952015	Dec 28, 2026	U-1491			
	>A> 8952015	Dec 28, 2026	U-1650			
	>A> 8952015	Dec 28, 2026	U-1946			
	>A> 8952015	Dec 28, 2026	U-1947			
	>A> 8952015	Dec 28, 2026	U-2241			
	>A> 8952015	Dec 28, 2026	U-2242			
	>A> 8957079	Dec 28, 2026	DS DP			
	>A> 8999999	Jun 03, 2031	U-1491			
	>A> 8999999	Jun 03, 2031	U-1946			
	>A> 8999999	Jun 03, 2031	U-2241			
	>A> 8999999	Jun 03, 2031	U-2242			
	>A> 9125889	Jun 03, 2031	U-1650			
	>A> 9181257	Dec 28, 2026	DS			
	>A> 9296753	Oct 30, 2033	DS			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>IBRUTINIB - IMBRUVICA</u>						
N 210563 002	>A> 9655857	Mar 03, 2036	DP			
	>A> 9725455	Jun 03, 2033	DS			
	>A> 9795604	Oct 24, 2034			U-2150	
	>A> 9801881	Jun 03, 2031			U-1491	
	>A> 9801881	Jun 03, 2031			U-2242	
	>A> 9801883	Jun 03, 2031			U-2159	
	>A> 9801883	Jun 03, 2031			U-2243	
	>A> 9814721	Jun 03, 2031			U-1947	
<u>IBRUTINIB - IMBRUVICA</u>						
N 210563 003	>A> 7514444	Dec 28, 2026	DS DP		>A> NCE	Nov 13, 2018
	>A> 8008309	Dec 28, 2026	DS DP			
	>A> 8476284	Dec 28, 2026			U-1456	
	>A> 8476284	Dec 28, 2026			U-1650	
	>A> 8476284	Dec 28, 2026			U-1946	
	>A> 8476284	Dec 28, 2026			U-1947	
	>A> 8476284	Dec 28, 2026			U-2241	
	>A> 8497277	Dec 28, 2026			U-1456	
	>A> 8497277	Dec 28, 2026			U-1491	
	>A> 8497277	Dec 28, 2026			U-1650	
	>A> 8497277	Dec 28, 2026			U-1946	
	>A> 8497277	Dec 28, 2026			U-1947	
	>A> 8497277	Dec 28, 2026			U-2241	
	>A> 8497277	Dec 28, 2026			U-2242	
	>A> 8563563	Apr 26, 2027			U-1491	
	>A> 8563563	Apr 26, 2027			U-1946	
	>A> 8563563	Apr 26, 2027			U-2241	
	>A> 8563563	Apr 26, 2027			U-2242	
	>A> 8697711	Dec 28, 2026	DS DP			
	>A> 8703780	Dec 28, 2026			U-1491	
	>A> 8703780	Dec 28, 2026			U-2242	
	>A> 8735403	Dec 28, 2026	DS DP			
	>A> 8754090	Jun 03, 2031			U-1456	
	>A> 8754091	Dec 28, 2026	DP			
	>A> 8952015	Dec 28, 2026			U-1456	
	>A> 8952015	Dec 28, 2026			U-1491	
	>A> 8952015	Dec 28, 2026			U-1650	
	>A> 8952015	Dec 28, 2026			U-1946	
	>A> 8952015	Dec 28, 2026			U-1947	
	>A> 8952015	Dec 28, 2026			U-2241	
	>A> 8952015	Dec 28, 2026			U-2242	
	>A> 8957079	Dec 28, 2026	DS DP			
	>A> 8999999	Jun 03, 2031			U-1491	
	>A> 8999999	Jun 03, 2031			U-1946	
	>A> 8999999	Jun 03, 2031			U-2241	
	>A> 8999999	Jun 03, 2031			U-2242	
	>A> 9125889	Jun 03, 2031			U-1650	
	>A> 9181257	Dec 28, 2026	DS			
	>A> 9296753	Oct 30, 2033	DS			
	>A> 9655857	Mar 03, 2036	DP			
	>A> 9725455	Jun 03, 2033	DS			
	>A> 9795604	Oct 24, 2034			U-2150	
	>A> 9801881	Jun 03, 2031			U-1491	
	>A> 9801881	Jun 03, 2031			U-2242	
	>A> 9801883	Jun 03, 2031			U-2159	
	>A> 9801883	Jun 03, 2031			U-2243	
	>A> 9814721	Jun 03, 2031			U-1947	
<u>IBRUTINIB - IMBRUVICA</u>						
N 210563 004	>A> 7514444	Dec 28, 2026	DS DP		>A> NCE	Nov 13, 2018
	>A> 8008309	Dec 28, 2026	DS DP			
	>A> 8476284	Dec 28, 2026			U-1456	
	>A> 8476284	Dec 28, 2026			U-1650	
	>A> 8476284	Dec 28, 2026			U-1946	
	>A> 8476284	Dec 28, 2026			U-1947	
	>A> 8476284	Dec 28, 2026			U-2241	

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>IBRUTINIB - IMBRUVICA</u>						
N 210563 004	>A> 8497277	Dec 28, 2026	U-1456			
	>A> 8497277	Dec 28, 2026	U-1491			
	>A> 8497277	Dec 28, 2026	U-1650			
	>A> 8497277	Dec 28, 2026	U-1946			
	>A> 8497277	Dec 28, 2026	U-1947			
	>A> 8497277	Dec 28, 2026	U-2241			
	>A> 8497277	Dec 28, 2026	U-2242			
	>A> 8563563	Apr 26, 2027	U-1491			
	>A> 8563563	Apr 26, 2027	U-1946			
	>A> 8563563	Apr 26, 2027	U-2241			
	>A> 8563563	Apr 26, 2027	U-2242			
	>A> 8697711	Dec 28, 2026	DS DP			
	>A> 8703780	Dec 28, 2026	U-1491			
	>A> 8703780	Dec 28, 2026	U-2242			
	>A> 8735403	Dec 28, 2026	DS DP			
	>A> 8754090	Jun 03, 2031	U-1456			
	>A> 8754091	Dec 28, 2026	DP			
	>A> 8952015	Dec 28, 2026	U-1456			
	>A> 8952015	Dec 28, 2026	U-1491			
	>A> 8952015	Dec 28, 2026	U-1650			
	>A> 8952015	Dec 28, 2026	U-1946			
	>A> 8952015	Dec 28, 2026	U-1947			
	>A> 8952015	Dec 28, 2026	U-2241			
	>A> 8952015	Dec 28, 2026	U-2242			
	>A> 8957079	Dec 28, 2026	DS DP			
	>A> 8999999	Jun 03, 2031	U-1491			
	>A> 8999999	Jun 03, 2031	U-1946			
	>A> 8999999	Jun 03, 2031	U-2241			
	>A> 8999999	Jun 03, 2031	U-2242			
	>A> 9125889	Jun 03, 2031	U-1650			
	>A> 9181257	Dec 28, 2026	DS			
	>A> 9296753	Oct 30, 2033	DS			
	>A> 9655857	Mar 03, 2036	DP			
	>A> 9725455	Jun 03, 2033	DS			
	>A> 9795604	Oct 24, 2034	U-2150			
	>A> 9801881	Jun 03, 2031	U-1491			
	>A> 9801881	Jun 03, 2031	U-2242			
	>A> 9801883	Jun 03, 2031	U-2159			
	>A> 9801883	Jun 03, 2031	U-2243			
	>A> 9814721	Jun 03, 2031	U-1947			
<u>INGENOL MEBUTATE - PICATO</u>						
N 202833 001	9861603	Dec 18, 2026	U-1440			
<u>INGENOL MEBUTATE - PICATO</u>						
N 202833 002	9861603	Dec 18, 2026	U-1440			
<u>INSULIN ASPART; INSULIN DEGLUDEC - RYZODEG 70/30</u>						
N 203313 001	>A> 9884094	May 01, 2033	U-2238			
<u>IVACAFTOR - KALYDECO</u>						
N 203188 001	>A> 8629162	Jun 24, 2025	U-2234			
<u>IVACAFTOR - KALYDECO</u>						
N 207925 001	>A> 8629162	Jun 24, 2025	U-2234			
<u>IVACAFTOR - KALYDECO</u>						
N 207925 002	>A> 8629162	Jun 24, 2025	U-2234			
<u>IVACAFTOR; IVACAFTOR, TEZACAFTOR - SYMDEKO (COPACKAGED)</u>						
N 210491 001	>A> 7495103	May 20, 2027	DS DP	>A> NCE		Feb 12, 2023
	>A> 7645789	May 01, 2027	DS DP			
	>A> 7776905	Jun 03, 2027	DS DP			
	>A> 8324242	Aug 05, 2027	U-2246			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>IVACAFTOR; IVACAFTOR, TEZACAFTOR - SYMDEKO (COPACKAGED)</u>						
N 210491 001	>A> 8410274	Dec 28, 2026	DP			
	>A> 8415387	Nov 12, 2027		U-2246		
	>A> 8598181	May 01, 2027		U-2246		
	>A> 8623905	May 01, 2027	DS DP			
	>A> 8629162	Jun 24, 2025		U-2247		
	>A> 8754224	Dec 28, 2026	DS DP			
	>A> 9012496	Jul 15, 2033		U-2248		
	>A> 9670163	Dec 28, 2026	DP	U-2246		
<u>IVACAFTOR; LUMACAFTOR - ORKAMBI</u>						
N 206038 001					M-218	Jan 25, 2021
<u>IVACAFTOR; LUMACAFTOR - ORKAMBI</u>						
N 206038 002					M-218	Jan 25, 2021
<u>LETERMOVIR - PREVYMIS</u>						
N 209939 001					>A> ODE-165	Nov 08, 2024
<u>LETERMOVIR - PREVYMIS</u>						
N 209939 002					>A> ODE-165	Nov 08, 2024
<u>LETERMOVIR - PREVYMIS</u>						
N 209940 001					>A> ODE-165	Nov 08, 2024
<u>LETERMOVIR - PREVYMIS</u>						
N 209940 002					>A> ODE-165	Nov 08, 2024
<u>LEVOTHYROXINE SODIUM - TIROSINT</u>						
N 021924 002	7723390	Mar 14, 2024	DP			
<u>LEVOTHYROXINE SODIUM - TIROSINT</u>						
N 021924 003	7723390	Mar 14, 2024	DP			
<u>LEVOTHYROXINE SODIUM - TIROSINT</u>						
N 021924 004	7723390	Mar 14, 2024	DP			
<u>LEVOTHYROXINE SODIUM - TIROSINT</u>						
N 021924 005	7723390	Mar 14, 2024	DP			
<u>LEVOTHYROXINE SODIUM - TIROSINT</u>						
N 021924 006	7723390	Mar 14, 2024	DP			
<u>LEVOTHYROXINE SODIUM - TIROSINT</u>						
N 021924 007	7723390	Mar 14, 2024	DP			
<u>LEVOTHYROXINE SODIUM - TIROSINT</u>						
N 021924 008	7723390	Mar 14, 2024	DP			
<u>LEVOTHYROXINE SODIUM - TIROSINT</u>						
N 021924 009	7723390	Mar 14, 2024	DP			
<u>LEVOTHYROXINE SODIUM - TIROSINT</u>						
N 021924 010	7723390	Mar 14, 2024	DP			
<u>LEVOTHYROXINE SODIUM - TIROSINT</u>						
N 021924 013	7691411	Mar 14, 2024	DP			
	7723390	Mar 14, 2024	DP			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>LIDOCAINE - ZTLIDO</u>						
N 207962 001 >A>	9283174	May 10, 2031	DP		>A> NP	Feb 28, 2021
<u>LIFITEGRAST - XIIDRA</u>						
N 208073 001 >A>	9890141	Oct 21, 2030	DS			
<u>LIXISENATIDE - ADLYXIN</u>						
N 208471 001	9440029	Jan 30, 2032	DP			
	9855388	Apr 24, 2029	DP U-1881			
<u>LIXISENATIDE - ADLYXIN</u>						
N 208471 002	9440029	Jan 30, 2032	DP			
	9855388	Apr 24, 2029	DP U-1881			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 001	9861622	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 002	9861622	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 003	9861622	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 004	9861622	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 005	9861622	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 006	9861622	Mar 07, 2025	U-1316			
<u>LULICONAZOLE - LUZU</u>						
N 204153 001					>A> NPP	Feb 20, 2021
<u>LURASIDONE HYDROCHLORIDE - LATUDA</u>						
N 200603 001	9174975	Feb 20, 2024	U-1770			
	9174975*PED	Aug 20, 2024				
<u>LURASIDONE HYDROCHLORIDE - LATUDA</u>						
N 200603 002	9174975	Feb 20, 2024	U-1770			
	9174975*PED	Aug 20, 2024				
<u>LURASIDONE HYDROCHLORIDE - LATUDA</u>						
N 200603 003	9174975	Feb 20, 2024	U-1770			
	9174975*PED	Aug 20, 2024				
<u>LURASIDONE HYDROCHLORIDE - LATUDA</u>						
N 200603 004	9174975	Feb 20, 2024	U-1770			
	9174975*PED	Aug 20, 2024				
<u>LURASIDONE HYDROCHLORIDE - LATUDA</u>						
N 200603 005	9174975	Feb 20, 2024	U-1770			
	9174975*PED	Aug 20, 2024				
<u>LUTETIUM DOTATATE LU-177 - LUTATHERA</u>						
N 208700 001					NCE	Jan 26, 2023

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>MACIMORELIN ACETATE - MACRILEN</u>						
N 205598 001	6861409	Aug 01, 2022	DS DP U-2220			
	8192719	Oct 12, 2027	U-2220			
<u>METFORMIN HYDROCHLORIDE - GLUMETZA</u>						
N 021748 002 >A>	8323692	Mar 30, 2023	DP			
<u>METHOTREXATE SODIUM - XATMEP</u>						
N 208400 001	9855215	Jan 02, 2033	DP			
<u>NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE - TARGINIO</u>						
N 205777 001 >A>	9907793	Apr 04, 2023	DP U-1556			
<u>NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE - TARGINIO</u>						
N 205777 002 >A>	9907793	Apr 04, 2023	DP U-1556			
<u>NILOTINIB HYDROCHLORIDE MONOHYDRATE - TASIGNA</u>						
N 022068 001					D-170	Dec 22, 2020
<u>NILOTINIB HYDROCHLORIDE MONOHYDRATE - TASIGNA</u>						
N 022068 002					D-170	Dec 22, 2020
<u>OLAPARIB - LYNPARZA</u>						
N 208558 001					I-762	Jan 12, 2021
<u>OLAPARIB - LYNPARZA</u>						
N 208558 002					I-762	Jan 12, 2021
<u>OSPEMIFENE - OSPHENA</u>						
N 203505 001	9855224	Feb 13, 2024	U-1369			
	9855224	Feb 13, 2024	U-1370			
<u>OZENOXACIN - XEPI</u>						
N 208945 001	6335447	Apr 06, 2019	DS			
	9180200	Jan 29, 2032	DP U-805			
	9399014	Dec 15, 2029	U-805			
<u>PIRFENIDONE - ESBRIET</u>						
N 208780 001 >A>	8420674	Dec 18, 2027	U-2079			
<u>PIRFENIDONE - ESBRIET</u>						
N 208780 003 >A>	8420674	Dec 18, 2027	U-2079			
<u>PLECANATIDE - TRULANCE</u>						
N 208745 001 >A>	9610321	Sep 15, 2031	U-1999		I-764	Jan 24, 2021
	>A> 9610321	Sep 15, 2031	U-2230			
<u>RIVAROXABAN - XARELTO</u>						
N 022406 001	9415053	Nov 13, 2024	DP U-1167			
	9415053	Nov 13, 2024	DP U-1200			
	9415053	Nov 13, 2024	DP U-1301			
	9415053	Nov 13, 2024	DP U-1302			
	9415053	Nov 13, 2024	DP U-2142			
	9539218	Feb 17, 2034	U-1953			
	9539218	Feb 17, 2034	U-1954			
	9539218	Feb 17, 2034	U-1955			
	9539218	Feb 17, 2034	U-1957			
	9539218	Feb 17, 2034	U-2143			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>RIVAROXABAN - XARELTO</u>						
N 022406 002	7157456	Aug 28, 2024	DS DP U-1301			
	7157456	Aug 28, 2024	DS DP U-1302			
<u>RIVAROXABAN - XARELTO</u>						
N 022406 003	7157456	Aug 28, 2024	DS DP U-1301			
	7157456	Aug 28, 2024	DS DP U-1302			
	9415053	Nov 13, 2024	DP U-1167			
	9415053	Nov 13, 2024	DP U-1200			
	9415053	Nov 13, 2024	DP U-1301			
	9415053	Nov 13, 2024	DP U-1302			
<u>ROFLUMILAST - DALIRESP</u>						
N 022522 001					NS	Jan 23, 2021
<u>ROFLUMILAST - DALIRESP</u>						
N 022522 002					NS	Jan 23, 2021
<u>ROPIVACAINE HYDROCHLORIDE - NAROPIN</u>						
N 020533 006	>A> 7828787	Oct 18, 2025	DP			
	>A> 7857802	Nov 28, 2026	DP			
	>A> 8118802	May 18, 2023	DP			
	>A> 8162915	May 23, 2024	DP			
<u>ROPIVACAINE HYDROCHLORIDE - NAROPIN</u>						
N 020533 007	>A> 7828787	Oct 18, 2025	DP			
	>A> 7857802	Nov 28, 2026	DP			
	>A> 8118802	May 18, 2023	DP			
	>A> 8162915	May 23, 2024	DP			
<u>RUCAPARIB CAMSYLATE - RUBRACA</u>						
N 209115 001	9861638	Feb 10, 2031	U-2012			
<u>RUCAPARIB CAMSYLATE - RUBRACA</u>						
N 209115 002	9861638	Feb 10, 2031	U-2012			
<u>RUCAPARIB CAMSYLATE - RUBRACA</u>						
N 209115 003	9861638	Feb 10, 2031	U-2012			
<u>SIMEPREVIR SODIUM - OLYSIO</u>						
N 205123 001	9856265	Jul 28, 2026	DS DP U-1467			
<u>SOFOSBUVIR; VELPATASVIR; VOXILAPREVIR - VOSEVI</u>						
N 209195 001	9868745	Nov 16, 2032	DS DP			
<u>TADALAFIL - CIALIS</u>						
N 021368 001					>A> M-219	Feb 15, 2021
					>A> PED	Aug 15, 2021
<u>TADALAFIL - CIALIS</u>						
N 021368 002					>A> M-219	Feb 15, 2021
					>A> PED	Aug 15, 2021
<u>TADALAFIL - CIALIS</u>						
N 021368 003					>A> M-219	Feb 15, 2021
					>A> PED	Aug 15, 2021
<u>TADALAFIL - CIALIS</u>						
N 021368 004					>A> M-219	Feb 15, 2021
					>A> PED	Aug 15, 2021

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2018

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>TASIMELTEON - HETLIOZ</u>						
N 205677 001	9855241	Jan 25, 2033	U-2149			
<u>VANDETANIB - CAPRELSA</u>						
N 022405 001	>A> 7173038	Aug 14, 2021	DS DP			
	>A> 8642608	Feb 06, 2022	U-1490			
<u>VANDETANIB - CAPRELSA</u>						
N 022405 002	>A> 7173038	Aug 14, 2021	DS DP			
	>A> 8642608	Feb 06, 2022	U-1490			
<u>VORTIOXETINE HYDROBROMIDE - TRINTELLIX</u>						
N 204447 001	9861630	Jun 15, 2027	U-1668			
<u>VORTIOXETINE HYDROBROMIDE - TRINTELLIX</u>						
N 204447 002	9861630	Jun 15, 2027	U-1668			
<u>VORTIOXETINE HYDROBROMIDE - TRINTELLIX</u>						
N 204447 003	9861630	Jun 15, 2027	U-1668			
<u>VORTIOXETINE HYDROBROMIDE - TRINTELLIX</u>						
N 204447 004	9861630	Jun 15, 2027	U-1668			

Footnote:

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

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

PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 38th 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

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