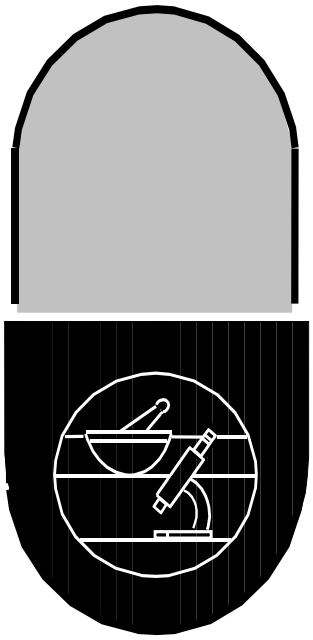
CUMULATIVE SUPPLEMENT 1
JANUARY 2018



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
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January 2018

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38th EDITION

CUMULATIVE SUPPLEMENT 1
January 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for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
SAGENT AGILA LLIC (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 Pharmas 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 Levothroid (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

CATEGORIES COUNTED	DEC 2017	MAR 2018	JUN 2018	SEP 2018	DEC 2018
DRUG PRODUCTS	19294				
LISTED SINGLE SOURCE	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				

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

1.7 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route 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 proceeded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

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

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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET;ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>A>		@ FOSUN PHARMA	300MG;30MG	A	081250	001	Jul 16, 1992	Jan CAHN
>A>		@	300MG;60MG	A	081249	001	Jul 16, 1992	Jan CAHN
>D>		@ SANDOZ	300MG;30MG	A	081250	001	Jul 16, 1992	Jan CAHN
>D>		@	300MG;60MG	A	081249	001	Jul 16, 1992	Jan CAHN

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

SOLUTION;ORAL

OXYCODONE AND ACETAMINOPHEN

>D>								
>D> AA	!	SPECGX LLC	325MG/5ML;5MG/5ML	A	040680	001	Sep 29, 2006	Jan DISC
>A>		@	325MG/5ML;5MG/5ML	A	040680	001	Sep 29, 2006	Jan DISC

OXYCODONE HYDROCHLORIDE AND ACETAMINOPHEN

>D>								
>D> AA		VINTAGE PHARMS	325MG/5ML;5MG/5ML	A	203573	001	Dec 18, 2014	Jan DISC
>A>		@	325MG/5ML;5MG/5ML	A	203573	001	Dec 18, 2014	Jan DISC

TABLET;ORAL

OXYCODONE AND ACETAMINOPHEN

>A> AA		ABHAI LLC	325MG;2.5MG	A	210644	001	Feb 09, 2018	Jan NEWA
>A> AA			325MG;5MG	A	210644	002	Feb 09, 2018	Jan NEWA
>A> AA			325MG;7.5MG	A	210644	003	Feb 09, 2018	Jan NEWA
>A> AA			325MG;10MG	A	210644	004	Feb 09, 2018	Jan NEWA

ADAPALENE; BENZOYL PEROXIDE

GEL;TOPICAL

ADAPALENE AND BENZOYL PEROXIDE

>A> AB		PERRIGO ISRAEL	0.1%;2.5%	A	205033	001	Jan 23, 2018	Jan NEWA
>A> AB		TARO	0.1%;2.5%	A	206959	001	Jan 24, 2018	Jan NEWA

ALBUTEROL SULFATE

TABLET;ORAL

ALBUTEROL SULFATE

>D>		@ FOSUN PHARMA	EQ 2MG BASE	A	072151	001	Dec 05, 1989	Jan CAHN
>D>		@	EQ 4MG BASE	A	072152	001	Dec 05, 1989	Jan CAHN
>A>		@ YAOPHARMA CO LTD	EQ 2MG BASE	A	072151	001	Dec 05, 1989	Jan CAHN
>A>		@	EQ 4MG BASE	A	072152	001	Dec 05, 1989	Jan CAHN

ALBUTEROL SULFATE; IPRATROPIUM BROMIDE

SOLUTION;INHALATION

ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE

>A>		@ FOSUN PHARMA	EQ 0.083% BASE;0.017%	A	076867	001	Dec 21, 2006	Jan CAHN
>D>		@ SANDOZ INC	EQ 0.083% BASE;0.017%	A	076867	001	Dec 21, 2006	Jan CAHN

ALLOPURINOL

TABLET;ORAL

ALLOPURINOL

>A>		@ FOSUN PHARMA	100MG	A	070268	001	Dec 31, 1985	Jan CAHN
>D>		@ SANDOZ	100MG	A	070268	001	Dec 31, 1985	Jan CAHN

AMANTADINE HYDROCHLORIDE

TABLET;ORAL

AMANTADINE HYDROCHLORIDE

>A> AB		JUBILANT GENERICS	100MG	A	210403	001	Feb 07, 2018	Jan NEWA

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET;ORAL

AMILORIDE HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>D>		@ FOSUN PHARMA	EQ 5MG ANHYDROUS;50MG	A	073357	001	Nov 27, 1991	Jan CAHN
>A>		@ YAOPHARMA CO LTD	EQ 5MG ANHYDROUS;50MG	A	073357	001	Nov 27, 1991	Jan CAHN

AMITRIPTYLINE HYDROCHLORIDE

TABLET;ORAL

AMITRIPTYLINE HYDROCHLORIDE

>D>		@ SUN PHARM INDS INC	10MG	A	089399	002	Jul 14, 1987	Jan CMFD
>A> AB			10MG	A	089399	002	Jul 14, 1987	Jan CMFD
>D>		@	25MG	A	089399	001	Jul 14, 1987	Jan CMFD
>A> AB			25MG	A	089399	001	Jul 14, 1987	Jan CMFD
>D>		@	50MG	A	089399	003	Jul 14, 1987	Jan CMFD
>A> AB			50MG	A	089399	003	Jul 14, 1987	Jan CMFD
>D>		@	75MG	A	089399	004	Jul 14, 1987	Jan CMFD

TABLET;ORAL
AMITRIPTYLINE HYDROCHLORIDE

>A> AB		75MG	A089399	004	Jul 14, 1987	Jan	CMFD
>D>	@	100MG	A089399	005	Jul 14, 1987	Jan	CMFD
>A> AB		100MG	A089399	005	Jul 14, 1987	Jan	CMFD
>D>	@	150MG	A089399	006	Jul 14, 1987	Jan	CMFD
>A> AB		150MG	A089399	006	Jul 14, 1987	Jan	CMFD

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET;ORAL
PERPHENAZINE AND AMITRIPTYLINE HYDROCHLORIDE

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

AMLODIPINE BESYLATE

TABLET;ORAL
AMLODIPINE BESYLATE

>D>	@ FOSUN PHARMA	EQ 2.5MG BASE	A076859	001	Sep 10, 2007	Jan	CAHN
>D>	@	EQ 5MG BASE	A076859	002	Sep 10, 2007	Jan	CAHN
>D>	@	EQ 10MG BASE	A076859	003	Sep 10, 2007	Jan	CAHN
>A>	@ YAOPHARMA CO LTD	EQ 2.5MG BASE	A076859	001	Sep 10, 2007	Jan	CAHN
>A>	@	EQ 5MG BASE	A076859	002	Sep 10, 2007	Jan	CAHN
>A>	@	EQ 10MG BASE	A076859	003	Sep 10, 2007	Jan	CAHN

ANASTROZOLE

TABLET;ORAL
ARIMIDEX

>A> AB	+! ANI PHARMS INC	1MG	N020541	001	Dec 27, 1995	Jan	CAHN
>D> AB	+! ASTRAZENECA PHARMS	1MG	N020541	001	Dec 27, 1995	Jan	CAHN

>D> ANGIOTENSIN II

>D> SOLUTION;IV (INFUSION)
>D> GIAPREZA

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

>A> ANGIOTENSIN II ACETATE

>A> SOLUTION;IV (INFUSION)
>A> GIAPREZA

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

APREPITANT

CAPSULE;ORAL
APREPITANT

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

ARGATROBAN

INJECTABLE;INJECTION
ARGATROBAN

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

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET;ORAL
BUTALBITAL, ASPIRIN AND CAFFEINE

>A>	@ FOSUN PHARMA	325MG;50MG;40MG	A086398	002	Apr 06, 1984	Jan	CAHN
>D>	@ SANDOZ	325MG;50MG;40MG	A086398	002	Apr 06, 1984	Jan	CAHN

ASPIRIN; CARISOPRODOL

TABLET;ORAL

CARISOPRODOL AND ASPIRIN

>D> AB	OXFORD PHARMS	325MG;200MG	A040252	001	Dec 10, 1997	Jan DISC
>A>	@	325MG;200MG	A040252	001	Dec 10, 1997	Jan DISC

ATROPINE SULFATE

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

ATROPINE SULFATE

>A>	+! FRESENIUS KABI USA	8MG/20ML (0.4MG/ML)	N209260	001	Jan 26, 2018	Jan NEWA

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET;ORAL

DIPHENOXYLATE HYDROCHLORIDE AND ATROPINE SULFATE

>A>	@ FOSUN PHARMA	0.025MG;2.5MG	A086173	001		Jan CAHN
>D>	@ SANDOZ	0.025MG;2.5MG	A086173	001		Jan CAHN

LONOX

>A>	@ FOSUN PHARMA	0.025MG;2.5MG	A085311	002		Jan CAHN
>D>	@ SANDOZ	0.025MG;2.5MG	A085311	002		Jan CAHN

AVIBACTAM SODIUM; CEFTAZIDIME

POWDER;IV (INFUSION)

AVYCAZ

>A>	+! ALLERGAN SALES LLC	EQ 0.5GM BASE;2GM/VIAL	N206494	001	Feb 25, 2015	Jan CAHN
>D>	+! CEREXA	EQ 0.5GM BASE;2GM/VIAL	N206494	001	Feb 25, 2015	Jan CAHN

BACITRACIN

INJECTABLE;INJECTION

BACITRACIN

>A>	@ MYLAN ASI	50,000 UNITS/VIAL	A090211	001	May 11, 2010	Jan DISC
>D> AP	SAGENT STRIDES	50,000 UNITS/VIAL	A090211	001	May 11, 2010	Jan DISC

BARIUM SULFATE

SUSPENSION;ORAL

VARIBAR THIN HONEY

>A>	+! BRACCO	40% (100GM/250ML)	N208143	006	Jan 23, 2018	Jan NEWA

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED;INHALATION

QVAR REDIHALER

>D>	+ NORTON WATERFORD	0.04MG/INH	N207921	001	Aug 03, 2017	Jan CHRS
>A>	+!	0.04MG/INH	N207921	001	Aug 03, 2017	Jan CHRS

BENZTROPINE MESYLATE

TABLET;ORAL

BENZTROPINE MESYLATE

>D>	@ ANDA REPOSITORY	1MG	A081264	001	Jan 23, 1992	Jan CAHN
>D>	@	2MG	A081265	001	Jan 23, 1992	Jan CAHN
>A>	@ CHARTWELL RX	1MG	A081264	001	Jan 23, 1992	Jan CAHN
>A>	@	2MG	A081265	001	Jan 23, 1992	Jan CAHN

BETAMETHASONE DIPROPIONATE

LOTION;TOPICAL

BETAMETHASONE DIPROPIONATE

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

LOTION, AUGMENTED;TOPICAL

BETAMETHASONE DIPROPIONATE

>A> AB	TELIGENT PHARMA INC	EQ 0.05% BASE	A206389	001	Feb 13, 2018	Jan NEWA

BETAMETHASONE VALERATE

LOTION;TOPICAL

>D>	BETA-VAL					
>D> AB	G AND W LABS INC	EQ 0.1% BASE	A070072	001	Jun 27, 1985	Jan DISC
>A>	@	EQ 0.1% BASE	A070072	001	Jun 27, 1985	Jan DISC

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

BETOPTIC

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

BICALUTAMIDE

TABLET;ORAL

CASODEX

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

BISMUTH SUBCITRATE POTASSIUM; METRONIDAZOLE; TETRACYCLINE

CAPSULE;ORAL

PYLERA

>A>	+!	ALLERGAN SALES LLC	140MG;125MG;125MG	N050786	001	Sep 28, 2006	Jan CAHN
>D>	+!	FOREST LABS LLC	140MG;125MG;125MG	N050786	001	Sep 28, 2006	Jan CAHN

BIVALIRUDIN

SOLUTION;IV (INFUSION)

BIVALIRUDIN IN 0.9% SODIUM CHLORIDE

>A>	+!	BAXTER HLTHCARE CORP	250MG/50ML (5MG/ML)	N208374	001	Dec 21, 2017	Jan CAHN
>A>	+!		500MG/100ML (5MG/ML)	N208374	002	Dec 21, 2017	Jan CAHN
>D>	+!	CELERITY PHARMS	250MG/50ML (5MG/ML)	N208374	001	Dec 21, 2017	Jan CAHN
>D>	+!		500MG/100ML (5MG/ML)	N208374	002	Dec 21, 2017	Jan CAHN

BUMETANIDE

TABLET;ORAL

BUMETANIDE

>A> AB		UPSHER-SMITH LABS	0.5MG	A209916	001	Jan 23, 2018	Jan NEWA
>A> AB			1MG	A209916	002	Jan 23, 2018	Jan NEWA
>A> AB			2MG	A209916	003	Jan 23, 2018	Jan NEWA

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

BUPROPION HYDROCHLORIDE

>A> AB2		SCIEGEN PHARMS INC	150MG	A206122	001	Aug 17, 2016	Jan CAHN
>D> AB2		TECH ORGANIZED	150MG	A206122	001	Aug 17, 2016	Jan CAHN

BUSPIRONE HYDROCHLORIDE

TABLET;ORAL

BUSPIRONE HYDROCHLORIDE

>A>	@	FOSUN PHARMA	5MG	A075413	001	Mar 19, 2002	Jan CAHN
>A>	@		10MG	A075413	002	Mar 19, 2002	Jan CAHN
>A>	@		15MG	A075413	003	Mar 19, 2002	Jan CAHN
>D>	@	SANDOZ	5MG	A075413	001	Mar 19, 2002	Jan CAHN
>D>	@		10MG	A075413	002	Mar 19, 2002	Jan CAHN
>D>	@		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

>D>	@	ICU MEDICAL INC	20MG/100ML;5GM/100ML;104MG/100ML;600MG/100ML;310MG/100ML	N019685	005	Oct 17, 1988	Jan CRLD
>A>	+ @		20MG/100ML;5GM/100ML;104MG/100ML;600MG/100ML;310MG/100ML	N019685	005	Oct 17, 1988	Jan CRLD
>D>	@		20MG/100ML;5GM/100ML;179MG/100ML;600MG/100ML;310MG/100ML	N019685	006	Oct 17, 1988	Jan CRLD
>A>	+ @		20MG/100ML;5GM/100ML;179MG/100ML;600MG/100ML;310MG/100ML	N019685	006	Oct 17, 1988	Jan CRLD

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

>D>	@	ICU MEDICAL INC	20MG/100ML;5GM/100ML;254MG/100ML;600MG/100ML;310MG/100ML	N019685	007	Oct 17, 1988	Jan CRLD
>A>	+ @		20MG/100ML;5GM/100ML;254MG/100ML;600MG/100ML;310MG/100ML	N019685	007	Oct 17, 1988	Jan CRLD

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

>D> AP		ICU MEDICAL INC	20MG/100ML;5GM/100ML;179MG/100ML;600MG/100ML;310MG/100ML	N019685	002	Oct 17, 1988	Jan CRLD
>A> AP	+		20MG/100ML;5GM/100ML;179MG/100ML;600MG/100ML;310MG/100ML	N019685	002	Oct 17, 1988	Jan CRLD
>D> AP			20MG/100ML;5GM/100ML;328MG/100ML;600MG/100ML;310MG/100ML	N019685	008	Oct 17, 1988	Jan DISC
>A>	+ @		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

>D>		@	ICU MEDICAL INC	20MG/100ML;5GM/100ML;254MG/100ML;600MG/100ML;310MG/100ML	N019685	003	Oct 17, 1988	Jan	CRLD
>A>		+ @		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

>D>	AP		ICU MEDICAL INC	20MG/100ML;5GM/100ML;328MG/100ML;600MG/100ML;310MG/100ML	N019685	004	Oct 17, 1988	Jan	DISC
>A>		+ @		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

>D>		@	ICU MEDICAL INC	20MG/100ML;5GM/100ML;104MG/100ML;600MG/100ML;310MG/100ML	N019685	001	Oct 17, 1988	Jan	CRLD
>A>		+ @		20MG/100ML;5GM/100ML;104MG/100ML;600MG/100ML;310MG/100ML	N019685	001	Oct 17, 1988	Jan	CRLD

CANDESARTAN CILEXETIL

TABLET;ORAL

ATACAND

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

CAPTOPRIL

TABLET;ORAL

CAPTOPRIL

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

CAPTOPRIL; HYDROCHLOROTHIAZIDE

TABLET;ORAL

CAPTOPRIL AND HYDROCHLOROTHIAZIDE

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

CARIPRAZINE HYDROCHLORIDE

CAPSULE;ORAL

VRAYLAR

>A>	+	ALLERGAN SALES LLC	EQ 1.5MG BASE	N204370	001	Sep 17, 2015	Jan CAHN
>A>	+		EQ 3MG BASE	N204370	002	Sep 17, 2015	Jan CAHN
>A>	+		EQ 4.5MG BASE	N204370	003	Sep 17, 2015	Jan CAHN
>A>	+!		EQ 6MG BASE	N204370	004	Sep 17, 2015	Jan CAHN
>D>	+	FOREST RES INST INC	EQ 1.5MG BASE	N204370	001	Sep 17, 2015	Jan CAHN
>D>	+		EQ 3MG BASE	N204370	002	Sep 17, 2015	Jan CAHN
>D>	+		EQ 4.5MG BASE	N204370	003	Sep 17, 2015	Jan CAHN
>D>	+!		EQ 6MG BASE	N204370	004	Sep 17, 2015	Jan CAHN

CARISOPRODOL

TABLET;ORAL

CARISOPRODOL

>A>	@	FOSUN PHARMA	350MG	A081025	001	Apr 13, 1989	Jan CAHN
>D>	@	SANDOZ	350MG	A081025	001	Apr 13, 1989	Jan CAHN

CEFEPIME HYDROCHLORIDE

INJECTABLE;INJECTION

CEFEPIME HYDROCHLORIDE

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

CEFTAROLINE FOSAMIL

POWDER;IV (INFUSION)

TEFLARO

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

CEFTIBUTEN DIHYDRATE

CAPSULE;ORAL

CEDAX

>D>	@	PERNIX THERAP	EQ 400MG BASE	N050685	002	Dec 20, 1995	Jan CAHN
>A>	@	SI PHARMS	EQ 400MG BASE	N050685	002	Dec 20, 1995	Jan CAHN

FOR SUSPENSION;ORAL

CEDAX

>D>	+ @	PERNIX THERAP	EQ 90MG BASE/5ML	N050686	001	Dec 20, 1995	Jan CAHN
>D>	+ @		EQ 180MG BASE/5ML	N050686	002	Dec 20, 1995	Jan CAHN
>A>	+ @	SI PHARMS	EQ 90MG BASE/5ML	N050686	001	Dec 20, 1995	Jan CAHN
>A>	+ @		EQ 180MG BASE/5ML	N050686	002	Dec 20, 1995	Jan CAHN

CEFUROXIME AXETIL

TABLET;ORAL

CEFUROXIME AXETIL

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

CELECOXIB

CAPSULE;ORAL

CELECOXIB

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

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE;ORAL

SONAZINE

>A>	@	FOSUN PHARMA	30MG/ML	A080983	004		Jan CAHN
>A>	@		100MG/ML	A080983	005		Jan CAHN
>D>	@	SANDOZ	30MG/ML	A080983	004		Jan CAHN
>D>	@		100MG/ML	A080983	005		Jan CAHN

SYRUP;ORAL
SONAZINE

>A>		@ FOSUN PHARMA	10MG/5ML	A083040	001		Jan CAHN
>D>		@ SANDOZ	10MG/5ML	A083040	001		Jan CAHN

CICLOPIROX

SOLUTION;TOPICAL
CICLOPIROX

>D>	AT	CIPLA LTD	8%	A078124	001	Sep 18, 2007	Jan CAHN
>A>	AT	INGENUS PHARMS LLC	8%	A078124	001	Sep 18, 2007	Jan CAHN

CIMETIDINE

TABLET;ORAL
CIMETIDINE

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

CIPROFLOXACIN

INJECTABLE;INJECTION
CIPROFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

>D>	AP	ACS DOBFAR INFO SA	200MG/100ML	A078252	001	Mar 18, 2008	Jan CAHN
>D>	AP		400MG/200ML	A078252	002	Mar 18, 2008	Jan CAHN
>A>	AP	INFORLIFE	200MG/100ML	A078252	001	Mar 18, 2008	Jan CAHN
>A>	AP		400MG/200ML	A078252	002	Mar 18, 2008	Jan CAHN

CIPROFLOXACIN HYDROCHLORIDE

TABLET;ORAL
CIPROFLOXACIN HYDROCHLORIDE

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

CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
CIPROFLOXACIN EXTENDED RELEASE

>A>		@ FOSUN PHARMA	212.6MG;EQ 287.5MG BASE	A078712	001	Dec 11, 2007	Jan CAHN
>D>		@ SANDOZ	212.6MG;EQ 287.5MG BASE	A078712	001	Dec 11, 2007	Jan CAHN

CITALOPRAM HYDROBROMIDE

TABLET;ORAL
CELEXA

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

CITALOPRAM HYDROBROMIDE

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

TABLET;ORAL
CITALOPRAM HYDROBROMIDE

>D>		@	EQ 40MG BASE	A077040	003	Aug 17, 2005	Jan CAHN

CLINDAMYCIN PHOSPHATE
SOLUTION;TOPICAL
CLINDAMYCIN PHOSPHATE

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

CLOBETASOL PROPIONATE
CREAM;TOPICAL
CLOBETASOL PROPIONATE

>A>	AB1		LUPIN LTD	0.05%	A210208	001	Jan 30, 2018	Jan NEWA

IMPOYZ

>A>		+!	ENCORE DERMAT	0.025%	N209483	001	Nov 28, 2017	Jan CAHN
>D>		+!	PROMIUS PHARMA LLC	0.025%	N209483	001	Nov 28, 2017	Jan CAHN

CLONIDINE HYDROCHLORIDE
TABLET;ORAL
CLONIDINE HYDROCHLORIDE

>A>		@	AUROLIFE PHARMA LLC	0.1MG	A070886	002	Aug 31, 1988	Jan CMS1
>A>		@		0.3MG	A070886	003	Aug 31, 1988	Jan CMS1

TABLET, EXTENDED RELEASE;ORAL
CLONIDINE HYDROCHLORIDE

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

CROMOLYN SODIUM
SOLUTION/DROPS;OPHTHALMIC
CROMOLYN SODIUM

>D>	AT		ALCON	4%	A075282	001	Jun 16, 1999	Jan CAHN
>A>	AT		SANDOZ INC	4%	A075282	001	Jun 16, 1999	Jan CAHN

CYPROHEPTADINE HYDROCHLORIDE
TABLET;ORAL
CYPROHEPTADINE HYDROCHLORIDE

>D>	AA		COREPHARMA	4MG	A040537	001	Sep 30, 2003	Jan CAHN
>A>		@	FOSUN PHARMA	4MG	A086808	001		Jan CAHN
>A>	AA		MOUNTAIN	4MG	A040537	001	Sep 30, 2003	Jan CAHN
>D>		@	SANDOZ	4MG	A086808	001		Jan CAHN

CYTARABINE
INJECTABLE;INJECTION
CYTARABINE

>A>	AP		MYLAN LABS LTD	20MG/ML	A200916	001	Dec 13, 2011	Jan CAHN
>D>	AP		MYLAN PHARMS INC	20MG/ML	A200916	001	Dec 13, 2011	Jan CAHN

DEXAMETHASONE
TABLET;ORAL
DEXAMETHASONE

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

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE
SYRUP;ORAL

>D>			PROMETH W/ DEXTROMETHORPHAN					
>D>	AA		G AND W LABS INC	15MG/5ML;6.25MG/5ML	A088762	001	Oct 31, 1984	Jan DISC
>A>		@		15MG/5ML;6.25MG/5ML	A088762	001	Oct 31, 1984	Jan DISC

DEXTROSE; SODIUM CHLORIDE
INJECTABLE;INJECTION
DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

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

DICYCLOMINE HYDROCHLORIDE

CAPSULE;ORAL

BENTYL

>A>	AB	+!	ALLERGAN SALES LLC	10MG	N007409	003	Oct 15, 1984	Jan CAHN
>D>	AB	+!	FOREST LABS INC	10MG	N007409	003	Oct 15, 1984	Jan CAHN

INJECTABLE;INJECTION

BENTYL

>A>	AP	+!	ALLERGAN SALES LLC	10MG/ML	N008370	001	Oct 15, 1984	Jan CAHN
>D>	AP	+!	FOREST LABS INC	10MG/ML	N008370	001	Oct 15, 1984	Jan CAHN

BENTYL PRESERVATIVE FREE

>A>	AP	+!	ALLERGAN SALES LLC	10MG/ML	N008370	002	Oct 15, 1984	Jan CAHN
>D>	AP	+!	FOREST LABS INC	10MG/ML	N008370	002	Oct 15, 1984	Jan CAHN

TABLET;ORAL

BENTYL

>A>	AB	+!	ALLERGAN SALES LLC	20MG	N007409	001	Oct 15, 1984	Jan CAHN
>D>	AB	+!	FOREST LABS INC	20MG	N007409	001	Oct 15, 1984	Jan CAHN

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE;ORAL

DIPHENHYDRAMINE HYDROCHLORIDE

>A>		@	FOSUN PHARMA	25MG	A080832	001		Jan CAHN
>A>		@		25MG	A080845	002		Jan CAHN
>A>		@		50MG	A080832	002		Jan CAHN
>A>		@		50MG	A080845	001		Jan CAHN
>D>		@	SANDOZ	25MG	A080832	001		Jan CAHN
>D>		@		25MG	A080845	002		Jan CAHN
>D>		@		50MG	A080832	002		Jan CAHN
>D>		@		50MG	A080845	001		Jan CAHN

DOCETAXEL

INJECTABLE;INJECTION

DOCETAXEL

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

DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC

DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE

>D>	AT		ZAMBON SPA	EQ 2% BASE;EQ 0.5% BASE	A091180	001	Dec 04, 2013	Jan DISC
>A>		@		EQ 2% BASE;EQ 0.5% BASE	A091180	001	Dec 04, 2013	Jan DISC

DOXAZOSIN MESYLATE

TABLET;ORAL

DOXAZOSIN MESYLATE

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

DOXEPIN HYDROCHLORIDE

TABLET;ORAL

DOXEPIN HYDROCHLORIDE

>D>	AB		ACTAVIS ELIZABETH	EQ 3MG BASE	A201951	001	Jul 26, 2013	Jan DISC
>A>		@		EQ 3MG BASE	A201951	001	Jul 26, 2013	Jan DISC
>D>	AB			EQ 6MG BASE	A201951	002	Jul 26, 2013	Jan DISC
>A>		@		EQ 6MG BASE	A201951	002	Jul 26, 2013	Jan DISC

SILENOR

>D>	AB	+	PERNIX THERAPS LLC	EQ 3MG BASE	N022036	001	Mar 17, 2010	Jan CTEC
>A>		+		EQ 3MG BASE	N022036	001	Mar 17, 2010	Jan CTEC
>D>	AB	+!		EQ 6MG BASE	N022036	002	Mar 17, 2010	Jan CTEC
>A>		+!		EQ 6MG BASE	N022036	002	Mar 17, 2010	Jan CTEC

EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL

EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE

>A>	AB		AUROBINDO PHARMA LTD	200MG;300MG	A090513	001	Jan 26, 2018	Jan NEWA

ERTUGLIFLOZIN; SITAGLIPTIN PHOSPHATE

TABLET;ORAL

STEGLUJAN

>A>		+	MERCK SHARP DOHME	5MG;EQ 100MG BASE	N209805	001	Dec 19, 2017	Jan CMS1
>A>		+!		15MG;EQ 100MG BASE	N209805	002	Dec 19, 2017	Jan CMS1

STELUJAN

>D>		+	MERCK SHARP DOHME	5MG;EQ 100MG BASE	N209805	001	Dec 19, 2017	Jan CMS1
>D>		+!		15MG;EQ 100MG BASE	N209805	002	Dec 19, 2017	Jan CMS1

ESCITALOPRAM OXALATE

SOLUTION;ORAL

LEXAPRO

>A>	AA	+!	ALLERGAN SALES LLC	EQ 5MG BASE/5ML	N021365	001	Nov 27, 2002	Jan CAHN
>D>	AA	+!	FOREST LABS	EQ 5MG BASE/5ML	N021365	001	Nov 27, 2002	Jan CAHN

TABLET;ORAL

LEXAPRO

>A>	AB	+	ALLERGAN SALES LLC	EQ 5MG BASE	N021323	001	Aug 14, 2002	Jan CAHN
>A>	AB	+		EQ 10MG BASE	N021323	002	Aug 14, 2002	Jan CAHN
>A>	AB	+!		EQ 20MG BASE	N021323	003	Aug 14, 2002	Jan CAHN
>D>	AB	+	FOREST LABS	EQ 5MG BASE	N021323	001	Aug 14, 2002	Jan CAHN
>D>	AB	+		EQ 10MG BASE	N021323	002	Aug 14, 2002	Jan CAHN
>D>	AB	+!		EQ 20MG BASE	N021323	003	Aug 14, 2002	Jan CAHN

ESTRADIOL

CREAM;VAGINAL

ESTRADIOL

>A>	AB		PERRIGO UK FINCO	0.01%	A210194	001	Jan 22, 2018	Jan NEWA

ESTRADIOL VALERATE

INJECTABLE;INJECTION

ESTRADIOL VALERATE

>A>		@	FOSUN PHARMA	10MG/ML	A040628	001	Oct 04, 2007	Jan CAHN
>A>		@		20MG/ML	A040628	002	Oct 04, 2007	Jan CAHN
>A>		@		40MG/ML	A040628	003	Oct 04, 2007	Jan CAHN
>D>		@	SANDOZ INC	10MG/ML	A040628	001	Oct 04, 2007	Jan CAHN
>D>		@		20MG/ML	A040628	002	Oct 04, 2007	Jan CAHN
>D>		@		40MG/ML	A040628	003	Oct 04, 2007	Jan CAHN

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET;ORAL

BALCOLTRA

>A>			NEUVOSYN LABS LLC	0.02MG;0.1MG	N208612	001	Jan 09, 2018	Jan NEWA

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET, CHEWABLE, TABLET;ORAL

LO MINASTRIN FE

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

FENOFIBRATE

TABLET;ORAL

FENOFIBRATE

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

FENTANYL

FILM, EXTENDED RELEASE;TRANSDERMAL

DURAGESIC-37

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

FLUCONAZOLE

INJECTABLE;INJECTION

FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

>D> AP	!	ACS DOBFAR INFO SA	200MG/100ML (2MG/ML)	A079104	001	Jul 30, 2009	Jan CAHN
>D> AP	!		400MG/200ML (2MG/ML)	A079104	002	Jul 30, 2009	Jan CAHN
>A> AP	!	INFORLIFE	200MG/100ML (2MG/ML)	A079104	001	Jul 30, 2009	Jan CAHN
>A> AP	!		400MG/200ML (2MG/ML)	A079104	002	Jul 30, 2009	Jan CAHN

FLUOCINOLONE ACETONIDE

CREAM;TOPICAL

FLUOCINOLONE ACETONIDE

>D> AT		G AND W LABS	0.025%	A089525	001	Jul 26, 1988	Jan DISC
>A>	@		0.025%	A089525	001	Jul 26, 1988	Jan DISC

SOLUTION;TOPICAL

FLUOCINOLONE ACETONIDE

>D> AT		G AND W LABS INC	0.01%	A207441	001	Sep 28, 2016	Jan DISC
>A>	@		0.01%	A207441	001	Sep 28, 2016	Jan DISC

FLUOXETINE HYDROCHLORIDE

TABLET;ORAL

FLUOXETINE HYDROCHLORIDE

>A>	@	FOSUN PHARMA	EQ 10MG BASE	A076024	001	Jan 29, 2002	Jan CAHN
>D>	@	SANDOZ	EQ 10MG BASE	A076024	001	Jan 29, 2002	Jan CAHN

FLUTAMIDE

CAPSULE;ORAL

FLUTAMIDE

>D>	@	FOSUN PHARMA	125MG	A075818	001	Sep 18, 2001	Jan CAHN
>A>	@	YAOPHARMA CO LTD	125MG	A075818	001	Sep 18, 2001	Jan CAHN

FLUTICASONE PROPIONATE

SPRAY, METERED;NASAL

XHANCE

>A>	+!	OPTINOSE US INC	0.093MG	N209022	001	Sep 18, 2017	Jan CMS1
>D>	+!	OPTNOSE US	0.093MG	N209022	001	Sep 18, 2017	Jan CMS1

FOSINOPRIL SODIUM; HYDROCHLOROTHIAZIDE

TABLET;ORAL

FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE

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

GEMFIBROZIL

TABLET;ORAL

GEMFIBROZIL

>D>	@	FOSUN PHARMA	600MG	A074615	001	Sep 29, 1995	Jan CAHN
>A>	@	YAOPHARMA CO LTD	600MG	A074615	001	Sep 29, 1995	Jan CAHN

GENTAMICIN SULFATE

OINTMENT;TOPICAL

GENTAMICIN SULFATE

>D>	@	G AND W LABS INC	EQ 0.1% BASE	A064054	001	Apr 29, 1994	Jan CMFD
>A> AT			EQ 0.1% BASE	A064054	001	Apr 29, 1994	Jan CMFD

GLATIRAMER ACETATE

INJECTABLE;SUBCUTANEOUS

GLATOPA

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

GLYBURIDE

TABLET;ORAL

GLYBURIDE (MICRONIZED)

>D>		@	FOSUN PHARMA	1.5MG	A075174	001	Jun 22, 1998	Jan CAHN
>D>		@		3MG	A075174	002	Jun 22, 1998	Jan CAHN
>A>		@	YAOPHARMA CO LTD	1.5MG	A075174	001	Jun 22, 1998	Jan CAHN
>A>		@		3MG	A075174	002	Jun 22, 1998	Jan CAHN

GRISEOFULVIN, ULTRAMICROSIZE

TABLET;ORAL

GRISEOFULVIN, ULTRAMICROSIZE

>D>	AB		COREPHARMA	125MG	A204371	001	Jan 09, 2014	Jan CAHN
>D>	AB			250MG	A204371	002	Jan 09, 2014	Jan CAHN
>A>	AB		MOUNTAIN	125MG	A204371	001	Jan 09, 2014	Jan CAHN
>A>	AB			250MG	A204371	002	Jan 09, 2014	Jan CAHN

GUANABENZ ACETATE

TABLET;ORAL

GUANABENZ ACETATE

>D>		@	SANDOZ	EQ 4MG BASE	A074517	001	Sep 30, 1998	Jan CAHN
>D>		@		EQ 8MG BASE	A074517	002	Sep 30, 1998	Jan CAHN
>A>		@	YAOPHARMA CO LTD	EQ 4MG BASE	A074517	001	Sep 30, 1998	Jan CAHN
>A>		@		EQ 8MG BASE	A074517	002	Sep 30, 1998	Jan CAHN

HALOPERIDOL LACTATE

INJECTABLE;INJECTION

HALOPERIDOL

>A>		@	FOSUN PHARMA	EQ 5MG BASE/ML	A076464	001	Sep 29, 2004	Jan CAHN
>D>		@	SANDOZ INC	EQ 5MG BASE/ML	A076464	001	Sep 29, 2004	Jan CAHN

HYDROCHLOROTHIAZIDE

TABLET;ORAL

HYDROCHLOROTHIAZIDE

>D>		@	FOSUN PHARMA	25MG	A087565	001	Mar 09, 1982	Jan CAHN
>D>		@		50MG	A084912	001		Jan CAHN
>A>	AB		SCIEGEN PHARMS INC	25MG	A203018	001	Jul 23, 2014	Jan CAHN
>A>	AB			50MG	A203018	002	Jul 23, 2014	Jan CAHN
>D>	AB		TECH ORGANIZED	25MG	A203018	001	Jul 23, 2014	Jan CAHN
>D>	AB			50MG	A203018	002	Jul 23, 2014	Jan CAHN
>A>		@	YAOPHARMA CO LTD	25MG	A087565	001	Mar 09, 1982	Jan CAHN
>A>		@		50MG	A084912	001		Jan CAHN

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET;ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

>D>		@	FOSUN PHARMA	15MG;250MG	A070182	001	Jan 15, 1986	Jan CAHN
>D>		@		25MG;250MG	A070183	001	Jan 15, 1986	Jan CAHN
>D>		@		30MG;500MG	A070543	001	Jan 15, 1986	Jan CAHN
>D>		@	SANDOZ	50MG;500MG	A070544	001	Jan 15, 1986	Jan CAHN
>A>		@	YAOPHARMA CO LTD	15MG;250MG	A070182	001	Jan 15, 1986	Jan CAHN
>A>		@		25MG;250MG	A070183	001	Jan 15, 1986	Jan CAHN
>A>		@		30MG;500MG	A070543	001	Jan 15, 1986	Jan CAHN
>A>		@		50MG;500MG	A070544	001	Jan 15, 1986	Jan CAHN

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET;ORAL

PROPRANOLOL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>D>		@	FOSUN PHARMA	25MG;40MG	A071060	001	Aug 26, 1987	Jan CAHN
>D>		@		25MG;80MG	A071061	001	Aug 26, 1987	Jan CAHN
>A>		@	YAOPHARMA CO LTD	25MG;40MG	A071060	001	Aug 26, 1987	Jan CAHN
>A>		@		25MG;80MG	A071061	001	Aug 26, 1987	Jan CAHN

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET;ORAL

SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

>D>		@ FOSUN PHARMA	25MG;25MG	A086881	001		Jan CAHN
>A>		@ YAOPHARMA CO LTD	25MG;25MG	A086881	001		Jan CAHN

HYDROCODONE BITARTRATE

TABLET, EXTENDED RELEASE;ORAL

VANTRELA ER

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

HYDROMORPHONE HYDROCHLORIDE

TABLET;ORAL

HYDROMORPHONE HYDROCHLORIDE

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

IBUTILIDE FUMARATE

INJECTABLE;INJECTION

IBUTILIDE FUMARATE

>D> AP		MYLAN INSTITUTIONAL	0.1MG/ML	A090924	001	Jan 11, 2010	Jan DISC
>A>	@		0.1MG/ML	A090924	001	Jan 11, 2010	Jan DISC

IMIQUIMOD

CREAM;TOPICAL

IMIQUIMOD

>D> AB		G AND W LABS INC	5%	A200481	001	Apr 18, 2011	Jan DISC
>A>	@		5%	A200481	001	Apr 18, 2011	Jan DISC

INDAPAMIDE

TABLET;ORAL

INDAPAMIDE

>D>		@ FOSUN PHARMA	1.25MG	A074594	001	May 23, 1996	Jan CAHN
>D>		@	2.5MG	A074594	002	May 23, 1996	Jan CAHN
>A>		@ YAOPHARMA CO LTD	1.25MG	A074594	001	May 23, 1996	Jan CAHN
>A>		@	2.5MG	A074594	002	May 23, 1996	Jan CAHN

IPRATROPIUM BROMIDE

SPRAY, METERED;NASAL

>D> ATROVENT

>D> AB	+!	BOEHRINGER INGELHEIM	0.021MG/SPRAY	N020393	001	Oct 20, 1995	Jan DISC
>A>	+ @		0.021MG/SPRAY	N020393	001	Oct 20, 1995	Jan DISC
>D> AB	+!		0.042MG/SPRAY	N020394	001	Oct 20, 1995	Jan DISC
>A>	+ @		0.042MG/SPRAY	N020394	001	Oct 20, 1995	Jan DISC

IPRATROPIUM BROMIDE

>D> AB		WEST-WARD PHARMS INT	0.021MG/SPRAY	A076664	001	Nov 05, 2003	Jan CHRS
>A> AB	!		0.021MG/SPRAY	A076664	001	Nov 05, 2003	Jan CHRS
>D> AB			0.042MG/SPRAY	A076598	001	Nov 05, 2003	Jan CHRS
>A> AB	!		0.042MG/SPRAY	A076598	001	Nov 05, 2003	Jan CHRS

KETOROLAC TROMETHAMINE

SOLUTION/DROPS;OPHTHALMIC

KETOROLAC TROMETHAMINE

>D> AT		ALCON PHARMS LTD	0.4%	A078721	001	Nov 05, 2009	Jan CAHN
>A> AT		SANDOZ INC	0.4%	A078721	001	Nov 05, 2009	Jan CAHN

LEFLUNOMIDE

TABLET;ORAL

LEFLUNOMIDE

>A>		@	FOSUN PHARMA	10MG	A077087	001	Sep 13, 2005	Jan CAHN
>A>		@		20MG	A077087	002	Sep 13, 2005	Jan CAHN
>D>		@	SANDOZ	10MG	A077087	001	Sep 13, 2005	Jan CAHN
>D>		@		20MG	A077087	002	Sep 13, 2005	Jan CAHN

LEVETIRACETAM

TABLET;ORAL

LEVETIRACETAM

>A>		@	FOSUN PHARMA	250MG	A077324	001	Jan 15, 2009	Jan CAHN
>A>		@		500MG	A077324	002	Jan 15, 2009	Jan CAHN
>A>		@		750MG	A077324	003	Jan 15, 2009	Jan CAHN
>A>		@		1GM	A077324	004	Jan 15, 2009	Jan CAHN
>D>		@	SANDOZ	250MG	A077324	001	Jan 15, 2009	Jan CAHN
>D>		@		500MG	A077324	002	Jan 15, 2009	Jan CAHN
>D>		@		750MG	A077324	003	Jan 15, 2009	Jan CAHN
>D>		@		1GM	A077324	004	Jan 15, 2009	Jan CAHN

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET;ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

>A>		@	FOSUN PHARMA	5MG	A090486	001	Mar 26, 2013	Jan CAHN
>D>		@	SANDOZ	5MG	A090486	001	Mar 26, 2013	Jan CAHN

LEVOFLOXACIN

INJECTABLE;INJECTION

LEVOFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

>D>	AP	!	ACS DOBFAR INFO SA	EQ 250MG/50ML (EQ 5MG/ML)	A090343	001	Jul 07, 2011	Jan CAHN
>D>	AP	!		EQ 500MG/100ML (EQ 5MG/ML)	A090343	002	Jul 07, 2011	Jan CAHN
>D>	AP	!		EQ 750MG/150ML (EQ 5MG/ML)	A090343	003	Jul 07, 2011	Jan CAHN
>A>	AP	!	INFORLIFE	EQ 250MG/50ML (EQ 5MG/ML)	A090343	001	Jul 07, 2011	Jan CAHN
>A>	AP	!		EQ 500MG/100ML (EQ 5MG/ML)	A090343	002	Jul 07, 2011	Jan CAHN
>A>	AP	!		EQ 750MG/150ML (EQ 5MG/ML)	A090343	003	Jul 07, 2011	Jan CAHN

LEVOMILNACIPRAN HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

FETZIMA

>A>		+	ALLERGAN SALES LLC	EQ 20MG BASE	N204168	001	Jul 25, 2013	Jan CAHN
>A>		+		EQ 40MG BASE	N204168	002	Jul 25, 2013	Jan CAHN
>A>		+		EQ 80MG BASE	N204168	003	Jul 25, 2013	Jan CAHN
>A>		+!		EQ 120MG BASE	N204168	004	Jul 25, 2013	Jan CAHN
>D>		+	FOREST LABS INC	EQ 20MG BASE	N204168	001	Jul 25, 2013	Jan CAHN
>D>		+		EQ 40MG BASE	N204168	002	Jul 25, 2013	Jan CAHN
>D>		+		EQ 80MG BASE	N204168	003	Jul 25, 2013	Jan CAHN
>D>		+!		EQ 120MG BASE	N204168	004	Jul 25, 2013	Jan CAHN

LEVOTHYROXINE SODIUM

POWDER;INTRAVENOUS

LEVOTHYROXINE SODIUM

>D>	AP		FERA PHARMS LLC	100MCG/VIAL	A206163	001	Jun 29, 2016	Jan CAHN
>D>	AP			500MCG/VIAL	A206163	002	Jun 29, 2016	Jan CAHN
>A>	AP		PIRAMAL CRITICAL	100MCG/VIAL	A206163	001	Jun 29, 2016	Jan CAHN
>A>	AP			500MCG/VIAL	A206163	002	Jun 29, 2016	Jan CAHN

LIDOCAINE

OINTMENT;TOPICAL

LIDOCAINE

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

LINACLOTIDE

CAPSULE;ORAL

LINZESS

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

LOPERAMIDE HYDROCHLORIDE

CAPSULE;ORAL

LOPERAMIDE HYDROCHLORIDE

>D>		@ FOSUN PHARMA	2MG	A	072993	001	Aug 28, 1992	Jan CAHN
>A>		@ YAOPHARMA CO LTD	2MG	A	072993	001	Aug 28, 1992	Jan CAHN

LORAZEPAM

TABLET;ORAL

LORAZEPAM

>A>		@ MYLAN	0.5MG	A	071591	002	Oct 13, 1987	Jan CMS1
>A>		@	1MG	A	071591	003	Oct 13, 1987	Jan CMS1

>A> LUTETIUM DOTATATE LU-177

>A> SOLUTION;IV (INFUSION)

>A> LUTATHERA

>A>	+!	AAA USA INC	10mCi/ML	N	208700	001	Jan 26, 2018	Jan NEWA

MACIMORELIN ACETATE

FOR SOLUTION;ORAL

MACRILEN

>D>	+!	AETERNA ZENTARIS	EQ 60MG BASE/POUCH	N	205598	001	Dec 21, 2017	Jan CAHN
>A>	+!	STRONGBRIDGE IRELAND	EQ 60MG BASE/POUCH	N	205598	001	Dec 21, 2017	Jan CAHN

MECLOFENAMATE SODIUM

CAPSULE;ORAL

MECLOFENAMATE SODIUM

>A>		@ FOSUN PHARMA	EQ 50MG BASE	A	072262	001	Nov 29, 1988	Jan CAHN
>A>		@	EQ 100MG BASE	A	072263	001	Nov 29, 1988	Jan CAHN
>D>		@ SANDOZ	EQ 50MG BASE	A	072262	001	Nov 29, 1988	Jan CAHN
>D>		@	EQ 100MG BASE	A	072263	001	Nov 29, 1988	Jan CAHN

MEMANTINE HYDROCHLORIDE

SOLUTION;ORAL

MEMANTINE HYDROCHLORIDE

>A>	AA	APOTEX INC	2MG/ML	A	209955	001	Feb 09, 2018	Jan NEWA

NAMENDA

>A>	AA +!	ALLERGAN SALES LLC	2MG/ML	N	021627	001	Apr 18, 2005	Jan CAHN
>D>	AA +!	FOREST LABS LLC	2MG/ML	N	021627	001	Apr 18, 2005	Jan CAHN

TABLET;ORAL

NAMENDA

>A>	AB +	ALLERGAN SALES LLC	5MG	N	021487	001	Oct 16, 2003	Jan CAHN
>A>	AB +!		10MG	N	021487	002	Oct 16, 2003	Jan CAHN
>D>	AB +	FOREST LABS LLC	5MG	N	021487	001	Oct 16, 2003	Jan CAHN
>D>	AB +!		10MG	N	021487	002	Oct 16, 2003	Jan CAHN

MEROPENEM; VABORBACTAM

POWDER;IV (INFUSION)

VABOMERE

>A>	+!	REMPEX PHARMS	1GM/VIAL;1GM/VIAL	N	209776	001	Aug 29, 2017	Jan CAHN
>D>	+!	REMPEX PHARMS MEDCNS	1GM/VIAL;1GM/VIAL	N	209776	001	Aug 29, 2017	Jan CAHN

MESALAMINE

ENEMA;RECTAL

MESALAMINE

>D>	AB	G AND W LABS INC	4GM/60ML	A	076841	001	Sep 30, 2004	Jan DISC
>A>		@	4GM/60ML	A	076841	001	Sep 30, 2004	Jan DISC

SUPPOSITORY;RECTAL

CANASA

>A>		@ ALLERGAN SALES LLC	500MG	N	021252	001	Jan 05, 2001	Jan CAHN
>A>	AB +!		1GM	N	021252	002	Nov 05, 2004	Jan CAHN
>D>		@ FOREST LABS LLC	500MG	N	021252	001	Jan 05, 2001	Jan CAHN
>D>	AB +!		1GM	N	021252	002	Nov 05, 2004	Jan CAHN

MESNA

INJECTABLE;INTRAVENOUS

MESNA

>D>	AP	MYLAN INSTITUTIONAL	100MG/ML	A	076488	001	Mar 08, 2012	Jan DISC
>A>		@	100MG/ML	A	076488	001	Mar 08, 2012	Jan DISC

METAXALONE

TABLET;ORAL

METAXALONE

>D>		COREPHARMA	400MG	A040486	001	Feb 27, 2015	Jan CAHN
>D>	@	EPIC PHARMA LLC	640MG	N022503	001	Jun 01, 2015	Jan CAHN
>A>		MOUNTAIN	400MG	A040486	001	Feb 27, 2015	Jan CAHN
>A>	@	PRIMUS PHARMS	640MG	N022503	001	Jun 01, 2015	Jan CAHN

METHOCARBAMOL

TABLET;ORAL

METHOCARBAMOL

>A>	@	FOSUN PHARMA	500MG	A084616	001		Jan CAHN
>A>	@		750MG	A084615	001		Jan CAHN
>D>	@	SANDOZ	500MG	A084616	001		Jan CAHN
>D>	@		750MG	A084615	001		Jan CAHN

METHYCLOTHIAZIDE

TABLET;ORAL

METHYCLOTHIAZIDE

>D>	@	FOSUN PHARMA	2.5MG	A089835	001	Aug 18, 1988	Jan CAHN
>D>	@		5MG	A089837	001	Aug 18, 1988	Jan CAHN
>A>	@	YAOPHARMA CO LTD	2.5MG	A089835	001	Aug 18, 1988	Jan CAHN
>A>	@		5MG	A089837	001	Aug 18, 1988	Jan CAHN

METHYLDOPA

TABLET;ORAL

METHYLDOPA

>D>	@	FOSUN PHARMA	250MG	N018934	001	Jun 29, 1984	Jan CAHN
>D>	@		500MG	N018934	002	Jun 29, 1984	Jan CAHN
>D>	@	SANDOZ	125MG	A071700	001	Mar 02, 1988	Jan CAHN
>A>	@	YAOPHARMA CO LTD	125MG	A071700	001	Mar 02, 1988	Jan CAHN
>A>	@		250MG	N018934	001	Jun 29, 1984	Jan CAHN
>A>	@		500MG	N018934	002	Jun 29, 1984	Jan CAHN

METHYLPHENIDATE HYDROCHLORIDE

TABLET;ORAL

METHYLPHENIDATE HYDROCHLORIDE

>D>	AB	COREPHARMA	5MG	A091159	001	Mar 12, 2014	Jan CAHN
>D>	AB		10MG	A091159	002	Mar 12, 2014	Jan CAHN
>D>	AB		20MG	A091159	003	Mar 12, 2014	Jan CAHN
>A>	AB	MOUNTAIN	5MG	A091159	001	Mar 12, 2014	Jan CAHN
>A>	AB		10MG	A091159	002	Mar 12, 2014	Jan CAHN
>A>	AB		20MG	A091159	003	Mar 12, 2014	Jan CAHN

TABLET, EXTENDED RELEASE;ORAL

METHYLPHENIDATE HYDROCHLORIDE

>A>	AB	AMNEAL PHARMS	18MG	A207515	001	Feb 01, 2018	Jan NEWA
>A>	AB		27MG	A207515	002	Feb 01, 2018	Jan NEWA
>A>	AB		36MG	A207515	003	Feb 01, 2018	Jan NEWA
>A>	AB		54MG	A207515	004	Feb 01, 2018	Jan NEWA
>D>	AB	COREPHARMA	18MG	A208607	001	Jul 14, 2017	Jan CAHN
>D>	AB		27MG	A208607	002	Jul 14, 2017	Jan CAHN
>D>	AB		36MG	A208607	003	Jul 14, 2017	Jan CAHN
>D>	AB		54MG	A208607	004	Jul 14, 2017	Jan CAHN
>A>	AB	MOUNTAIN	18MG	A208607	001	Jul 14, 2017	Jan CAHN
>A>	AB		27MG	A208607	002	Jul 14, 2017	Jan CAHN
>A>	AB		36MG	A208607	003	Jul 14, 2017	Jan CAHN
>A>	AB		54MG	A208607	004	Jul 14, 2017	Jan CAHN
>D>		OSMOTICA	72MG	A205327	005	Jul 28, 2017	Jan CHRS
>A>	!		72MG	A205327	005	Jul 28, 2017	Jan CHRS

METOCLOPRAMIDE HYDROCHLORIDE

TABLET;ORAL

METOCLOPRAMIDE HYDROCHLORIDE

>D>	@	FOSUN PHARMA	EQ 5MG BASE	A074478	001	Oct 05, 1995	Jan CAHN
>D>	@		EQ 10MG BASE	A072215	001	Jan 30, 1990	Jan CAHN
>D>	@		EQ 10MG BASE	A074478	002	Oct 05, 1995	Jan CAHN
>A>	@	YAOPHARMA CO LTD	EQ 5MG BASE	A074478	001	Oct 05, 1995	Jan CAHN
>A>	@		EQ 10MG BASE	A072215	001	Jan 30, 1990	Jan CAHN
>A>	@		EQ 10MG BASE	A074478	002	Oct 05, 1995	Jan CAHN

METOPROLOL SUCCINATE

>A>		CAPSULE, EXTENDED RELEASE;ORAL					
>A>		METOPROLOL SUCCINATE					
>A>	+	SPIL	EQ 25MG TARTRATE	N210428	001	Jan 26, 2018	Jan NEWA
>A>	+		EQ 50MG TARTRATE	N210428	002	Jan 26, 2018	Jan NEWA
>A>	+		EQ 100MG TARTRATE	N210428	003	Jan 26, 2018	Jan NEWA
>A>	+!		EQ 200MG TARTRATE	N210428	004	Jan 26, 2018	Jan NEWA
		TABLET, EXTENDED RELEASE;ORAL					
		METOPROLOL SUCCINATE					
>A>	AB	NOVAST LABS LTD	EQ 25MG TARTRATE	A204106	001	Feb 06, 2018	Jan NEWA
>A>	AB		EQ 50MG TARTRATE	A204106	002	Feb 06, 2018	Jan NEWA
>A>	AB		EQ 100MG TARTRATE	A204106	003	Feb 06, 2018	Jan NEWA
>A>	AB		EQ 200MG TARTRATE	A204106	004	Feb 06, 2018	Jan NEWA

METOPROLOL TARTRATE

		TABLET;ORAL					
		METOPROLOL TARTRATE					
>D>		@ FOSUN PHARMA	50MG	A073288	001	Mar 25, 1994	Jan CAHN
>D>		@	100MG	A073289	001	Mar 25, 1994	Jan CAHN
>D>		@ PRINSTON INC	50MG	A074453	001	Apr 27, 1995	Jan CAHN
>D>		@	100MG	A074453	002	Apr 27, 1995	Jan CAHN
>A>		@ RENATA	50MG	A074453	001	Apr 27, 1995	Jan CAHN
>A>		@	100MG	A074453	002	Apr 27, 1995	Jan CAHN
>A>		@ YAOPHARMA CO LTD	50MG	A073288	001	Mar 25, 1994	Jan CAHN
>A>		@	100MG	A073289	001	Mar 25, 1994	Jan CAHN

METRONIDAZOLE

		TABLET;ORAL					
		METRONIDAZOLE					
>A>		@ FOSUN PHARMA	250MG	N018620	001	Mar 04, 1982	Jan CAHN
>A>		@	250MG	N018740	001	Oct 22, 1982	Jan CAHN
>A>		@	500MG	N018620	002	Jun 02, 1983	Jan CAHN
>A>		@	500MG	N018740	002	Oct 22, 1982	Jan CAHN
>D>		@ SANDOZ	250MG	N018620	001	Mar 04, 1982	Jan CAHN
>D>		@	250MG	N018740	001	Oct 22, 1982	Jan CAHN
>D>		@	500MG	N018620	002	Jun 02, 1983	Jan CAHN
>D>		@	500MG	N018740	002	Oct 22, 1982	Jan CAHN

MINOCYCLINE HYDROCHLORIDE

		INJECTABLE;INJECTION					
		MINOCIN					
>A>	+!	REMPEX PHARMS	EQ 100MG BASE/VIAL	N050444	001		Jan CAHN
>D>	+!	REMPEX PHARMS INC	EQ 100MG BASE/VIAL	N050444	001		Jan CAHN
		TABLET, EXTENDED RELEASE;ORAL					
		MINOCYCLINE HYDROCHLORIDE					
>D>		@ BARR LABS INC	EQ 65MG BASE	A065485	004	May 18, 2012	Jan CMFD
>A>	AB		EQ 65MG BASE	A065485	004	May 18, 2012	Jan CMFD
>D>		@	EQ 115MG BASE	A065485	005	May 18, 2012	Jan CMFD
>A>	AB		EQ 115MG BASE	A065485	005	May 18, 2012	Jan CMFD

NALTREXONE HYDROCHLORIDE

		TABLET;ORAL					
		NALTREXONE HYDROCHLORIDE					
>A>		@ FOSUN PHARMA	50MG	A075434	001	Mar 08, 2000	Jan CAHN
>D>		@ SANDOZ	50MG	A075434	001	Mar 08, 2000	Jan CAHN

NAPROXEN

		TABLET;ORAL					
		NAPROXEN					
>A>		@ FOSUN PHARMA	250MG	A074140	001	Dec 21, 1993	Jan CAHN
>A>		@	375MG	A074140	002	Dec 21, 1993	Jan CAHN
>A>		@	500MG	A074140	003	Dec 21, 1993	Jan CAHN
>D>		@ SANDOZ	250MG	A074140	001	Dec 21, 1993	Jan CAHN
>D>		@	375MG	A074140	002	Dec 21, 1993	Jan CAHN
>D>		@	500MG	A074140	003	Dec 21, 1993	Jan CAHN
		TABLET, DELAYED RELEASE;ORAL					
		NAPROXEN					
>A>		@ FOSUN PHARMA	375MG	A075061	001	Feb 18, 1998	Jan CAHN
>A>		@	500MG	A075061	002	Feb 18, 1998	Jan CAHN
>D>		@ SANDOZ	375MG	A075061	001	Feb 18, 1998	Jan CAHN
>D>		@	500MG	A075061	002	Feb 18, 1998	Jan CAHN

NEBIVOLOL HYDROCHLORIDE

TABLET;ORAL

BYSTOLIC

>A>	+	ALLERGAN SALES LLC	EQ 2.5MG BASE	N021742	002	Dec 17, 2007	Jan CAHN
>A>	+		EQ 5MG BASE	N021742	003	Dec 17, 2007	Jan CAHN
>A>	+		EQ 10MG BASE	N021742	004	Dec 17, 2007	Jan CAHN
>A>	+!		EQ 20MG BASE	N021742	005	Oct 08, 2008	Jan CAHN
>D>	+	FOREST LABS	EQ 2.5MG BASE	N021742	002	Dec 17, 2007	Jan CAHN
>D>	+		EQ 5MG BASE	N021742	003	Dec 17, 2007	Jan CAHN
>D>	+		EQ 10MG BASE	N021742	004	Dec 17, 2007	Jan CAHN
>D>	+!		EQ 20MG BASE	N021742	005	Oct 08, 2008	Jan CAHN

NEBIVOLOL HYDROCHLORIDE; VALSARTAN

TABLET;ORAL

BYVALSON

>A>	+!	ALLERGAN SALES LLC	EQ 5MG BASE;80MG	N206302	001	Jun 03, 2016	Jan CAHN
>D>	+!	FOREST LABS LLC	EQ 5MG BASE;80MG	N206302	001	Jun 03, 2016	Jan CAHN

NEFAZODONE HYDROCHLORIDE

TABLET;ORAL

NEFAZODONE HYDROCHLORIDE

>A>	@	FOSUN PHARMA	50MG	A076302	001	Sep 16, 2003	Jan CAHN
>A>	@		100MG	A076302	002	Sep 16, 2003	Jan CAHN
>A>	@		150MG	A076302	003	Sep 16, 2003	Jan CAHN
>A>	@		200MG	A076302	004	Sep 16, 2003	Jan CAHN
>A>	@		250MG	A076302	005	Sep 16, 2003	Jan CAHN
>D>	@	SANDOZ	50MG	A076302	001	Sep 16, 2003	Jan CAHN
>D>	@		100MG	A076302	002	Sep 16, 2003	Jan CAHN
>D>	@		150MG	A076302	003	Sep 16, 2003	Jan CAHN
>D>	@		200MG	A076302	004	Sep 16, 2003	Jan CAHN
>D>	@		250MG	A076302	005	Sep 16, 2003	Jan CAHN

NEVIRAPINE

TABLET;ORAL

NEVIRAPINE

>D>	AB	TECH ORGANIZED	200MG	A203176	001	May 22, 2012	Jan DISC
>A>	@		200MG	A203176	001	May 22, 2012	Jan DISC

TABLET, EXTENDED RELEASE;ORAL

NEVIRAPINE

>D>	AB	APOTEX INC	400MG	A205258	001	Apr 03, 2014	Jan DISC
>A>	@		400MG	A205258	001	Apr 03, 2014	Jan DISC

NIACIN

TABLET, EXTENDED RELEASE;ORAL

NIACIN

>A>	AB	AUROBINDO PHARMA LTD	500MG	A209236	001	Feb 01, 2018	Jan NEWA
>A>	AB		750MG	A209236	002	Feb 01, 2018	Jan NEWA
>A>	AB		1GM	A209236	003	Feb 01, 2018	Jan NEWA

NITROGLYCERIN

OINTMENT;INTRA-ANAL

RECTIV

>A>	+!	ALLERGAN SALES LLC	0.4%	N021359	001	Jun 21, 2011	Jan CAHN
>D>	+!	FOREST LABS INC	0.4%	N021359	001	Jun 21, 2011	Jan CAHN

TABLET;SUBLINGUAL

NITROGLYCERIN

>D>	AB	GLENMARK PHARMS LTD	0.3MG	A206391	001	Sep 19, 2017	Jan CAHN
>D>	AB		0.4MG	A206391	002	Sep 19, 2017	Jan CAHN
>D>	AB		0.6MG	A206391	003	Sep 19, 2017	Jan CAHN
>A>	AB	GLENMARK PHARMS SA	0.3MG	A206391	001	Sep 19, 2017	Jan CAHN
>A>	AB		0.4MG	A206391	002	Sep 19, 2017	Jan CAHN
>A>	AB		0.6MG	A206391	003	Sep 19, 2017	Jan CAHN

NYSTATIN

OINTMENT;TOPICAL

NYSTATIN

>D>	AT	G AND W LABS INC	100,000 UNITS/GM	A209114	001	Oct 06, 2017	Jan DISC
>A>	@		100,000 UNITS/GM	A209114	001	Oct 06, 2017	Jan DISC

SUSPENSION;ORAL

NYSTATIN

>D>	AA	G AND W LABS INC	100,000 UNITS/ML	A062349	001	Jul 14, 1982	Jan DISC

SUSPENSION;ORAL
NYSTATIN

>A>	@	100,000 UNITS/ML	A062349	001	Jul 14, 1982	Jan DISC	

NYSTATIN; TRIAMCINOLONE ACETONIDE

OINTMENT;TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE

>A> AT	STRIDES PHARMA	100,000 UNITS/GM;0.1%	A210077	001	Jan 29, 2018	Jan NEWA	

ORITAVANCIN DIPHOSPHATE

POWDER;IV (INFUSION)
ORBACTIV

>A>	+! MELINTA	EQ 400MG BASE/VIAL	N206334	001	Aug 06, 2014	Jan CAHN	
>D>	+! THE MEDICINES CO	EQ 400MG BASE/VIAL	N206334	001	Aug 06, 2014	Jan CAHN	

OXYMORPHONE HYDROCHLORIDE

TABLET;ORAL
OXYMORPHONE HYDROCHLORIDE

>A> AB	ASCENT PHARMS INC	5MG	A210175	001	Feb 02, 2018	Jan NEWA	
>A> AB		10MG	A210175	002	Feb 02, 2018	Jan NEWA	

PEMOLINE

TABLET;ORAL
PEMOLINE

>A>	@ FOSUN PHARMA	18.75MG	A075286	001	Dec 27, 1999	Jan CAHN	
>A>	@	37.5MG	A075286	002	Jun 30, 1999	Jan CAHN	
>A>	@	75MG	A075286	003	Jun 30, 1999	Jan CAHN	
>D>	@ SANDOZ	18.75MG	A075286	001	Dec 27, 1999	Jan CAHN	
>D>	@	37.5MG	A075286	002	Jun 30, 1999	Jan CAHN	
>D>	@	75MG	A075286	003	Jun 30, 1999	Jan CAHN	

PERINDOPRIL ERBUMINE

TABLET;ORAL
PERINDOPRIL ERBUMINE

>D> AB	APOTEX	2MG	A090463	001	Aug 30, 2010	Jan DISC	
>A>	@	2MG	A090463	001	Aug 30, 2010	Jan DISC	
>D> AB		4MG	A090463	002	Aug 30, 2010	Jan DISC	
>A>	@	4MG	A090463	002	Aug 30, 2010	Jan DISC	
>D> AB		8MG	A090463	003	Aug 30, 2010	Jan DISC	
>A>	@	8MG	A090463	003	Aug 30, 2010	Jan DISC	

PHENTERMINE HYDROCHLORIDE

CAPSULE;ORAL
PHENTERMINE HYDROCHLORIDE

>A>	@ ELITE LABS INC	15MG	A040460	001	Jan 14, 2003	Jan CAHN	
>D>	@ MIKAH PHARMA	15MG	A040460	001	Jan 14, 2003	Jan CAHN	

PHENYLBUTAZONE

CAPSULE;ORAL
PHENYLBUTAZONE

>A>	@ FOSUN PHARMA	100MG	A087774	001	Jun 16, 1982	Jan CAHN	
>D>	@ SANDOZ	100MG	A087774	001	Jun 16, 1982	Jan CAHN	

TABLET;ORAL
PHENYLBUTAZONE

>A>	@ FOSUN PHARMA	100MG	A084339	001		Jan CAHN	
>D>	@ SANDOZ	100MG	A084339	001		Jan CAHN	

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP;ORAL
PHENYLEPHRINE HYDROCHLORIDE AND PROMETHAZINE HYDROCHLORIDE

>D> AA	VINTAGE	5MG/5ML;6.25MG/5ML	A040654	001	Dec 07, 2006	Jan CHRS	
>A> AA	!	5MG/5ML;6.25MG/5ML	A040654	001	Dec 07, 2006	Jan CHRS	
>D>	PROMETH VC PLAIN						
>D> AA	! G AND W LABS INC	5MG/5ML;6.25MG/5ML	A088761	001	Nov 08, 1984	Jan DISC	
>A>	@	5MG/5ML;6.25MG/5ML	A088761	001	Nov 08, 1984	Jan DISC	

PHENYTOIN

SUSPENSION;ORAL

PHENYTOIN

>A>	AB		WOCKHARDT BIO AG	125MG/5ML	A040420	001	Apr 19, 2002	Jan CAHN
>D>	AB		WOCKHARDT EU OPERATN	125MG/5ML	A040420	001	Apr 19, 2002	Jan CAHN

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE;INJECTION

PIPERACILLIN AND TAZOBACTAM

>D>	AP		WOCKHARDT BIO AG	EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A207146	001	Mar 17, 2017	Jan CPOT
>A>	AP			EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A207146	001	Mar 17, 2017	Jan CPOT

PIROXICAM

CAPSULE;ORAL

PIROXICAM

>A>	AB		STRIDES PHARMA	10MG	A210347	001	Jan 26, 2018	Jan NEWA
>A>	AB			20MG	A210347	002	Jan 26, 2018	Jan NEWA

POLIDOCANOL

>D>			SOLUTION;INTRAMUSCULAR, SUBCUTANEOUS					
>D>			VARITHENA					
>D>		+!	PROVENSIS	77.5MG/7.75ML (10MG/ML)	N205098	002	Dec 21, 2017	Jan CDFR
>A>			SOLUTION;INTRAVENOUS					
>A>			VARITHENA					
>A>		+!	PROVENSIS	77.5MG/7.75ML (10MG/ML)	N205098	002	Dec 21, 2017	Jan CDFR

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE;ORAL

K-TAB

>D>	BC	+	ABBVIE	10MEQ	N018279	001		Jan CTEC
>A>	AB3	+		10MEQ	N018279	001		Jan CTEC
>D>	BC	+!		20MEQ	N018279	003	Nov 25, 2013	Jan CTEC
>A>	AB2	+!		20MEQ	N018279	003	Nov 25, 2013	Jan CTEC

POTASSIUM CHLORIDE

>A>	AB3		PADDOCK LLC	10MEQ	A209688	001	Jan 12, 2018	Jan NEWA
>A>	AB2			20MEQ	A209688	002	Jan 12, 2018	Jan NEWA

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE;ORAL

POTASSIUM CITRATE

>D>	AB		COREPHARMA	5MEQ	A077440	001	Jun 09, 2006	Jan CAHN
>D>	AB			10MEQ	A077440	002	Jun 09, 2006	Jan CAHN
>A>	AB		MOUNTAIN	5MEQ	A077440	001	Jun 09, 2006	Jan CAHN
>A>	AB			10MEQ	A077440	002	Jun 09, 2006	Jan CAHN

PRASUGREL HYDROCHLORIDE

TABLET;ORAL

PRASUGREL

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

PREDNISOLONE

TABLET;ORAL

PREDNISOLONE

>A>		@	FOSUN PHARMA	5MG	A080339	001		Jan CAHN
>D>		@	SANDOZ	5MG	A080339	001		Jan CAHN

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION;ORAL

PREDNISOLONE SODIUM PHOSPHATE

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

PROPRANOLOL HYDROCHLORIDE

INJECTABLE;INJECTION

PROPRANOLOL HYDROCHLORIDE

>A>		@	FOSUN PHARMA	1MG/ML	A	076400	001	Feb 26, 2003 Jan CAHN
>D>		@	SANDOZ INC	1MG/ML	A	076400	001	Feb 26, 2003 Jan CAHN

TABLET;ORAL

PROPRANOLOL HYDROCHLORIDE

>D>		@	SANDOZ	10MG	A	070663	001	Jun 13, 1986 Jan CAHN
>D>		@		20MG	A	070664	001	Jun 13, 1986 Jan CAHN
>D>		@		40MG	A	070665	001	Jun 13, 1986 Jan CAHN
>D>		@		60MG	A	070666	001	Oct 10, 1986 Jan CAHN
>D>		@		80MG	A	070667	001	Jun 13, 1986 Jan CAHN
>A>		@	YAOPHARMA CO LTD	10MG	A	070663	001	Jun 13, 1986 Jan CAHN
>A>		@		20MG	A	070664	001	Jun 13, 1986 Jan CAHN
>A>		@		40MG	A	070665	001	Jun 13, 1986 Jan CAHN
>A>		@		60MG	A	070666	001	Oct 10, 1986 Jan CAHN
>A>		@		80MG	A	070667	001	Jun 13, 1986 Jan CAHN

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET;ORAL

CORPHED

>A>		@	FOSUN PHARMA	60MG;2.5MG	A	088602	001	Apr 11, 1985 Jan CAHN
>D>		@	SANDOZ	60MG;2.5MG	A	088602	001	Apr 11, 1985 Jan CAHN

PYRIMETHAMINE

TABLET;ORAL

DARAPRIM

>D>		+!	TURING PHARMS LLC	25MG	N	008578	001	Jan CAHN
>A>		+!	VYERA PHARMS LLC	25MG	N	008578	001	Jan CAHN

QUINAPRIL HYDROCHLORIDE

TABLET;ORAL

QUINAPRIL HYDROCHLORIDE

>D>		@	FOSUN PHARMA	EQ 5MG BASE	A	076803	001	Mar 02, 2005 Jan CAHN
>D>		@		EQ 10MG BASE	A	076803	002	Mar 02, 2005 Jan CAHN
>D>		@		EQ 20MG BASE	A	076803	003	Mar 02, 2005 Jan CAHN
>D>		@		EQ 40MG BASE	A	076803	004	Mar 02, 2005 Jan CAHN
>A>		@	YAOPHARMA CO LTD	EQ 5MG BASE	A	076803	001	Mar 02, 2005 Jan CAHN
>A>		@		EQ 10MG BASE	A	076803	002	Mar 02, 2005 Jan CAHN
>A>		@		EQ 20MG BASE	A	076803	003	Mar 02, 2005 Jan CAHN
>A>		@		EQ 40MG BASE	A	076803	004	Mar 02, 2005 Jan CAHN

QUINIDINE SULFATE

>D>		TABLET, EXTENDED RELEASE;ORAL						
>D>		QUINIDINE SULFATE						
>D>		!	G AND W LABS INC	300MG	A	040045	001	Jun 30, 1994 Jan DISC
>A>		@		300MG	A	040045	001	Jun 30, 1994 Jan DISC

RAMIPRIL

CAPSULE;ORAL

RAMIPRIL

>D>		@	FOSUN PHARMA	1.25MG	A	077514	001	Jun 18, 2008 Jan CAHN
>D>		@		2.5MG	A	077514	002	Jun 18, 2008 Jan CAHN
>D>		@		5MG	A	077514	003	Jun 18, 2008 Jan CAHN
>D>		@		10MG	A	077514	004	Jun 18, 2008 Jan CAHN
>A>		@	YAOPHARMA CO LTD	1.25MG	A	077514	001	Jun 18, 2008 Jan CAHN
>A>		@		2.5MG	A	077514	002	Jun 18, 2008 Jan CAHN
>A>		@		5MG	A	077514	003	Jun 18, 2008 Jan CAHN
>A>		@		10MG	A	077514	004	Jun 18, 2008 Jan CAHN

REMIFENTANIL HYDROCHLORIDE

INJECTABLE;INJECTION

>A>			REMIFENTANIL HYDROCHLORIDE					
>A>	AP		FRESENIUS KABI USA	EQ 1MG BASE/VIAL	A	206223	001	Jan 16, 2018 Jan NEWA
>A>	AP			EQ 2MG BASE/VIAL	A	206223	002	Jan 16, 2018 Jan NEWA
>A>	AP			EQ 5MG BASE/VIAL	A	206223	003	Jan 16, 2018 Jan NEWA
			ULTIVA					
>D>		+	MYLAN INSTITUTIONAL	EQ 1MG BASE/VIAL	N	020630	001	Jul 12, 1996 Jan CFTG
>A>	AP	+		EQ 1MG BASE/VIAL	N	020630	001	Jul 12, 1996 Jan CFTG
>D>		+		EQ 2MG BASE/VIAL	N	020630	002	Jul 12, 1996 Jan CFTG
>A>	AP	+		EQ 2MG BASE/VIAL	N	020630	002	Jul 12, 1996 Jan CFTG

INJECTABLE;INJECTION
ULTIVA

>D>		+!		EQ 5MG BASE/VIAL	N020630	003	Jul 12, 1996	Jan CFTG
>A>	AP	+!		EQ 5MG BASE/VIAL	N020630	003	Jul 12, 1996	Jan CFTG

RISPERIDONE
TABLET;ORAL
RISPERIDONE

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

ROFLUMILAST
TABLET;ORAL
DALIRESP

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

ROPINIROLE HYDROCHLORIDE
TABLET;ORAL
ROPINIROLE HYDROCHLORIDE

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

SERTRALINE HYDROCHLORIDE
TABLET;ORAL
SERTRALINE HYDROCHLORIDE

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

SIMVASTATIN
TABLET;ORAL
SIMVASTATIN

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

SINECATECHINS

OINTMENT;TOPICAL

VEREGEN

>A>		+!	FOUGERA PHARMS INC	15%	N021902	001	Oct 31, 2006	Jan CAHN
>D>		+!	MEDIGENE AG	15%	N021902	001	Oct 31, 2006	Jan CAHN

SUCRALFATE

SUSPENSION;ORAL

CARAFATE

>A>		+!	ALLERGAN SALES LLC	1GM/10ML	N019183	001	Dec 16, 1993	Jan CAHN
>D>		+!	FOREST LABS INC	1GM/10ML	N019183	001	Dec 16, 1993	Jan CAHN

TABLET;ORAL

CARAFATE

>A>	AB	+!	ALLERGAN SALES LLC	1GM	N018333	001		Jan CAHN
>D>	AB	+!	FOREST LABS INC	1GM	N018333	001		Jan CAHN

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET;ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

>A>		@	FOSUN PHARMA	400MG;80MG	A070889	001	Nov 13, 1986	Jan CAHN
>A>		@		400MG;80MG	N018598	003	May 19, 1982	Jan CAHN
>A>		@		800MG;160MG	A070890	001	Nov 13, 1986	Jan CAHN
>D>		@	SANDOZ	400MG;80MG	A070889	001	Nov 13, 1986	Jan CAHN
>D>		@		400MG;80MG	N018598	003	May 19, 1982	Jan CAHN
>D>		@		800MG;160MG	A070890	001	Nov 13, 1986	Jan CAHN

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

>A>		@	FOSUN PHARMA	800MG;160MG	N018598	004	May 19, 1982	Jan CAHN
>D>		@	SANDOZ	800MG;160MG	N018598	004	May 19, 1982	Jan CAHN

SULINDAC

TABLET;ORAL

SULINDAC

>A>		@	FOSUN PHARMA	150MG	A072712	001	Aug 30, 1991	Jan CAHN
>A>		@		200MG	A072713	001	Aug 30, 1991	Jan CAHN
>D>		@	SANDOZ	150MG	A072712	001	Aug 30, 1991	Jan CAHN
>D>		@		200MG	A072713	001	Aug 30, 1991	Jan CAHN

SUMATRIPTAN SUCCINATE

TABLET;ORAL

SUMATRIPTAN SUCCINATE

>A>		@	FOSUN PHARMA	EQ 25MG BASE	A076976	001	Aug 10, 2009	Jan CAHN
>A>		@		EQ 50MG BASE	A076976	002	Aug 10, 2009	Jan CAHN
>A>		@		EQ 100MG BASE	A076976	003	Aug 10, 2009	Jan CAHN
>D>		@	SANDOZ	EQ 25MG BASE	A076976	001	Aug 10, 2009	Jan CAHN
>D>		@		EQ 50MG BASE	A076976	002	Aug 10, 2009	Jan CAHN
>D>		@		EQ 100MG BASE	A076976	003	Aug 10, 2009	Jan CAHN

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE;INJECTION

CIS-MDP

>D>	AP		PHARMALUCENCE	N/A	N018124	001		Jan CTEC
>A>				N/A	N018124	001		Jan CTEC

MDP-BRACCO

>D>	AP		CARDINAL HEALTH 414	N/A	N018107	001		Jan DISC
>A>		@		N/A	N018107	001		Jan DISC

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE;INJECTION

DTPA

>D>		+!	DRAXIMAGE	N/A	N018511	001	Dec 29, 1989	Jan CAHN
>A>		+!	JUBILANT DRAXIMAGE	N/A	N018511	001	Dec 29, 1989	Jan CAHN

TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL

TENOFOVIR DISOPROXIL FUMARATE

>A>	AB		AUROBINDO PHARMA LTD	150MG	A090647	001	Jan 26, 2018	Jan NEWA
>A>	AB			200MG	A090647	002	Jan 26, 2018	Jan NEWA
>A>	AB			250MG	A090647	003	Jan 26, 2018	Jan NEWA
>A>	AB			300MG	A090647	004	Jan 26, 2018	Jan NEWA
>A>	AB		CIPLA LTD	300MG	A078800	001	Jan 26, 2018	Jan NEWA
>A>	AB		HETERO LABS LTD III	300MG	A090636	001	Jan 26, 2018	Jan NEWA

TABLET;ORAL
TENOFOVIR DISOPROXIL FUMARATE

>A>	AB		MACLEODS PHARMS LTD	300MG		A203232	001	Jan 26, 2018 Jan NEWA
>A>	AB		STRIDES PHARMA	300MG		A090742	001	Jan 26, 2018 Jan NEWA
>A>	AB		TEVA PHARMS USA	150MG		A091612	002	Jan 26, 2018 Jan NEWA
>A>	AB			200MG		A091612	003	Jan 26, 2018 Jan NEWA
>A>	AB			250MG		A091612	004	Jan 26, 2018 Jan NEWA

VIREAD

>D>		+	GILEAD SCIENCES INC	150MG		N021356	002	Jan 18, 2012 Jan CFTG
>A>	AB	+		150MG		N021356	002	Jan 18, 2012 Jan CFTG
>D>		+		200MG		N021356	003	Jan 18, 2012 Jan CFTG
>A>	AB	+		200MG		N021356	003	Jan 18, 2012 Jan CFTG
>D>		+		250MG		N021356	004	Jan 18, 2012 Jan CFTG
>A>	AB	+		250MG		N021356	004	Jan 18, 2012 Jan CFTG

TESTOSTERONE

GEL;TRANSDERMAL
TESTOSTERONE

>D>	BX		ANI PHARMS INC	25MG/2.5GM PACKET		N202763	001	Feb 14, 2012 Jan DISC
>A>		@		25MG/2.5GM PACKET		N202763	001	Feb 14, 2012 Jan DISC
>D>	BX			50MG/5GM PACKET		N202763	002	Feb 14, 2012 Jan DISC
>A>		@		50MG/5GM PACKET		N202763	002	Feb 14, 2012 Jan DISC

SOLUTION, METERED;TRANSDERMAL
TESTOSTERONE

>A>	AT		CIPLA LTD	30MG/1.5ML ACTUATION		A209533	001	Jan 29, 2018 Jan NEWA

THEOPHYLLINE

TABLET, EXTENDED RELEASE;ORAL
THEOCHRON

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

THIORIDAZINE HYDROCHLORIDE

TABLET;ORAL
THIORIDAZINE HYDROCHLORIDE

>A>		@	FOSUN PHARMA	10MG		A088131	001	Aug 30, 1983 Jan CAHN
>A>		@		25MG		A088133	001	Aug 30, 1983 Jan CAHN
>A>		@		50MG		A088134	001	Aug 30, 1983 Jan CAHN
>A>		@		100MG		A088135	001	Nov 20, 1984 Jan CAHN
>A>		@		200MG		A088137	001	Sep 17, 1986 Jan CAHN
>D>		@	SANDOZ	10MG		A088131	001	Aug 30, 1983 Jan CAHN
>D>		@		25MG		A088133	001	Aug 30, 1983 Jan CAHN
>D>		@		50MG		A088134	001	Aug 30, 1983 Jan CAHN
>D>		@		100MG		A088135	001	Nov 20, 1984 Jan CAHN
>D>	AB			150MG		A088136	001	Sep 17, 1986 Jan CAHN
>D>		@		200MG		A088137	001	Sep 17, 1986 Jan CAHN
>A>		@	SANDOZ INC	150MG		A088136	001	Sep 17, 1986 Jan CAHN

THIOTHIXENE

CAPSULE;ORAL
NAVANE

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

TICLOPIDINE HYDROCHLORIDE

TABLET;ORAL
TICLOPIDINE HYDROCHLORIDE

>D>		@	FOSUN PHARMA	250MG		A075318	001	Aug 20, 1999 Jan CAHN
>D>		@		250MG		A075326	001	Aug 20, 1999 Jan CAHN
>A>		@	YAOPHARMA CO LTD	250MG		A075318	001	Aug 20, 1999 Jan CAHN
>A>		@		250MG		A075326	001	Aug 20, 1999 Jan CAHN

TIGECYCLINE
POWDER;IV (INFUSION)
TIGECYCLINE

>A>		ACCORD HLTHCARE INC	50MG/VIAL	N208744	001	Jan 18, 2018	Jan NEWA

TIMOLOL MALEATE
SOLUTION/DROPS;OPHTHALMIC
TIMOPTIC

>D>	+ @	ATON	EQ 0.25% BASE	N018086	001		Jan CMFD
>A> AT	+		EQ 0.25% BASE	N018086	001		Jan CMFD
>D>	+ @		EQ 0.5% BASE	N018086	002		Jan CMFD
>A> AT1	+		EQ 0.5% BASE	N018086	002		Jan CMFD

TABLET;ORAL
TIMOLOL MALEATE

>D>	@	FOSUN PHARMA	5MG	A072550	001	Apr 13, 1989	Jan CAHN
>D>	@		10MG	A072551	001	Apr 13, 1989	Jan CAHN
>D>	@		20MG	A072552	001	Apr 13, 1989	Jan CAHN
>A>	@	YAOPHARMA CO LTD	5MG	A072550	001	Apr 13, 1989	Jan CAHN
>A>	@		10MG	A072551	001	Apr 13, 1989	Jan CAHN
>A>	@		20MG	A072552	001	Apr 13, 1989	Jan CAHN

TOLAZAMIDE
TABLET;ORAL
TOLAZAMIDE

>D>	@	FOSUN PHARMA	250MG	A070289	001	Mar 13, 1986	Jan CAHN
>D>	@		500MG	A070290	001	Mar 13, 1986	Jan CAHN
>D>	@	SANDOZ	100MG	A071633	001	Dec 09, 1987	Jan CAHN
>A>	@	YAOPHARMA CO LTD	100MG	A071633	001	Dec 09, 1987	Jan CAHN
>A>	@		250MG	A070289	001	Mar 13, 1986	Jan CAHN
>A>	@		500MG	A070290	001	Mar 13, 1986	Jan CAHN

TOLBUTAMIDE
TABLET;ORAL
TOLBUTAMIDE

>D>	@	SANDOZ	500MG	A086574	001		Jan CAHN
>A>	@	YAOPHARMA CO LTD	500MG	A086574	001		Jan CAHN

TOLMETIN SODIUM
CAPSULE;ORAL
TOLMETIN SODIUM

>A>	@	FOSUN PHARMA	EQ 400MG BASE	A073462	001	Apr 30, 1992	Jan CAHN
>D>	@	SANDOZ	EQ 400MG BASE	A073462	001	Apr 30, 1992	Jan CAHN

TABLET;ORAL
TOLMETIN SODIUM

>A>	@	FOSUN PHARMA	EQ 200MG BASE	A073588	001	Jul 31, 1992	Jan CAHN
>A>	@		EQ 600MG BASE	A074002	001	Sep 27, 1993	Jan CAHN
>D>	@	SANDOZ	EQ 200MG BASE	A073588	001	Jul 31, 1992	Jan CAHN
>D>	@		EQ 600MG BASE	A074002	001	Sep 27, 1993	Jan CAHN

TOPIRAMATE
CAPSULE;ORAL
TOPIRAMATE

>A>	@	FOSUN PHARMA	15MG	A079206	001	Oct 14, 2009	Jan CAHN
>A>	@		25MG	A079206	002	Oct 14, 2009	Jan CAHN
>D>	@	SANDOZ	15MG	A079206	001	Oct 14, 2009	Jan CAHN
>D>	@		25MG	A079206	002	Oct 14, 2009	Jan CAHN

TRAMADOL HYDROCHLORIDE
TABLET;ORAL
TRAMADOL HYDROCHLORIDE

>A>	@	FOSUN PHARMA	50MG	A075968	001	Jun 25, 2002	Jan CAHN
>D>	@	SANDOZ	50MG	A075968	001	Jun 25, 2002	Jan CAHN

TRAZODONE HYDROCHLORIDE
TABLET;ORAL
TRAZODONE HYDROCHLORIDE

>A>	@	FOSUN PHARMA	100MG	A072483	001	Apr 30, 1990	Jan CAHN
>D>	@	SANDOZ	100MG	A072483	001	Apr 30, 1990	Jan CAHN

TRIENTINE HYDROCHLORIDE

CAPSULE;ORAL

SYPRINE

>D>	+!	ATON	250MG	N019194	001	Nov 08, 1985	Jan CFTG
>A> AB	+!		250MG	N019194	001	Nov 08, 1985	Jan CFTG

TRIENTINE HYDROCHLORIDE

>A> AB		WATSON LABS TEVA	250MG	A207567	001	Feb 07, 2018	Jan NEWA

TRIFLUOPERAZINE HYDROCHLORIDE

CONCENTRATE;ORAL

TRIFLUOPERAZINE HYDROCHLORIDE

>A>	@	FOSUN PHARMA	EQ 10MG BASE/ML	A085787	001	Apr 15, 1982	Jan CAHN
>D>	@	SANDOZ	EQ 10MG BASE/ML	A085787	001	Apr 15, 1982	Jan CAHN

VANCOMYCIN HYDROCHLORIDE

FOR SOLUTION;ORAL

>A> FIRVANQ KIT

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

VENLAFAXINE HYDROCHLORIDE

TABLET;ORAL

VENLAFAXINE HYDROCHLORIDE

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

VERAPAMIL HYDROCHLORIDE

SOLUTION;INTRAVENOUS

VERAPAMIL HYDROCHLORIDE

>D> AP	!	HOSPIRA	10MG/4ML (2.5MG/ML)	A070738	001	May 06, 1987	Jan CPOT
>A> AP	!		5MG/2ML (2.5MG/ML)	A070738	001	May 06, 1987	Jan CPOT

TABLET;ORAL

VERAPAMIL HYDROCHLORIDE

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

VILAZODONE HYDROCHLORIDE

TABLET;ORAL

VIIBRYD

>A>	+!	ALLERGAN SALES LLC	10MG	N022567	001	Jan 21, 2011	Jan CAHN
>A>	+		20MG	N022567	002	Jan 21, 2011	Jan CAHN
>A>	+		40MG	N022567	003	Jan 21, 2011	Jan CAHN
>D>	+!	FOREST LABS LLC	10MG	N022567	001	Jan 21, 2011	Jan CAHN
>D>	+		20MG	N022567	002	Jan 21, 2011	Jan CAHN
>D>	+		40MG	N022567	003	Jan 21, 2011	Jan CAHN

WARFARIN SODIUM

TABLET;ORAL

WARFARIN SODIUM

>D>	@	FOSUN PHARMA	1MG	A040196	001	Sep 30, 1997	Jan CAHN
>D>	@		2MG	A040196	002	Sep 30, 1997	Jan CAHN
>D>	@		2.5MG	A040196	003	Sep 30, 1997	Jan CAHN
>D>	@		3MG	A040196	008	Jul 26, 2000	Jan CAHN
>D>	@		4MG	A040196	004	Sep 30, 1997	Jan CAHN
>D>	@		5MG	A040196	005	Sep 30, 1997	Jan CAHN
>D>	@		6MG	A040196	009	Jul 26, 2000	Jan CAHN
>D>	@		7.5MG	A040196	006	Sep 30, 1997	Jan CAHN
>D>	@		10MG	A040196	007	Sep 30, 1997	Jan CAHN
>A>	@	YAOPHARMA CO LTD	1MG	A040196	001	Sep 30, 1997	Jan CAHN

TABLET;ORAL

WARFARIN SODIUM

>A>		@	2MG		A040196	002	Sep 30, 1997	Jan CAHN
>A>		@	2.5MG		A040196	003	Sep 30, 1997	Jan CAHN
>A>		@	3MG		A040196	008	Jul 26, 2000	Jan CAHN
>A>		@	4MG		A040196	004	Sep 30, 1997	Jan CAHN
>A>		@	5MG		A040196	005	Sep 30, 1997	Jan CAHN
>A>		@	6MG		A040196	009	Jul 26, 2000	Jan CAHN
>A>		@	7.5MG		A040196	006	Sep 30, 1997	Jan CAHN
>A>		@	10MG		A040196	007	Sep 30, 1997	Jan CAHN

ZOLEDRONIC ACID

INJECTABLE;IV (INFUSION)

ZOLEDRONIC ACID

>D>	AP	ACS DOBFAR INFO SA	EQ 4MG BASE/100ML		N203231	001	Aug 02, 2013	Jan CAHN
>D>	AP		EQ 5MG BASE/100ML		A202828	001	Sep 23, 2013	Jan CAHN
>A>	AP	INFORLIFE	EQ 4MG BASE/100ML		N203231	001	Aug 02, 2013	Jan CAHN
>A>	AP		EQ 5MG BASE/100ML		A202828	001	Sep 23, 2013	Jan CAHN

ACETAMINOPHEN

SUPPOSITORY;RECTAL

ACEPHEN

>D>	G AND W LABS	325MG	N018060	003	Dec 18, 1986	Jan DISC
>A>	@	325MG	N018060	003	Dec 18, 1986	Jan DISC
>D>		650MG	N018060	002		Jan DISC
>A>	@	650MG	N018060	002		Jan DISC

CLEMASTINE FUMARATE

TABLET;ORAL

CLEMASTINE FUMARATE

>A>	PLD ACQUISITIONS LLC	1.34MG	A073458	001	Oct 31, 1993	Jan CAHN
>D>	SANDOZ	1.34MG	A073458	001	Oct 31, 1993	Jan CAHN

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET;ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

>A>	DR REDDYS LABS LTD	5MG	A210375	001	Jan 19, 2018	Jan NEWA

LORATADINE

TABLET;ORAL

LORATADINE

>A>	PLD ACQUISITIONS LLC	10MG	A075209	001	Jan 21, 2003	Jan CAHN
>D>	SANDOZ	10MG	A075209	001	Jan 21, 2003	Jan CAHN

MICONAZOLE NITRATE

CREAM, SUPPOSITORY;TOPICAL, VAGINAL

>D> MICONAZOLE 7 COMBINATION PACK

>D>	G AND W LABS	2%,100MG	A076585	001	Mar 26, 2004	Jan DISC
>A>	@	2%,100MG	A076585	001	Mar 26, 2004	Jan DISC

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

CUMULATIVE SUPPLEMENT NUMBER 1 JANUARY 2018

NO JANUARY 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 JANUARY 2018 ADDITIONS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 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
AFATINIB DIMALEATE - GILOTRIF						
N 201292 001					>A> I-763	Jan 12, 2021
AFATINIB DIMALEATE - GILOTRIF						
N 201292 002					>A> I-763	Jan 12, 2021
AFATINIB DIMALEATE - GILOTRIF						
N 201292 003					>A> I-763	Jan 12, 2021
AMANTADINE HYDROCHLORIDE - GOCOVRI						
N 208944 001	>A> 9867791	Dec 02, 2030	U-2106			
	>A> 9867792	Dec 02, 2030	U-2106			
	>A> 9867793	Dec 02, 2030	U-2106			
	>A> 9877933	Dec 02, 2030	U-2224			
AMANTADINE HYDROCHLORIDE - GOCOVRI						
N 208944 002	>A> 9867791	Dec 02, 2030	U-2106			
	>A> 9867792	Dec 02, 2030	U-2106			
	>A> 9867793	Dec 02, 2030	U-2106			
	>A> 9877933	Dec 02, 2030	U-2224			
ANGIOTENSIN II ACETATE - GIAPREZA						
N 209360 001	>A> 9220745	Dec 18, 2034	U-2217		>A> NCE	Dec 21, 2022
	>A> 9220745	Dec 18, 2034	U-2218			
	>A> 9572856	Sep 20, 2030	U-2221			
ANGIOTENSIN II ACETATE - GIAPREZA						
N 209360 002	>A> 9220745	Dec 18, 2034	U-2217		>A> NCE	Dec 21, 2022
	>A> 9220745	Dec 18, 2034	U-2218			
	>A> 9572856	Sep 20, 2030	U-2221			
ASENAPINE MALEATE - SAPHRIS						
N 022117 001					>A> M-158	Mar 12, 2018
					>A> NPP	Mar 12, 2018
					>A> PED	Sep 12, 2018
					>A> PED	Sep 12, 2018
ASENAPINE MALEATE - SAPHRIS						
N 022117 002					>A> M-158	Mar 12, 2018
					>A> NPP	Mar 12, 2018
					>A> PED	Sep 12, 2018
					>A> PED	Sep 12, 2018
BENDAMUSTINE HYDROCHLORIDE - BENDEKA						
N 208194 001	>A> 8791270	Jan 12, 2026	DP U-1790			
BRIMONIDINE TARTRATE - MIRVASO						
N 204708 001	>A> 9861631	Mar 25, 2031	U-1428			
	>A> 9861632	Mar 25, 2031	U-1428			
BRIMONIDINE TARTRATE - LUMIFY						
N 208144 001	>A> 8293742	Jul 14, 2030	U-2222			
BUPRENORPHINE - SUBLOCADE						
N 209819 001					>A> NP	Nov 30, 2020
BUPRENORPHINE - SUBLOCADE						
N 209819 002					>A> NP	Nov 30, 2020

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CALCIFEDIOL - RAYALDEE							
N 208010	001	>A> 9861644	Mar 14, 2034	DP			
CEFTOLOZANE SULFATE; TAZOBACTAM SODIUM - ZERBAXA							
N 206829	001	>A> 9872906	Mar 14, 2034	DP			
COCAINE HYDROCHLORIDE - GOPRELTO							
N 209963	001	>A> 9867815	Feb 07, 2037	U-2225		>A> NCE	Dec 14, 2022
		>A> 9867815	Feb 07, 2037	U-2226			
		>A> 9867815	Feb 07, 2037	U-2227			
CYSTEAMINE BITARTRATE - PROCYSBI							
N 203389	001					>A> ODE-162	Dec 22, 2024
CYSTEAMINE BITARTRATE - PROCYSBI							
N 203389	002					>A> ODE-162	Dec 22, 2024
DANTROLENE SODIUM - RYANODEX							
N 205579	001	>A> 9884044	Jun 13, 2022	DP U-1546			
DAPAGLIFLOZIN PROPANEDIOL - FARXIGA							
N 202293	001	>A> 7456254	Jun 30, 2025	DP U-2139			
		>A> 8329648	Aug 18, 2026	U-2139			
		>A> 8329648	Aug 18, 2026	U-2212			
		>A> 8329648	Aug 18, 2026	U-2213			
		>A> 8431685	Apr 13, 2025	DP U-2139			
		>A> 8461105	Apr 13, 2025	DP U-2139			
		>A> 8906851	Aug 18, 2026	U-2139			
		>A> 9238076	Apr 15, 2024	DP U-2139			
DAPAGLIFLOZIN PROPANEDIOL - FARXIGA							
N 202293	002	>A> 7456254	Jun 30, 2025	DP U-2139			
		>A> 8329648	Aug 18, 2026	U-2139			
		>A> 8329648	Aug 18, 2026	U-2212			
		>A> 8329648	Aug 18, 2026	U-2213			
		>A> 8431685	Apr 13, 2025	DP U-2139			
		>A> 8461105	Apr 13, 2025	DP U-2139			
		>A> 8906851	Aug 18, 2026	U-2139			
		>A> 9238076	Apr 15, 2024	DP U-2139			
DOXEPIN HYDROCHLORIDE - SILENOR							
N 022036	001	>A> 9861607	May 18, 2027	U-620			
DOXEPIN HYDROCHLORIDE - SILENOR							
N 022036	002	>A> 9861607	May 18, 2027	U-620			
EFAVIRENZ - EFAVIRENZ							
A 091471	001					>A> PC	Feb 14, 2018
EFINACONAZOLE - JUBLIA							
N 203567	001	>A> 9877955	Jan 03, 2028	U-1969			
ERTUGLIFLOZIN - STEGLATRO							
N 209803	001	>A> 8080580	Jul 13, 2030	DS DP U-2214			
ERTUGLIFLOZIN - STEGLATRO							
N 209803	002	>A> 8080580	Jul 13, 2030	DS DP U-2214			
ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET							
N 209806	001	>A> 8080580	Jul 13, 2030	DS DP U-2214			
		>A> 9308204	Oct 21, 2030	DP			
		>A> 9439902	Oct 21, 2030	U-2214			

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APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET							
N 209806	001	>A> 8080580	Jul 13, 2030	DS DP U-2214			
		>A> 9308204	Oct 21, 2030	DP			
		>A> 9439902	Oct 21, 2030	U-2214			
ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET							
N 209806	002	>A> 8080580	Jul 13, 2030	DS DP U-2214			
		>A> 9308204	Oct 21, 2030	DP			
		>A> 9439902	Oct 21, 2030	U-2214			
ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET							
N 209806	003	>A> 8080580	Jul 13, 2030	DS DP U-2214			
		>A> 9308204	Oct 21, 2030	DP			
		>A> 9439902	Oct 21, 2030	U-2214			
ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET							
N 209806	004	>A> 8080580	Jul 13, 2030	DS DP U-2214			
		>A> 9308204	Oct 21, 2030	DP			
		>A> 9439902	Oct 21, 2030	U-2214			
ERTUGLIFLOZIN; SITAGLIPTIN PHOSPHATE - STEGLUJAN							
N 209805	001	>A> 6699871	Jul 26, 2022	DS DP U-2214			
		>A> 6890898	Feb 02, 2019	U-2215			
		>A> 7078381	Feb 02, 2019	U-2216			
		>A> 7326708	Nov 24, 2026	DS DP U-2214			
		>A> 7459428	Feb 02, 2019	U-2215			
		>A> 8080580	Jul 13, 2030	DS DP U-2214			
		>A> 9308204	Oct 21, 2030	DP			
		>A> 9439901	Oct 21, 2030	U-2214			
ERTUGLIFLOZIN; SITAGLIPTIN PHOSPHATE - STEGLUJAN							
N 209805	002	>A> 6699871	Jul 26, 2022	DS DP U-2214			
		>A> 6890898	Feb 02, 2019	U-2215			
		>A> 7078381	Feb 02, 2019	U-2216			
		>A> 7326708	Nov 24, 2026	DS DP U-2214			
		>A> 7459428	Feb 02, 2019	U-2215			
		>A> 8080580	Jul 13, 2030	DS DP U-2214			
		>A> 9308204	Oct 21, 2030	DP			
		>A> 9439901	Oct 21, 2030	U-2214			
FENTANYL CITRATE - LAZANDA							
N 022569	001	>A> 9814705	Jan 08, 2024	DP			
FENTANYL CITRATE - LAZANDA							
N 022569	002	>A> 9814705	Jan 08, 2024	DP			
FENTANYL CITRATE - LAZANDA							
N 022569	003	>A> 9814705	Jan 08, 2024	DP			
FLUTICASONE FUROATE; UMECLIDINIUM BROMIDE; VILANTEROL TRIFENATATE - TRELEGY ELLIPTA							
N 209482	001	>A> 9750726	Nov 29, 2030	DP			
FORMOTEROL FUMARATE - PERFOROMIST							
N 022007	001	>A> 9730890	Jun 22, 2021	DP			
HYDROCODONE BITARTRATE - HYSINGLA							
N 206627	001	>A> 9872837	Dec 21, 2031	DP			
HYDROCODONE BITARTRATE - HYSINGLA							
N 206627	002	>A> 9872837	Dec 21, 2031	DP			

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HYDROCODONE BITARTRATE - HYSINGLA							
N 206627 003	>A>	9872837	Dec 21, 2031	DP			
HYDROCODONE BITARTRATE - HYSINGLA							
N 206627 004	>A>	9872837	Dec 21, 2031	DP			
HYDROCODONE BITARTRATE - HYSINGLA							
N 206627 005	>A>	9872837	Dec 21, 2031	DP			
HYDROCODONE BITARTRATE - HYSINGLA							
N 206627 006	>A>	9872837	Dec 21, 2031	DP			
HYDROCODONE BITARTRATE - HYSINGLA							
N 206627 007	>A>	9872837	Dec 21, 2031	DP			
IBRUTINIB - IMBRUVICA							
N 205552 001	>A>	8563563	Apr 26, 2027			U-1491	
	>A>	8563563	Apr 26, 2027			U-1946	
	>A>	8563563	Apr 26, 2027			U-2219	
IBRUTINIB - IMBRUVICA							
N 205552 002	>A>	7514444	Dec 28, 2026	DS DP			
	>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>	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>	8563563	Apr 26, 2027			U-1491	
	>A>	8563563	Apr 26, 2027			U-1946	
	>A>	8563563	Apr 26, 2027			U-2219	
	>A>	8697711	Dec 28, 2026	DS DP			
	>A>	8703780	Dec 28, 2026			U-1491	
	>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>	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-2228	
	>A>	9125889	Jun 03, 2031			U-1650	
	>A>	9181257	Dec 28, 2026	DS			
	>A>	9296753	Oct 30, 2033	DS			
	>A>	9540382	Aug 18, 2033			U-1456	
	>A>	9540382	Aug 18, 2033			U-1491	
	>A>	9540382	Aug 18, 2033			U-1650	
	>A>	9540382	Aug 18, 2033			U-1946	
	>A>	9540382	Aug 18, 2033			U-1947	
	>A>	9713617	Jun 03, 2033	DP			
	>A>	9725455	Jun 03, 2033	DS			
	>A>	9795604	Oct 24, 2034			U-2150	
	>A>	9801881	Jun 03, 2031			U-1491	
	>A>	9801883	Jun 03, 2031			U-2159	
	>A>	9814721	Jun 03, 2031			U-1947	

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INGENOL MEBUTATE - PICATO						
N 202833 001	>A> 9861603	Dec 18, 2026	U-1440			
INGENOL MEBUTATE - PICATO						
N 202833 002	>A> 9861603	Dec 18, 2026	U-1440			
IVACAFTOR; LUMACAFTOR - ORKAMBI						
N 206038 001					>A> M-218	Jan 25, 2021
IVACAFTOR; LUMACAFTOR - ORKAMBI						
N 206038 002					>A> M-218	Jan 25, 2021
LEVOTHYROXINE SODIUM - TIROSINT						
N 021924 002	>A> 7723390	Mar 14, 2024	DP			
LEVOTHYROXINE SODIUM - TIROSINT						
N 021924 003	>A> 7723390	Mar 14, 2024	DP			
LEVOTHYROXINE SODIUM - TIROSINT						
N 021924 004	>A> 7723390	Mar 14, 2024	DP			
LEVOTHYROXINE SODIUM - TIROSINT						
N 021924 005	>A> 7723390	Mar 14, 2024	DP			
LEVOTHYROXINE SODIUM - TIROSINT						
N 021924 006	>A> 7723390	Mar 14, 2024	DP			
LEVOTHYROXINE SODIUM - TIROSINT						
N 021924 007	>A> 7723390	Mar 14, 2024	DP			
LEVOTHYROXINE SODIUM - TIROSINT						
N 021924 008	>A> 7723390	Mar 14, 2024	DP			
LEVOTHYROXINE SODIUM - TIROSINT						
N 021924 009	>A> 7723390	Mar 14, 2024	DP			
LEVOTHYROXINE SODIUM - TIROSINT						
N 021924 010	>A> 7723390	Mar 14, 2024	DP			
LEVOTHYROXINE SODIUM - TIROSINT						
N 021924 013	>A> 7691411	Mar 14, 2024	DP			
	>A> 7723390	Mar 14, 2024	DP			
LIXISENATIDE - ADLYXIN						
N 208471 001	>A> 9440029	Jan 30, 2032	DP			
	>A> 9855388	Apr 24, 2029	DP U-1881			
LIXISENATIDE - ADLYXIN						
N 208471 002	>A> 9440029	Jan 30, 2032	DP			
	>A> 9855388	Apr 24, 2029	DP U-1881			
LOMITAPIDE MESYLATE - JUXTAPID						
N 203858 001	>A> 9861622	Mar 07, 2025	U-1316			
LOMITAPIDE MESYLATE - JUXTAPID						
N 203858 002	>A> 9861622	Mar 07, 2025	U-1316			
LOMITAPIDE MESYLATE - JUXTAPID						
N 203858 003	>A> 9861622	Mar 07, 2025	U-1316			

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LOMITAPIDE MESYLATE - JUXTAPID						
N 203858 004	>A> 9861622	Mar 07, 2025	U-1316			
LOMITAPIDE MESYLATE - JUXTAPID						
N 203858 005	>A> 9861622	Mar 07, 2025	U-1316			
LOMITAPIDE MESYLATE - JUXTAPID						
N 203858 006	>A> 9861622	Mar 07, 2025	U-1316			
LURASIDONE HYDROCHLORIDE - LATUDA						
N 200603 001	>A> 9174975	Feb 20, 2024	U-1770			
	>A> 9174975*PED	Aug 20, 2024				
LURASIDONE HYDROCHLORIDE - LATUDA						
N 200603 002	>A> 9174975	Feb 20, 2024	U-1770			
	>A> 9174975*PED	Aug 20, 2024				
LURASIDONE HYDROCHLORIDE - LATUDA						
N 200603 003	>A> 9174975	Feb 20, 2024	U-1770			
	>A> 9174975*PED	Aug 20, 2024				
LURASIDONE HYDROCHLORIDE - LATUDA						
N 200603 004	>A> 9174975	Feb 20, 2024	U-1770			
	>A> 9174975*PED	Aug 20, 2024				
LURASIDONE HYDROCHLORIDE - LATUDA						
N 200603 005	>A> 9174975	Feb 20, 2024	U-1770			
	>A> 9174975*PED	Aug 20, 2024				
LUTETIUM DOTATATE LU-177 - LUTATHERA						
N 208700 001					>A> NCE	Jan 26, 2023
MACIMORELIN ACETATE - MACRILEN						
N 205598 001	>A> 6861409	Aug 01, 2022	DS DP U-2220			
	>A> 8192719	Oct 12, 2027	U-2220			
METHOTREXATE SODIUM - XATMEP						
N 208400 001	>A> 9855215	Jan 02, 2033	DP			
NILOTINIB HYDROCHLORIDE MONOHYDRATE - TASIGNA						
N 022068 001					>A> D-170	Dec 22, 2020
NILOTINIB HYDROCHLORIDE MONOHYDRATE - TASIGNA						
N 022068 002					>A> D-170	Dec 22, 2020
OLAPARIB - LYNPARZA						
N 208558 001					>A> I-762	Jan 12, 2021
OLAPARIB - LYNPARZA						
N 208558 002					>A> I-762	Jan 12, 2021
OSPEMIFENE - OSPHENA						
N 203505 001	>A> 9855224	Feb 13, 2024	U-1369			
	>A> 9855224	Feb 13, 2024	U-1370			
OZENOXACIN - XEPI						
N 208945 001	>A> 6335447	Apr 06, 2019	DS			
	>A> 9180200	Jan 29, 2032	DP U-805			
	>A> 9399014	Dec 15, 2029	U-805			

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PLECANATIDE - TRULANCE						
N 208745 001					>A> I-764	Jan 24, 2021
RIVAROXABAN - XARELTO						
N 022406 001	>A> 9415053	Nov 13, 2024	DP U-1167			
	>A> 9415053	Nov 13, 2024	DP U-1200			
	>A> 9415053	Nov 13, 2024	DP U-1301			
	>A> 9415053	Nov 13, 2024	DP U-1302			
	>A> 9415053	Nov 13, 2024	DP U-2142			
	>A> 9539218	Feb 17, 2034	U-1953			
	>A> 9539218	Feb 17, 2034	U-1954			
	>A> 9539218	Feb 17, 2034	U-1955			
	>A> 9539218	Feb 17, 2034	U-1957			
	>A> 9539218	Feb 17, 2034	U-2143			
RIVAROXABAN - XARELTO						
N 022406 002	>A> 7157456	Aug 28, 2024	DS DP U-1301			
	>A> 7157456	Aug 28, 2024	DS DP U-1302			
RIVAROXABAN - XARELTO						
N 022406 003	>A> 7157456	Aug 28, 2024	DS DP U-1301			
	>A> 7157456	Aug 28, 2024	DS DP U-1302			
	>A> 9415053	Nov 13, 2024	DP U-1167			
	>A> 9415053	Nov 13, 2024	DP U-1200			
	>A> 9415053	Nov 13, 2024	DP U-1301			
	>A> 9415053	Nov 13, 2024	DP U-1302			
ROFLUMILAST - DALIRESP						
N 022522 001					>A> NS	Jan 23, 2021
ROFLUMILAST - DALIRESP						
N 022522 002					>A> NS	Jan 23, 2021
RUCAPARIB CAMSYLATE - RUBRACA						
N 209115 001	>A> 9861638	Feb 10, 2031	U-2012			
RUCAPARIB CAMSYLATE - RUBRACA						
N 209115 002	>A> 9861638	Feb 10, 2031	U-2012			
RUCAPARIB CAMSYLATE - RUBRACA						
N 209115 003	>A> 9861638	Feb 10, 2031	U-2012			
SIMEPREVIR SODIUM - OLYSIO						
N 205123 001	>A> 9856265	Jul 28, 2026	DS DP U-1467			
SOFOSBUVIR; VELPATASVIR; VOXILAPREVIR - VOSEVI						
N 209195 001	>A> 9868745	Nov 16, 2032	DS DP			
TASIMELTEON - HETLIOZ						
N 205677 001	>A> 9855241	Jan 25, 2033	U-2149			
VORTIOXETINE HYDROBROMIDE - TRINTELLIX						
N 204447 001	>A> 9861630	Jun 15, 2027	U-1668			
VORTIOXETINE HYDROBROMIDE - TRINTELLIX						
N 204447 002	>A> 9861630	Jun 15, 2027	U-1668			
VORTIOXETINE HYDROBROMIDE - TRINTELLIX						
N 204447 003	>A> 9861630	Jun 15, 2027	U-1668			

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VORTIOXETINE HYDROBROMIDE - TRINTELLIX						
N 204447 004	>A> 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

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