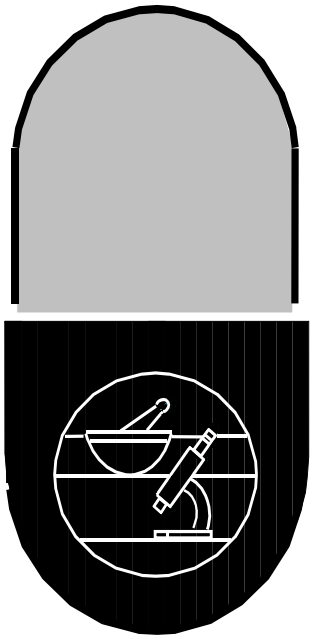
CUMULATIVE SUPPLEMENT 1
JANUARY 2023



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

43rd 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

2023

Prepared By
Food and Drug Administration
Office of Medical Products and Tobacco
Center for Drug Evaluation and Research
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CUMULATIVE SUPPLEMENT 1
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1.0 INTRODUCTION

This Cumulative Supplement is one of a series of monthly updates to the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the List, commonly known as the Orange Book). 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for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.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., How To Use The Drug Product Lists, describes the layout and usage of the List.

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.
- All product changes received and processed as of the date of publication.
  - Refer to CS Section 1.7 Cumulative Supplement Legend for types of changes

- 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 is current as of the date of publication.

Every effort is made to ensure the Cumulative Supplement is accurate. Applicant holders are requested to inform the FDA Division of Orange Book Publication and Regulatory Assessment (DOBPRA) of any changes or corrections. The DOBPRA can be contacted by email at orangebook@fda.hhs.gov.

1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each 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)
ALEOR DERMACEUTICALS LTD (ALEOR DERMACEUTICALS)	ALEMBIC PHARMACEUTICALS LTD (ALEMBIC PHARMS)
EMCURE PHARMACEUTICALS LTD (EMCURE PHARMS)	AVET LIFESCIENCES LTD (AVET LIFESCIENCES)
EMCURE PHARMACEUTICALS LTD (EMCURE PHARMS LTD)	AVET LIFESCIENCES LTD (AVET LIFESCIENCES)

1.4 LEVOTHYROXINE SODIUM[1]

Because there are multiple reference listed drugs for 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 therapeutic equivalence codes may be potentially confusing and inadequate for these drug products. Looking at the Orange Book listing alone for a product identified as a reference listed drug or reference standard, it may be difficult to determine to which therapeutic equivalence code the reference listed drugs and/or reference standard designation corresponds. For example, Unithroid 0.3 mg strength has been assigned the therapeutic equivalence codes AB1, AB2, and AB3 and it is identified as the reference listed drug and reference standard, but it is unclear that the reference listed drug and reference standard designations are associated with the AB1 therapeutic equivalence code.

Accordingly, FDA provides the following chart, which identifies (1) a reference listed drug for each therapeutic equivalence code in the Orange Book and (2) and the reference standard products in the Active Section of the Orange Book.[2]

- Therapeutic equivalence has been established between products that have the same AB+number therapeutic equivalence code (i.e. AB1, AB2, AB3 or AB4).

- More than one therapeutic equivalence code may apply to some products. One common therapeutic equivalence code indicates therapeutic equivalence between products. For example, Unithroid has been assigned therapeutic equivalence codes AB1, AB2, and AB3 therefore Unithroid tablets are considered therapeutically equivalent to other levothyroxine sodium products of the same strength with these therapeutic equivalence codes.

TE Code	Proprietary Name	Applicant	Strength	Appl No	RLD	RS
AB1	UNITHROID	STEVENS J	0.3MG	N021210	RLD	RS
AB2	SYNTHROID	ABBVIE	0.3MG	N021402	RLD	RS
AB3	LEVOXYL	KING PHARMS	0.2MG	N021301	RLD	RS
AB4	THYRO-TABS	ALVOGEN INC	0.3MG	N021116	RLD	–

[1] In previous editions of the Orange Book, FDA provided a chart outlining therapeutic equivalence codes for all .025 mg levothyroxine sodium drug products in the Active Section of the Orange Book. FDA has decided, for ease of review, to revise the chart to identify the NDAs for the reference listed drugs for each therapeutic equivalence code (i.e., AB1, AB2, AB3, and AB4), and their corresponding reference standards, which are identified in 0.2 and 0.3 mg strengths.
[2] Please consult the Active Section of the Orange Book for information on other strengths.

AB4	LEVOTHYROXINE SODIUM[3]	MYLAN	0.3MG	A076187	–	RS

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,
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,
https://www.fda.gov/about-fda/reports-manuals-forms/forms.

[3] Lloyd's Thyro-Tabs tablets (NDA 021116) (previously known as Levothroid) previously was listed in the Discontinued Drug Product List section of the Orange Book. It is the RLD for therapeutic equivalents identified with the AB4 code. During this time, Mylan's levothyroxine product (ANDA 076187) was selected as the reference standard for ANDA applicants to use to establish bioequivalence to Thyro-Tabs. It remains the reference standard for ANDA applicants to use to establish bioequivalence to Thyro-Tabs. If an ANDA that uses Mylan's levothyroxine product as its reference standard is approved, the ANDA will receive an AB4 rating. The ANDA applicant also may obtain an AB rating for its product to the other reference listed drugs (i.e., Unithroid, Synthroid, and Levoxyl) by submitting supplements that demonstrate that the generic product is bioequivalent to these other reference listed drugs and satisfies all other therapeutic equivalence criteria with respect to these reference listed drugs. See Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA to Teri Nataline, Principal Consultant, Lachman Consultant Services, Inc., Docket No. FDA-2015-P-0403 (May 27, 2016).

The current listing of the Orphan Product Designations and Approvals is available at https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products.

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 2022	MAR 2023	JUN 2023	SEP 2023	DEC 2024
DRUG PRODUCTS	21983				
LISTED SINGLE SOURCE	2718 (12.4%)				
MULTISOURCE	19265 (87.6%)				
THERAPEUTICALLY EQUIVALENT	19165 (87.2%)				

NOT THERAPEUTICALLY EQUIVALENT	100 (0.5%)
EXCEPTIONS[4]	46 (0.2%)
NEW MOLECULAR ENTITIES APPROVED	8
NUMBER OF APPLICANTS	1211

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
NFTG	New first-time generic approval
CAHN[5]	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 TE Code is added when a first time generic for an innovator is approved.

[4] Amino acid containing products of varying composition (see Introduction, page xx of the List).
[5] 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 250-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.

CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMKT	Change. RX to OTC marketing status switch.
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 appear in the discontinued section in the next edition.

ABIRATERONE ACETATE

TABLET;ORAL

ABIRATERONE ACETATE

>A>	AB	TEVA PHARMS USA	500MG	A210726	001	Jan 26, 2023	Jan NEWA

ACETAMINOPHEN; BUTALBITAL

TABLET;ORAL

BUTALBITAL AND ACETAMINOPHEN

>D>	AA	RISE PHARMA	300MG;50MG	A214088	001	Apr 07, 2022	Jan CAHN
>D>	AA		325MG;25MG	A214088	002	Apr 07, 2022	Jan CAHN
>D>	AA		325MG;50MG	A214088	003	Apr 07, 2022	Jan CAHN
>A>	AA	SENORES PHARMS	300MG;50MG	A214088	001	Apr 07, 2022	Jan CAHN
>A>	AA		325MG;25MG	A214088	002	Apr 07, 2022	Jan CAHN
>A>	AA		325MG;50MG	A214088	003	Apr 07, 2022	Jan CAHN

ACETAZOLAMIDE

TABLET;ORAL

ACETAZOLAMIDE

>D>	AB	BRECKENRIDGE	125MG	A207503	001	Apr 30, 2020	Jan DISC
>A>		@	125MG	A207503	001	Apr 30, 2020	Jan DISC
>D>	AB		250MG	A207503	002	Apr 30, 2020	Jan DISC
>A>		@	250MG	A207503	002	Apr 30, 2020	Jan DISC

ACETIC ACID, GLACIAL

SOLUTION/DROPS;OTIC

ACETIC ACID

>A>		@ CHARTWELL RX	2%	A040166	001	Jul 26, 1996	Jan CAHN
>D>		@ WOCKHARDT BIO AG	2%	A040166	001	Jul 26, 1996	Jan CAHN

ALBUTEROL SULFATE; BUDESONIDE

AEROSOL, METERED;INHALATION

>A>		AIRSUPRA						
>A>		+! BOND	EQ 90MCG BASE/INH;80MCG/INH	N214070	001	Jan 10, 2023	Jan NEWA

ALVIMOPAN

CAPSULE;ORAL

ALVIMOPAN

>A>	AB	PAR PHARM	12MG	A216843	001	Jan 24, 2023	Jan NEWA

AMINO ACIDS

INJECTABLE;INJECTION

>D>		FREAMINE HBC 6.9%						
>D>		B BRAUN	6.9% (6.9GM/100ML)	N016822	006	May 17, 1983	Jan DISC
>A>		@	6.9% (6.9GM/100ML)	N016822	006	May 17, 1983	Jan DISC
>D>		FREAMINE III 10%						
>D>		B BRAUN	10% (10GM/100ML)	N016822	005		Jan DISC
>A>		@	10% (10GM/100ML)	N016822	005		Jan DISC
>D>		FREAMINE III 8.5%						
>D>		B BRAUN	8.5% (8.5GM/100ML)	N016822	004		Jan DISC
>A>		@	8.5% (8.5GM/100ML)	N016822	004		Jan DISC
>D>		HEPATAMINE 8%						
>D>		B BRAUN	8% (8GM/100ML)	N018676	001	Aug 03, 1982	Jan DISC
>A>		@	8% (8GM/100ML)	N018676	001	Aug 03, 1982	Jan DISC

>D> AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE;INJECTION

PROCALAMINE

>D>		B BRAUN	3%;26MG/100ML;3GM/100ML;54MG/100ML;41MG/100ML;150MG/100ML;200MG/100ML;120MG/100ML	N018582	001	May 08, 1982	Jan DISC
>A>		@	3%;26MG/100ML;3GM/100ML;54MG/100ML;41MG/100ML;150MG/100ML;200MG/100ML;120MG/100ML	N018582	001	May 08, 1982	Jan DISC

AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE

INJECTABLE;INJECTION

FREAMINE III 8.5% W/ ELECTROLYTES

>D>		B BRAUN	8.5%;110MG/100ML;230MG/100ML;10MG/100ML;440MG/100ML;690MG/100ML	N016822	007	Jul 01, 1988	Jan	DISC
>A>	@		8.5%;110MG/100ML;230MG/100ML;10MG/100ML;440MG/100ML;690MG/100ML	N016822	007	Jul 01, 1988	Jan	DISC

AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE;INJECTION

FREAMINE III 3% W/ ELECTROLYTES

>D>		B BRAUN	3%;54MG/100ML;40MG/100ML;150MG/100ML;200MG/100ML;120MG/100ML	N016822	003		Jan	DISC
>A>	@		3%;54MG/100ML;40MG/100ML;150MG/100ML;200MG/100ML;120MG/100ML	N016822	003		Jan	DISC

AMOXICILLIN

FOR SUSPENSION;ORAL

AMOXICILLIN

>D>	@	BELCHER PHARMS	125MG/5ML	A062059	001		Jan	CAHN
>D>	@		250MG/5ML	A062059	002		Jan	CAHN
>A>	@	CHARTWELL RX	125MG/5ML	A062059	001		Jan	CAHN
>A>	@		250MG/5ML	A062059	002		Jan	CAHN

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE;ORAL

DETROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>A>	AB	GRANULES	1.25MG;1.25MG;1.25MG;1.25MG	A217027	001	Jan 23, 2023	Jan	NEWA
>A>	AB		2.5MG;2.5MG;2.5MG;2.5MG	A217027	002	Jan 23, 2023	Jan	NEWA
>A>	AB		3.75MG;3.75MG;3.75MG;3.75MG	A217027	003	Jan 23, 2023	Jan	NEWA
>A>	AB		5MG;5MG;5MG;5MG	A217027	004	Jan 23, 2023	Jan	NEWA
>A>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A217027	005	Jan 23, 2023	Jan	NEWA

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>A>	AB	GRANULES	7.5MG;7.5MG;7.5MG;7.5MG	A217027	006	Jan 23, 2023	Jan	NEWA

AMPICILLIN SODIUM

INJECTABLE;INJECTION

AMPICILLIN SODIUM

>D>	@	MYLAN LABS LTD	EQ 250MG BASE/VIAL	A201025	001	Apr 09, 2014	Jan	CAHN
>D>	@		EQ 500MG BASE/VIAL	A201025	002	Apr 09, 2014	Jan	CAHN
>D>	AP		EQ 1GM BASE/VIAL	A201025	003	Apr 09, 2014	Jan	CAHN
>D>	AP		EQ 2GM BASE/VIAL	A201025	004	Apr 09, 2014	Jan	CAHN
>D>	AP		EQ 10GM BASE/VIAL	A202198	001	Apr 07, 2014	Jan	CAHN
>A>	@	STERISCIENCE	EQ 250MG BASE/VIAL	A201025	001	Apr 09, 2014	Jan	CAHN
>A>	@		EQ 500MG BASE/VIAL	A201025	002	Apr 09, 2014	Jan	CAHN
>A>	AP		EQ 1GM BASE/VIAL	A201025	003	Apr 09, 2014	Jan	CAHN
>A>	AP		EQ 2GM BASE/VIAL	A201025	004	Apr 09, 2014	Jan	CAHN
>A>	AP		EQ 10GM BASE/VIAL	A202198	001	Apr 07, 2014	Jan	CAHN

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE;INJECTION

AMPICILLIN AND SULBACTAM

>D>	AP	MYLAN LABS LTD	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A201024	001	Apr 07, 2014	Jan	CAHN
>D>	AP		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A201024	002	Apr 07, 2014	Jan	CAHN
>D>	AP		EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	A202197	001	Apr 07, 2014	Jan	CAHN
>A>	AP	STERISCIENCE	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A201024	001	Apr 07, 2014	Jan	CAHN
>A>	AP		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A201024	002	Apr 07, 2014	Jan	CAHN
>A>	AP		EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	A202197	001	Apr 07, 2014	Jan	CAHN

AZITHROMYCIN

TABLET;ORAL

AZITHROMYCIN

>D>	AB	ACI	EQ 250MG BASE	A215772	001	Jul 15, 2022	Jan	DISC
>A>	@		EQ 250MG BASE	A215772	001	Jul 15, 2022	Jan	DISC
>D>	AB		EQ 500MG BASE	A215773	001	Jul 12, 2022	Jan	DISC
>A>	@		EQ 500MG BASE	A215773	001	Jul 12, 2022	Jan	DISC

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT;OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC AND HYDROCORTISONE

>D>	AT		AKORN	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A065213	001	Jul 25, 2012	Jan DISC
>A>		@		400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A065213	001	Jul 25, 2012	Jan DISC
>D>	AT	!	BAUSCH AND LOMB	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A064068	001	Oct 30, 1995	Jan CTEC
>A>		!		400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A064068	001	Oct 30, 1995	Jan CTEC

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT;OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC

>D>	AT		AKORN	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A065088	001	Feb 06, 2004	Jan DISC
>A>		@		400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A065088	001	Feb 06, 2004	Jan DISC

BENDAMUSTINE HYDROCHLORIDE

SOLUTION;INTRAVENOUS

BENDAMUSTINE HYDROCHLORIDE

>D>		+!	HOSPIRA	25MG/ML (25MG/ML)	N211530	001	Dec 15, 2022	Jan DISC
>A>		+ @		25MG/ML (25MG/ML)	N211530	001	Dec 15, 2022	Jan DISC
>D>		+!		100MG/4ML (25MG/ML)	N211530	002	Dec 15, 2022	Jan DISC
>A>		+ @		100MG/4ML (25MG/ML)	N211530	002	Dec 15, 2022	Jan DISC
>D>		+!		200MG/8ML (25MG/ML)	N211530	003	Dec 15, 2022	Jan DISC
>A>		+ @		200MG/8ML (25MG/ML)	N211530	003	Dec 15, 2022	Jan DISC

BETAMETHASONE ACETATE; BETAMETHASONE SODIUM PHOSPHATE

INJECTABLE;INJECTION

BETAMETHASONE ACETATE AND BETAMETHASONE SODIUM PHOSPHATE

>A>	AB		HIKMA	3MG/ML;EQ 3MG BASE/ML	A077838	001	Jan 17, 2023	Jan NEWA

>A> BEXAGLIFLOZIN

>A> TABLET;ORAL

>A> BRENZAVVY

>A>		+!	THERACOSBIO	20MG	N214373	001	Jan 20, 2023	Jan NEWA

BICALUTAMIDE

TABLET;ORAL

BICALUTAMIDE

>A>	AB		PINNACLE LIFE SCI	50MG	A079089	001	Jul 06, 2009	Jan CAHN
>D>	AB		ZYDUS PHARMS USA INC	50MG	A079089	001	Jul 06, 2009	Jan CAHN

BIMATOPROST

IMPLANT;OPHTHALMIC

DURYSTA

>A>		+!	ABBVIE	10MCG	N211911	001	Mar 04, 2020	Jan CAHN
>D>		+!	ALLERGAN INC	10MCG	N211911	001	Mar 04, 2020	Jan CAHN

BREXPIPRAZOLE

TABLET;ORAL

BREXPIPRAZOLE

>A>	AB		AJANTA PHARMA LTD	0.25MG	A213718	001	Feb 03, 2023	Jan NEWA
>A>	AB			0.5MG	A213718	002	Feb 03, 2023	Jan NEWA
>A>	AB			1MG	A213718	003	Feb 03, 2023	Jan NEWA
>A>	AB			2MG	A213718	004	Feb 03, 2023	Jan NEWA
>A>	AB			3MG	A213718	005	Feb 03, 2023	Jan NEWA
>A>	AB			4MG	A213718	006	Feb 03, 2023	Jan NEWA
>A>	AB		AMNEAL	0.25MG	A213562	001	Jan 31, 2023	Jan NEWA
>A>	AB			0.5MG	A213562	002	Jan 31, 2023	Jan NEWA
>A>	AB			1MG	A213562	003	Jan 31, 2023	Jan NEWA
>A>	AB			2MG	A213562	004	Jan 31, 2023	Jan NEWA
>A>	AB			3MG	A213562	005	Jan 31, 2023	Jan NEWA
>A>	AB			4MG	A213562	006	Jan 31, 2023	Jan NEWA

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP;ORAL

BROMPHENIRAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE

>D>	AA		BRECKENRIDGE	2MG/5ML;10MG/5ML;30MG/5ML	A203997	001	Sep 30, 2020	Jan DISC
>A>		@		2MG/5ML;10MG/5ML;30MG/5ML	A203997	001	Sep 30, 2020	Jan DISC

BUSULFAN

INJECTABLE;INJECTION

BUSULFAN

>D>	AP		AM REGENT	6MG/ML	A202259	001	Dec 22, 2015	Jan DISC
>A>		@		6MG/ML	A202259	001	Dec 22, 2015	Jan DISC

CABAZITAXEL

SOLUTION;INTRAVENOUS

CABAZITAXEL

>A>		+!	SANDOZ INC	45MG/4.5ML (10MG/ML)	N208715	001	Jan 05, 2023	Jan NEWA
>A>		+!		60MG/6ML (10MG/ML)	N208715	002	Jan 05, 2023	Jan NEWA

CAPTOPRIL

TABLET;ORAL

CAPTOPRIL

>A>	AB		CHANGZHOU PHARM	12.5MG	A214442	001	Jan 27, 2023	Jan NEWA
>A>	AB			25MG	A214442	002	Jan 27, 2023	Jan NEWA
>A>	AB			50MG	A214442	003	Jan 27, 2023	Jan NEWA
>A>	AB			100MG	A214442	004	Jan 27, 2023	Jan NEWA

CARBAMAZEPINE

SUSPENSION;ORAL

CARBAMAZEPINE

>A>	AB		CHARTWELL RX	100MG/5ML	A075714	001	Jun 05, 2002	Jan CAHN
>D>	AB		WOCKHARDT BIO AG	100MG/5ML	A075714	001	Jun 05, 2002	Jan CAHN

CARIPRAZINE HYDROCHLORIDE

CAPSULE;ORAL

VRAYLAR

>A>		+!	ABBVIE	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>		+!	ALLERGAN	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

CHLORHEXIDINE GLUCONATE

SOLUTION;DENTAL

CHLORHEXIDINE GLUCONATE

>A>	AT		CHARTWELL RX	0.12%	A075006	001	Mar 03, 2004	Jan CAHN
>D>	AT		WOCKHARDT BIO AG	0.12%	A075006	001	Mar 03, 2004	Jan CAHN

CHLORZOXAZONE

TABLET;ORAL

CHLORZOXAZONE

>A>	AB		APPCO	375MG	A212047	001	Jan 27, 2023	Jan NEWA
>A>	AB			750MG	A212047	002	Jan 27, 2023	Jan NEWA
>A>	AA		BELCHER	250MG	A215540	001	Jan 24, 2023	Jan NEWA

CICLOPIROX

SOLUTION;TOPICAL

CICLOPIROX

>D>	AT		PADAGIS US	8%	A077623	001	Sep 18, 2007	Jan CHRS
>A>	AT	!		8%	A077623	001	Sep 18, 2007	Jan CHRS

PENLAC

>D>	AT	+!	VALEANT BERMUDA	8%	N021022	001	Dec 17, 1999	Jan DISC
>A>		+ @		8%	N021022	001	Dec 17, 1999	Jan DISC

CIPROFLOXACIN
INJECTABLE, SUSPENSION;OTIC
OTIPRIO

>D>		+! ALK ABELLO	6% (60MG/ML)	N207986	001	Dec 10, 2015	Jan DISC
>A>		+ @	6% (60MG/ML)	N207986	001	Dec 10, 2015	Jan DISC

CLINDAMYCIN PHOSPHATE
SOLUTION;TOPICAL
CLINDAMYCIN PHOSPHATE

>D>		@ WOCKHARDT BIO AG	EQ 1% BASE	A063304	001	Jul 15, 1997	Jan CAHN
>A>		@ XTTRIUM LABS INC	EQ 1% BASE	A063304	001	Jul 15, 1997	Jan CAHN

CLONAZEPAM
TABLET;ORAL
CLONAZEPAM

>D>		@ AUROBINDO PHARMA USA	0.5MG	A075150	001	Oct 05, 1998	Jan CMFD
>A>	AB		0.5MG	A075150	001	Oct 05, 1998	Jan CMFD
>D>		@	1MG	A075150	002	Oct 05, 1998	Jan CMFD
>A>	AB		1MG	A075150	002	Oct 05, 1998	Jan CMFD
>D>		@	2MG	A075150	003	Oct 05, 1998	Jan CMFD
>A>	AB		2MG	A075150	003	Oct 05, 1998	Jan CMFD

COLESEVELAM HYDROCHLORIDE
FOR SUSPENSION;ORAL
COLESEVELAM HYDROCHLORIDE

>A>	AB	IMPAX	3.75GM/PACKET	A212886	001	Jan 18, 2023	Jan NEWA

CYCLOSPORINE
EMULSION;OPHTHALMIC
CYCLOSPORINE

>A>	AB	APOTEX	0.05%	A207606	001	Jan 12, 2023	Jan NEWA

SOLUTION;ORAL
CYCLOSPORINE

>D>	AB2	WOCKHARDT BIO AG	100MG/ML	A065133	001	Sep 17, 2004	Jan CAHN
>A>	AB2	XTTRIUM LABS INC	100MG/ML	A065133	001	Sep 17, 2004	Jan CAHN

CYSTEINE HYDROCHLORIDE
INJECTABLE;INJECTION
CYSTEINE HYDROCHLORIDE

>A>		NIVAGEN PHARMS INC	7.25%	A213073	001	Jan 26, 2023	Jan NFTG

DAPTOMYCIN
POWDER;INTRAVENOUS
DAPTOMYCIN

>A>		+! XELLIA PHARMS APS	350MG/VIAL	N217415	001	Jan 30, 2023	Jan NEWA
>A>		+!	500MG/VIAL	N217415	002	Jan 30, 2023	Jan NEWA

DEXAMETHASONE
ELIXIR;ORAL
DEXAMETHASONE

>D>		+ @ WOCKHARDT BIO AG	0.5MG/5ML	A088254	001	Jul 27, 1983	Jan CAHN
>A>		+ @ XTTRIUM LABS INC	0.5MG/5ML	A088254	001	Jul 27, 1983	Jan CAHN

DEXTROAMPHETAMINE SULFATE
TABLET;ORAL
DEXTROAMPHETAMINE SULFATE

>D>		ARBOR PHARMS LLC	2.5MG	A090533	001	Oct 25, 2011	Jan CTEC
>A>	AA		2.5MG	A090533	001	Oct 25, 2011	Jan CTEC
>D>			7.5MG	A090533	003	Oct 25, 2011	Jan CTEC
>A>	AA		7.5MG	A090533	003	Oct 25, 2011	Jan CTEC
>D>			15MG	A090533	005	Oct 25, 2011	Jan CTEC
>A>	AA		15MG	A090533	005	Oct 25, 2011	Jan CTEC
>D>			20MG	A090533	006	Oct 25, 2011	Jan CTEC
>A>	AA		20MG	A090533	006	Oct 25, 2011	Jan CTEC
>D>			30MG	A090533	007	Oct 25, 2011	Jan CTEC
>A>	AA		30MG	A090533	007	Oct 25, 2011	Jan CTEC
>D>		@ WINDER LABS LLC	2.5MG	A212160	001	Jun 07, 2021	Jan CMFD
>A>	AA		2.5MG	A212160	001	Jun 07, 2021	Jan CMFD
>D>		@	5MG	A212160	002	Jun 07, 2021	Jan CMFD
>A>	AA		5MG	A212160	002	Jun 07, 2021	Jan CMFD
>D>		@	7.5MG	A212160	003	Jun 07, 2021	Jan CMFD

TABLET;ORAL
DEXTROAMPHETAMINE SULFATE

>A>	AA		7.5MG	A212160	003	Jun 07, 2021	Jan	CMFD
>D>		@	10MG	A212160	004	Jun 07, 2021	Jan	CMFD
>A>	AA		10MG	A212160	004	Jun 07, 2021	Jan	CMFD
>D>		@	15MG	A212160	005	Jun 07, 2021	Jan	CMFD
>A>	AA		15MG	A212160	005	Jun 07, 2021	Jan	CMFD
>D>		@	20MG	A212160	006	Jun 07, 2021	Jan	CMFD
>A>	AA		20MG	A212160	006	Jun 07, 2021	Jan	CMFD
>D>		@	30MG	A212160	007	Jun 07, 2021	Jan	CMFD
>A>	AA		30MG	A212160	007	Jun 07, 2021	Jan	CMFD

DICLOFENAC SODIUM

SOLUTION;TOPICAL
DICLOFENAC SODIUM

>A>	AB		AUROLIFE PHARMA LLC	2%	A213040	001	Feb 03, 2023	Jan NEWA

DONEPEZIL HYDROCHLORIDE

TABLET;ORAL
DONEPEZIL HYDROCHLORIDE

>A>		@	CHARTWELL RX	23MG	A203419	001	Apr 12, 2016	Jan CAHN
>D>		@	INDICUS PHARMA	23MG	A203419	001	Apr 12, 2016	Jan CAHN

DULOXETINE HYDROCHLORIDE

CAPSULE, DELAYED REL PELLETS;ORAL
DRIZALMA SPRINKLE

>D>		+	SUN PHARM	EQ 40MG BASE	N212516	003	Jul 19, 2019	Jan DISC
>A>		+ @		EQ 40MG BASE	N212516	003	Jul 19, 2019	Jan DISC

>A> ELACESTRANT DIHYDROCHLORIDE

>A> TABLET;ORAL
>A> ORSERDU

>A>		+	STEMLINE THERAP	EQ 86MG BASE	N217639	001	Jan 27, 2023	Jan NEWA
>A>		+!		EQ 345MG BASE	N217639	002	Jan 27, 2023	Jan NEWA

EMPAGLIFLOZIN

TABLET;ORAL
>D> EMPAGLIFLOZIN

>D>	AB		ZYDUS PHARMS	10MG	A212138	001	Aug 03, 2022	Jan DISC
>A>		@		10MG	A212138	001	Aug 03, 2022	Jan DISC
>D>	AB			25MG	A212138	002	Aug 03, 2022	Jan DISC
>A>		@		25MG	A212138	002	Aug 03, 2022	Jan DISC
		JARDIANCE						
>D>	AB	+	BOEHRINGER INGELHEIM	10MG	N204629	001	Aug 01, 2014	Jan CTEC
>A>		+		10MG	N204629	001	Aug 01, 2014	Jan CTEC
>D>	AB	+!		25MG	N204629	002	Aug 01, 2014	Jan CTEC
>A>		+!		25MG	N204629	002	Aug 01, 2014	Jan CTEC

ERYTHROMYCIN

TABLET;ORAL
ERYTHROMYCIN

>D>	AB	!	ARBOR PHARMS LLC	500MG	A061621	002		Jan CHRS
>A>	AB			500MG	A061621	002		Jan CHRS
>D>	AB		CADILA PHARMS LTD	500MG	A213628	002	Jun 28, 2021	Jan CHRS
>A>	AB	!		500MG	A213628	002	Jun 28, 2021	Jan CHRS

ESCITALOPRAM OXALATE

SOLUTION;ORAL
LEXAPRO

>A>		+ @	ABBVIE	EQ 5MG BASE/5ML	N021365	001	Nov 27, 2002	Jan CAHN
>D>		+ @	ALLERGAN	EQ 5MG BASE/5ML	N021365	001	Nov 27, 2002	Jan CAHN

TABLET;ORAL
LEXAPRO

>A>	AB	+	ABBVIE	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	+	ALLERGAN	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

ESMOLOL HYDROCHLORIDE

INJECTABLE;INJECTION

BREVIBLOC DOUBLE STRENGTH IN PLASTIC CONTAINER

>D>		+!	BAXTER HLTHCARE	2GM/100ML	N019386	005	Jan 27, 2003	Jan CTEC
>A>	AP	+!		2GM/100ML	N019386	005	Jan 27, 2003	Jan CTEC

BREVIBLOC IN PLASTIC CONTAINER

>D>		+!	BAXTER HLTHCARE	1GM/100ML	N019386	004	Feb 16, 2001	Jan CTEC
>A>	AP	+!		1GM/100ML	N019386	004	Feb 16, 2001	Jan CTEC

ESMOLOL HYDROCHLORIDE

>D>	AP		AMNEAL	10MG/ML	A216603	001	Dec 13, 2022	Jan CPOT
>D>	AP			20MG/ML	A216603	002	Dec 13, 2022	Jan CPOT
>A>	AP			1GM/100ML	A216603	001	Dec 13, 2022	Jan CPOT
>A>	AP			2GM/100ML	A216603	002	Dec 13, 2022	Jan CPOT
>D>	AP		EUGIA PHARMA	10MG/ML	A216244	001	Mar 21, 2022	Jan CPOT
>D>	AP			20MG/ML	A216244	002	Mar 21, 2022	Jan CPOT
>A>	AP			1GM/100ML	A216244	001	Mar 21, 2022	Jan CPOT
>A>	AP			2GM/100ML	A216244	002	Mar 21, 2022	Jan CPOT
>D>	AP		HQ SPCLT PHARMA	10MG/ML	A214172	001	Dec 02, 2022	Jan CPOT
>D>	AP			20MG/ML	A214172	002	Dec 02, 2022	Jan CPOT
>A>	AP			1GM/100ML	A214172	001	Dec 02, 2022	Jan CPOT
>A>	AP			2GM/100ML	A214172	002	Dec 02, 2022	Jan CPOT
>D>	AP		MYLAN LABS LTD	10MG/ML	A206608	001	Jun 08, 2018	Jan CPOT
>D>	AP			20MG/ML	A206608	002	Jun 08, 2018	Jan CPOT
>A>	AP			1GM/100ML	A206608	001	Jun 08, 2018	Jan CPOT
>A>	AP			2GM/100ML	A206608	002	Jun 08, 2018	Jan CPOT
>D>	AP		SAGENT PHARMS INC	10MG/ML	A207107	001	Jun 08, 2018	Jan CPOT
>D>	AP			20MG/ML	A207107	002	Jun 08, 2018	Jan CPOT
>A>	AP			1GM/100ML	A207107	001	Jun 08, 2018	Jan CPOT
>A>	AP			2GM/100ML	A207107	002	Jun 08, 2018	Jan CPOT

ESOMEPRAZOLE SODIUM

INJECTABLE;INTRAVENOUS

ESOMEPRAZOLE SODIUM

>D>	AP	!	EUGIA PHARMA	EQ 40MG BASE/VIAL	A204657	002	Aug 10, 2016	Jan CHRS
>A>	AP			EQ 40MG BASE/VIAL	A204657	002	Aug 10, 2016	Jan CHRS

ESTRADIOL

INSERT;VAGINAL

IMVEXXY

>A>		+	MAYNE PHARMA	0.004MG	N208564	001	May 29, 2018	Jan CAHN
>A>		+!		0.01MG	N208564	002	May 29, 2018	Jan CAHN
>D>		+	THERAPEUTICSMD INC	0.004MG	N208564	001	May 29, 2018	Jan CAHN
>D>		+!		0.01MG	N208564	002	May 29, 2018	Jan CAHN

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET;ORAL-28

LEVONORGESTREL AND ETHINYL ESTRADIOL

>D>	AB1		AMNEAL PHARMS	0.02MG;0.1MG	A201108	001	Feb 05, 2014	Jan DISC
>A>		@		0.02MG;0.1MG	A201108	001	Feb 05, 2014	Jan DISC
>D>	AB			0.03MG;0.15MG	A201095	001	Dec 08, 2014	Jan DISC
>A>		@		0.03MG;0.15MG	A201095	001	Dec 08, 2014	Jan DISC
>D>	BX		LUPIN LTD	0.03MG,0.04MG,0.03MG;0.05MG,0.075MG,0.125MG	A200248	001	Nov 19, 2015	Jan CTEC
>A>	AB			0.03MG,0.04MG,0.03MG;0.05MG,0.075MG,0.125MG	A200248	001	Nov 19, 2015	Jan CTEC

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET;ORAL-28

>D>			PIRMELLA 1/35					
>D>	BX		LUPIN LTD	0.035MG;1MG	A201512	001	Apr 24, 2013	Jan DISC
>A>		@		0.035MG;1MG	A201512	001	Apr 24, 2013	Jan DISC
>D>			PIRMELLA 7/7/7					
>D>	BX		LUPIN LTD	0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG	A201510	001	Apr 24, 2013	Jan DISC
>A>		@		0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG	A201510	001	Apr 24, 2013	Jan DISC

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET;ORAL-28

NORGESTIMATE AND ETHINYL ESTRADIOL

>D>	AB	AMNEAL PHARMS	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A203870	001	Nov 12, 2015	Jan DISC
>A>		@	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A203870	001	Nov 12, 2015	Jan DISC

ETHINYL ESTRADIOL; SEGESTERONE ACETATE

RING;VAGINAL

ANNOVERA

>A>		+! MAYNE PHARMA	0.013MG/24HR;0.15MG/24HR	N209627	001	Aug 10, 2018	Jan CAHN
>D>		+! THERAPEUTICSMD INC	0.013MG/24HR;0.15MG/24HR	N209627	001	Aug 10, 2018	Jan CAHN

FAMOTIDINE

TABLET;ORAL

FAMOTIDINE

>D>	AB	ALKEM LABS LTD	20MG	A215630	001	Jan 07, 2022	Jan CAHN
>D>	AB		40MG	A215630	002	Jan 07, 2022	Jan CAHN
>A>	AB	VKT PHARMA	20MG	A215630	001	Jan 07, 2022	Jan CAHN
>A>	AB		40MG	A215630	002	Jan 07, 2022	Jan CAHN

FEBUXOSTAT

TABLET;ORAL

FEBUXOSTAT

>A>	AB	ZYDUS LIFESCIENCES	40MG	A205443	001	Jan 09, 2023	Jan CAHN
>A>	AB		80MG	A205443	002	Jan 09, 2023	Jan CAHN
>D>	AB	ZYDUS PHARMS	40MG	A205443	001	Jan 09, 2023	Jan CAHN
>D>	AB		80MG	A205443	002	Jan 09, 2023	Jan CAHN

FENTANYL

FILM, EXTENDED RELEASE;TRANSDERMAL

FENTANYL-100

>A>	AB	ZYDUS NOVELTECH INC	100MCG/HR	A209655	008	Jan 24, 2023	Jan NEWA

FENTANYL-12

>A>	AB	ZYDUS NOVELTECH INC	12.5MCG/HR	A209655	001	Jan 24, 2023	Jan NEWA

FENTANYL-25

>A>	AB	ZYDUS NOVELTECH INC	25MCG/HR	A209655	002	Jan 24, 2023	Jan NEWA

FENTANYL-37

>A>	AB	ZYDUS NOVELTECH INC	37.5MCG/HR	A209655	003	Jan 24, 2023	Jan NEWA

FENTANYL-50

>A>	AB	ZYDUS NOVELTECH INC	50MCG/HR	A209655	004	Jan 24, 2023	Jan NEWA

FENTANYL-62

>A>	AB	ZYDUS NOVELTECH INC	62.5MCG/HR	A209655	005	Jan 24, 2023	Jan NEWA

FENTANYL-75

>A>	AB	ZYDUS NOVELTECH INC	75MCG/HR	A209655	006	Jan 24, 2023	Jan NEWA

FENTANYL-87

>D>		MYLAN TECHNOLOGIES	87.5MCG/HR	A076258	008	Dec 29, 2014	Jan CTEC
>A>	AB		87.5MCG/HR	A076258	008	Dec 29, 2014	Jan CTEC
>A>	AB	ZYDUS NOVELTECH INC	87.5MCG/HR	A209655	007	Jan 24, 2023	Jan NEWA

FENTANYL CITRATE

INJECTABLE;INJECTION

FENTANYL CITRATE

>A>		+! HIKMA	EQ 0.025MG BASE/0.5ML	N019101	002	Jan 20, 2023	Jan NEWA
>A>	AP	+!	EQ 0.05MG BASE/ML	N019101	001	Jul 11, 1984	Jan CTNA

FENTANYL CITRATE PRESERVATIVE FREE

>D>	AP	+! HIKMA	EQ 0.05MG BASE/ML	N019101	001	Jul 11, 1984	Jan CTNA

FINAFLOXACIN

SUSPENSION/DROPS;OTIC

XTORO

>A>		+ @ FONSECA BIOSCIENCES	0.3%	N206307	001	Dec 17, 2014	Jan CAHN
>D>		+ @ MERLION PHARMS GMBH	0.3%	N206307	001	Dec 17, 2014	Jan CAHN

FINGOLIMOD HYDROCHLORIDE

CAPSULE;ORAL

FINGOLIMOD HYDROCHLORIDE

>D>		@ BIOCON LTD	EQ 0.5MG BASE	A207979	001	Dec 04, 2019	Jan CMFD
>A>	AB		EQ 0.5MG BASE	A207979	001	Dec 04, 2019	Jan CMFD

FINGOLIMOD LAURYL SULFATE

TABLET, ORALLY DISINTEGRATING;ORAL

TASCENSO ODT

>A>		+	CYCLE	EQ 0.25MG BASE	N214962	001	Dec 23, 2021	Jan CAHN
>A>		+!		EQ 0.5MG BASE	N214962	002	Dec 09, 2022	Jan CAHN
>D>		+	HANDA	EQ 0.25MG BASE	N214962	001	Dec 23, 2021	Jan CAHN
>D>		+!		EQ 0.5MG BASE	N214962	002	Dec 09, 2022	Jan CAHN

FLUDARABINE PHOSPHATE

INJECTABLE;INJECTION

FLUDARABINE PHOSPHATE

>D>	AP		ACTAVIS LLC	50MG/2ML (25MG/ML)	A203738	001	Feb 28, 2017	Jan CTEC
>A>	AP2			50MG/2ML (25MG/ML)	A203738	001	Feb 28, 2017	Jan CTEC
>D>	AP		AREVA PHARMS	50MG/2ML (25MG/ML)	A090724	001	Sep 27, 2010	Jan CTEC
>A>	AP1			50MG/2ML (25MG/ML)	A090724	001	Sep 27, 2010	Jan CTEC
>D>	AP	!	FRESENIUS KABI USA	50MG/2ML (25MG/ML)	A078393	001	Oct 15, 2007	Jan CTEC
>A>	AP1			50MG/2ML (25MG/ML)	A078393	001	Oct 15, 2007	Jan CTEC
>D>	AP		SAGENT PHARMS INC	50MG/2ML (25MG/ML)	A076661	001	Apr 28, 2004	Jan CTEC
>A>	AP1			50MG/2ML (25MG/ML)	A076661	001	Apr 28, 2004	Jan CTEC
>D>	AP	+!	SANDOZ	50MG/2ML (25MG/ML)	N022137	001	Sep 21, 2007	Jan CTEC
>A>	AP2	+!		50MG/2ML (25MG/ML)	N022137	001	Sep 21, 2007	Jan CTEC

FLUDEOXYGLUCOSE F-18

INJECTABLE;INTRAVENOUS

FLUDEOXYGLUCOSE F18

>D>	AP		ESSENTIAL ISOTOPES	20-300mCi/ML	A203946	001	Feb 05, 2014	Jan DISC
>A>		@		20-300mCi/ML	A203946	001	Feb 05, 2014	Jan DISC

FLUOROMETHOLONE

SUSPENSION/DROPS;OPHTHALMIC

FML

>A>		+!	ABBVIE	0.1%	N016851	002	Jul 28, 1982	Jan CAHN
>D>		+!	ALLERGAN	0.1%	N016851	002	Jul 28, 1982	Jan CAHN

FML FORTE

>A>		+!	ABBVIE	0.25%	N019216	001	Apr 23, 1986	Jan CAHN
>D>		+!	ALLERGAN	0.25%	N019216	001	Apr 23, 1986	Jan CAHN

FLUOXETINE HYDROCHLORIDE

SOLUTION;ORAL

FLUOXETINE HYDROCHLORIDE

>D>	AA		WOCKHARDT BIO AG	EQ 20MG BASE/5ML	A075514	001	Aug 29, 2002	Jan CAHN
>A>	AA		XTTRIUM LABS INC	EQ 20MG BASE/5ML	A075514	001	Aug 29, 2002	Jan CAHN

FLUVOXAMINE MALEATE

TABLET;ORAL

LUVOX

>D>	AB		ANI PHARMS	25MG	N021519	001	Dec 20, 2007	Jan CRLD
>A>	AB	+		25MG	N021519	001	Dec 20, 2007	Jan CRLD
>D>	AB			50MG	N021519	002	Dec 20, 2007	Jan CRLD
>A>	AB	+		50MG	N021519	002	Dec 20, 2007	Jan CRLD
>D>	AB			100MG	N021519	003	Dec 20, 2007	Jan CRLD
>A>	AB	+		100MG	N021519	003	Dec 20, 2007	Jan CRLD

FUROSEMIDE

SOLUTION;ORAL

FUROSEMIDE

>D>		@	WOCKHARDT BIO AG	10MG/ML	A070655	001	Oct 02, 1987	Jan CAHN
>A>		@	XTTRIUM LABS INC	10MG/ML	A070655	001	Oct 02, 1987	Jan CAHN

GABAPENTIN

SOLUTION;ORAL

GABAPENTIN

>A>	AA		RUBICON	250MG/5ML	A216492	001	Jan 18, 2023	Jan NEWA

GATIFLOXACIN

SOLUTION/DROPS;OPHTHALMIC

ZYMAXID

>A>	AT	+!	ABBVIE	0.5%	N022548	001	May 18, 2010	Jan CAHN
>D>	AT	+!	ALLERGAN	0.5%	N022548	001	May 18, 2010	Jan CAHN

GENTAMICIN SULFATE; PREDNISOLONE ACETATE

>D>		OINTMENT;OPHTHALMIC						
>D>		PRED-G						
>D>	+!	ALLERGAN	EQ 0.3% BASE;0.6%	N050612	001	Dec 01, 1989	Jan DISC
>A>	+ @		EQ 0.3% BASE;0.6%	N050612	001	Dec 01, 1989	Jan DISC

GLUCAGON

		SOLUTION;SUBCUTANEOUS						
		GVOKE PFS						
>D>	+!	XERIS	0.5MG/0.1ML (0.5MG/0.1ML)	N212097	001	Sep 10, 2019	Jan DISC
>A>	+ @		0.5MG/0.1ML (0.5MG/0.1ML)	N212097	001	Sep 10, 2019	Jan DISC

GLYCEROL PHENYLBUTYRATE

		LIQUID;ORAL						
		RAVICTI						
>D>	+!	HORIZON THERAP	1.1GM/ML	N203284	001	Feb 01, 2013	Jan CAHN
>A>	+!	HORIZON THERAP US	1.1GM/ML	N203284	001	Feb 01, 2013	Jan CAHN

GLYCOPYRROLATE

		INJECTABLE;INJECTION						
		GLYCOPYRROLATE						
>A>	AP	LUPIN LTD	0.2MG/ML	A213655	001	Feb 07, 2023	Jan NEWA
		TABLET;ORAL						
		GLYCOPYRROLATE						
>A>	AA	AUROBINDO PHARMA	1MG	A202675	001	Apr 15, 2013	Jan CAHN
>A>	AA		2MG	A202675	002	Oct 30, 2018	Jan CAHN
>D>	AA	AUROLIFE PHARMA LLC	1MG	A202675	001	Apr 15, 2013	Jan CAHN
>D>	AA		2MG	A202675	002	Oct 30, 2018	Jan CAHN

HALOPERIDOL

		TABLET;ORAL						
		HALOPERIDOL						
>D>	AB	ACTAVIS GROUP	0.5MG	A200854	001	Jul 01, 2022	Jan DISC
>A>	@		0.5MG	A200854	001	Jul 01, 2022	Jan DISC
>D>	AB		1MG	A200854	002	Jul 01, 2022	Jan DISC
>A>	@		1MG	A200854	002	Jul 01, 2022	Jan DISC
>D>	AB		2MG	A200854	003	Jul 01, 2022	Jan DISC
>A>	@		2MG	A200854	003	Jul 01, 2022	Jan DISC
>D>	AB		5MG	A200854	004	Jul 01, 2022	Jan DISC
>A>	@		5MG	A200854	004	Jul 01, 2022	Jan DISC
>D>	AB		10MG	A200854	005	Jul 01, 2022	Jan DISC
>A>	@		10MG	A200854	005	Jul 01, 2022	Jan DISC
>D>	AB		20MG	A200854	006	Jul 01, 2022	Jan DISC
>A>	@		20MG	A200854	006	Jul 01, 2022	Jan DISC
>A>	AB	ZYDUS PHARMS USA	0.5MG	A077580	001	Jan 17, 2023	Jan NEWA
>A>	AB		1MG	A077580	002	Jan 17, 2023	Jan NEWA
>A>	AB		2MG	A077580	006	Jan 17, 2023	Jan NEWA

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

		TABLET;ORAL						
		QUINAPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE						
>A>	AB	APOTEX	12.5MG;EQ 10MG BASE	A091524	001	Mar 12, 2013	Jan CAHN
>A>	AB		12.5MG;EQ 20MG BASE	A091524	002	Mar 12, 2013	Jan CAHN
>A>	AB		25MG;EQ 20MG BASE	A091524	003	Mar 12, 2013	Jan CAHN
>D>	AB	APOTEX CORP	12.5MG;EQ 10MG BASE	A091524	001	Mar 12, 2013	Jan CAHN
>D>	AB		12.5MG;EQ 20MG BASE	A091524	002	Mar 12, 2013	Jan CAHN
>D>	AB		25MG;EQ 20MG BASE	A091524	003	Mar 12, 2013	Jan CAHN

HYDROXYPROPYL CELLULOSE

		INSERT;OPHTHALMIC						
		LACRISERT						
>A>	+!	BAUSCH AND LOMB INC	5MG	N018771	001		Jan CAHN
>D>	+!	VALEANT PHARMS INTL	5MG	N018771	001		Jan CAHN

HYDROXYZINE HYDROCHLORIDE

		TABLET;ORAL						
		HYDROXYZINE HYDROCHLORIDE						
>D>	AB	AIPING LIFE SCI	10MG	A040804	001	Jun 30, 2008	Jan CAHN
>D>	AB		25MG	A040804	002	Jun 30, 2008	Jan CAHN
>D>	AB		50MG	A040804	003	Jun 30, 2008	Jan CAHN
>A>	AB	CHARTWELL RX	10MG	A040804	001	Jun 30, 2008	Jan CAHN

TABLET;ORAL
HYDROXYZINE HYDROCHLORIDE

>A> AB		25MG	A040804	002	Jun 30, 2008	Jan CAHN
>A> AB		50MG	A040804	003	Jun 30, 2008	Jan CAHN

IMATINIB MESYLATE

TABLET;ORAL
IMATINIB MESYLATE

>A> AB	CHARTWELL RX	EQ 100MG BASE	A208429	001	Jan 17, 2019	Jan CAHN
>A> AB		EQ 400MG BASE	A208429	002	Jan 17, 2019	Jan CAHN
>D> AB	WOCKHARDT BIO AG	EQ 100MG BASE	A208429	001	Jan 17, 2019	Jan CAHN
>D> AB		EQ 400MG BASE	A208429	002	Jan 17, 2019	Jan CAHN

IVERMECTIN

CREAM;TOPICAL
IVERMECTIN

>D> AB	ZYDUS	1%	A215210	001	Aug 02, 2022	Jan DISC
>A>	@	1%	A215210	001	Aug 02, 2022	Jan DISC

KETAMINE HYDROCHLORIDE

INJECTABLE;INJECTION
KETAMINE HYDROCHLORIDE

>A> AP	FRESENIUS KABI USA	EQ 10MG BASE/ML	A215808	001	Jan 13, 2023	Jan NEWA
>A> AP		EQ 50MG BASE/ML	A215808	002	Jan 13, 2023	Jan NEWA
>A> AP	GLAND PHARMA LTD	EQ 10MG BASE/ML	A216809	001	Jan 24, 2023	Jan NEWA
>A> AP		EQ 50MG BASE/ML	A216809	002	Jan 24, 2023	Jan NEWA
>A> AP		EQ 100MG BASE/ML	A216809	003	Jan 24, 2023	Jan NEWA

KETOROLAC TROMETHAMINE

SOLUTION/DROPS;OPHTHALMIC
ACULAR

>A> AT	+! ABBVIE	0.5%	N019700	001	Nov 09, 1992	Jan CAHN
>D> AT	+! ALLERGAN	0.5%	N019700	001	Nov 09, 1992	Jan CAHN

KETOROLAC TROMETHAMINE

>D> AT	AKORN	0.5%	A078434	001	Nov 05, 2009	Jan DISC
>A>	@	0.5%	A078434	001	Nov 05, 2009	Jan DISC

LACOSAMIDE

SOLUTION;ORAL
LACOSAMIDE

>A> AA	MEDLEY PHARMS	10MG/ML	A216461	001	Feb 06, 2023	Jan NEWA

TABLET;ORAL
LACOSAMIDE

>D> AB	ACCORD HLTHCARE	50MG	A205011	001	Jul 12, 2022	Jan DISC
>A>	@	50MG	A205011	001	Jul 12, 2022	Jan DISC
>D> AB		100MG	A205011	002	Jul 12, 2022	Jan DISC
>A>	@	100MG	A205011	002	Jul 12, 2022	Jan DISC
>D> AB		150MG	A205011	003	Jul 12, 2022	Jan DISC
>A>	@	150MG	A205011	003	Jul 12, 2022	Jan DISC
>D> AB		200MG	A205011	004	Jul 12, 2022	Jan DISC
>A>	@	200MG	A205011	004	Jul 12, 2022	Jan DISC

LAMOTRIGINE

TABLET;ORAL
LAMOTRIGINE

>A>	@ CHARTWELL MOLECULAR	25MG	A077783	001	Nov 01, 2010	Jan CAHN
>A>	@	100MG	A077783	002	Nov 01, 2010	Jan CAHN
>A>	@	150MG	A077783	003	Nov 01, 2010	Jan CAHN
>A>	@	200MG	A077783	004	Nov 01, 2010	Jan CAHN
>D>	@ CIPLA	25MG	A077783	001	Nov 01, 2010	Jan CAHN
>D>	@	100MG	A077783	002	Nov 01, 2010	Jan CAHN
>D>	@	150MG	A077783	003	Nov 01, 2010	Jan CAHN
>D>	@	200MG	A077783	004	Nov 01, 2010	Jan CAHN

LATANOPROST

SOLUTION/DROPS;OPHTHALMIC
LATANOPROST

>D> AT	AKORN	0.005%	A090887	001	Jul 19, 2011	Jan DISC
>A>	@	0.005%	A090887	001	Jul 19, 2011	Jan DISC

LENALIDOMIDE

CAPSULE;ORAL

LENALIDOMIDE

>A>	AB		SUN PHARM	5MG	A211846	001	Feb 08, 2023	Jan NEWA
>A>	AB			10MG	A211846	002	Feb 08, 2023	Jan NEWA
>A>	AB			15MG	A211846	003	Feb 08, 2023	Jan NEWA
>A>	AB			25MG	A211846	004	Feb 08, 2023	Jan NEWA

LEVETIRACETAM

INJECTABLE;INTRAVENOUS

LEVETIRACETAM IN SODIUM CHLORIDE

>A>	AP		FRESENIUS KABI USA	500MG/100ML (5MG/ML)	A208619	001	Jan 31, 2023	Jan NEWA
>A>	AP			1GM/100ML (10MG/ML)	A208619	002	Jan 31, 2023	Jan NEWA
>A>	AP			1.5GM/100ML (15MG/ML)	A208619	003	Jan 31, 2023	Jan NEWA

LEVOFLOXACIN

SOLUTION/DROPS;OPHTHALMIC

LEVOFLOXACIN

>D>	AT		AKORN	0.5%	A090268	001	Dec 20, 2010	Jan DISC
>A>		@		0.5%	A090268	001	Dec 20, 2010	Jan DISC
>D>	AT	!	RISING	0.5%	A077700	001	Dec 20, 2010	Jan CTEC
>A>		!		0.5%	A077700	001	Dec 20, 2010	Jan CTEC

LEVOMILNACIPRAN HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

FETZIMA

>A>	AB	+	ABBVIE	EQ 20MG BASE	N204168	001	Jul 25, 2013	Jan CAHN
>A>	AB	+		EQ 40MG BASE	N204168	002	Jul 25, 2013	Jan CAHN
>A>	AB	+		EQ 80MG BASE	N204168	003	Jul 25, 2013	Jan CAHN
>A>	AB	+!		EQ 120MG BASE	N204168	004	Jul 25, 2013	Jan CAHN
>D>	AB	+	ALLERGAN	EQ 20MG BASE	N204168	001	Jul 25, 2013	Jan CAHN
>D>	AB	+		EQ 40MG BASE	N204168	002	Jul 25, 2013	Jan CAHN
>D>	AB	+		EQ 80MG BASE	N204168	003	Jul 25, 2013	Jan CAHN
>D>	AB	+!		EQ 120MG BASE	N204168	004	Jul 25, 2013	Jan CAHN

LEVORPHANOL TARTRATE

TABLET;ORAL

LEVORPHANOL TARTRATE

>D>		@	HIKMA	2MG	A074278	001	Mar 31, 2000	Jan CMFD
>A>	AB			2MG	A074278	001	Mar 31, 2000	Jan CMFD

LEVOTHYROXINE SODIUM **

**See current Annual Edition, 1.8 Description of Special Situations, Levothyroxine Sodium

TABLET;ORAL

LEVOTHYROXINE SODIUM

>A>	AB4		ASCENT PHARMS INC	0.025MG	A215259	001	Jan 18, 2023	Jan NEWA
>A>	AB4			0.05MG	A215259	002	Jan 18, 2023	Jan NEWA
>A>	AB4			0.075MG	A215259	003	Jan 18, 2023	Jan NEWA
>A>	AB4			0.088MG	A215259	004	Jan 18, 2023	Jan NEWA
>A>	AB4			0.1MG	A215259	005	Jan 18, 2023	Jan NEWA
>A>	AB4			0.112MG	A215259	006	Jan 18, 2023	Jan NEWA
>A>	AB4			0.125MG	A215259	007	Jan 18, 2023	Jan NEWA
>A>	AB4			0.137MG	A215259	008	Jan 18, 2023	Jan NEWA
>A>	AB4			0.15MG	A215259	009	Jan 18, 2023	Jan NEWA
>A>	AB4			0.175MG	A215259	010	Jan 18, 2023	Jan NEWA
>A>	AB4			0.2MG	A215259	011	Jan 18, 2023	Jan NEWA
>A>	AB4			0.3MG	A215259	012	Jan 18, 2023	Jan NEWA
>D>	AB1, AB2		MACLEODS PHARMS LTD	0.025MG	A211417	001	Dec 21, 2022	Jan CTEC
>A>	AB2			0.025MG	A211417	001	Dec 21, 2022	Jan CTEC
>D>	AB1, AB2			0.05MG	A211417	002	Dec 21, 2022	Jan CTEC
>A>	AB2			0.05MG	A211417	002	Dec 21, 2022	Jan CTEC
>D>	AB1, AB2			0.075MG	A211417	003	Dec 21, 2022	Jan CTEC
>A>	AB2			0.075MG	A211417	003	Dec 21, 2022	Jan CTEC
>D>	AB1, AB2			0.088MG	A211417	004	Dec 21, 2022	Jan CTEC
>A>	AB2			0.088MG	A211417	004	Dec 21, 2022	Jan CTEC
>D>	AB1, AB2			0.1MG	A211417	005	Dec 21, 2022	Jan CTEC
>A>	AB2			0.1MG	A211417	005	Dec 21, 2022	Jan CTEC
>D>	AB1,			0.112MG	A211417	006	Dec 21, 2022	Jan CTEC

TABLET;ORAL
LEVOTHYROXINE SODIUM

	AB2						
>A>	AB2		0.112MG	A211417	006	Dec 21, 2022	Jan CTEC
>D>	AB1,		0.125MG	A211417	007	Dec 21, 2022	Jan CTEC
	AB2						
>A>	AB2		0.125MG	A211417	007	Dec 21, 2022	Jan CTEC
>D>	AB1,		0.137MG	A211417	008	Dec 21, 2022	Jan CTEC
	AB2						
>A>	AB2		0.137MG	A211417	008	Dec 21, 2022	Jan CTEC
>D>	AB1,		0.15MG	A211417	009	Dec 21, 2022	Jan CTEC
	AB2						
>A>	AB2		0.15MG	A211417	009	Dec 21, 2022	Jan CTEC
>D>	AB1,		0.175MG	A211417	010	Dec 21, 2022	Jan CTEC
	AB2						
>A>	AB2		0.175MG	A211417	010	Dec 21, 2022	Jan CTEC
>D>	AB1,		0.2MG	A211417	011	Dec 21, 2022	Jan CTEC
	AB2						
>A>	AB2		0.2MG	A211417	011	Dec 21, 2022	Jan CTEC
>D>	AB1,		0.3MG	A211417	012	Dec 21, 2022	Jan CTEC
	AB2						
>A>	AB2		0.3MG	A211417	012	Dec 21, 2022	Jan CTEC

LINACLOTIDE

CAPSULE;ORAL
LINACLOTIDE

>A>	AB	AUROBINDO PHARMA	145MCG	A209611	001	Feb 07, 2023	Jan NEWA
>A>	AB		290MCG	A209611	002	Feb 07, 2023	Jan NEWA

LINZESS

>D>		+! ALLERGAN	145MCG	N202811	001	Aug 30, 2012	Jan CTEC
>A>	AB	+!	145MCG	N202811	001	Aug 30, 2012	Jan CTEC
>D>		+	290MCG	N202811	002	Aug 30, 2012	Jan CTEC
>A>	AB	+	290MCG	N202811	002	Aug 30, 2012	Jan CTEC

LOPERAMIDE HYDROCHLORIDE

CAPSULE;ORAL
LOPERAMIDE HYDROCHLORIDE

>A>	AB	RUBICON	2MG	A216876	001	Jan 26, 2023	Jan NEWA

LUBIPROSTONE

CAPSULE;ORAL
LUBIPROSTONE

>D>		@ AMNEAL	8MCG	A209450	001	Nov 30, 2021	Jan CMFD
>A>	AB		8MCG	A209450	001	Nov 30, 2021	Jan CMFD
>D>		@	24MCG	A209450	002	Nov 30, 2021	Jan CMFD
>A>	AB		24MCG	A209450	002	Nov 30, 2021	Jan CMFD

MECLOFENAMATE SODIUM

CAPSULE;ORAL
MECLOFENAMATE SODIUM

>A>		@ CHARTWELL RX	EQ 50MG BASE	A072262	001	Nov 29, 1988	Jan CAHN
>A>		@	EQ 100MG BASE	A072263	001	Nov 29, 1988	Jan CAHN
>D>		@ FOSUN PHARMA	EQ 50MG BASE	A072262	001	Nov 29, 1988	Jan CAHN
>D>		@	EQ 100MG BASE	A072263	001	Nov 29, 1988	Jan CAHN

MEGESTROL ACETATE

SUSPENSION;ORAL
MEGESTROL ACETATE

>D>	AB	BRECKENRIDGE	125MG/ML	A204688	001	Dec 01, 2017	Jan DISC
>A>		@	125MG/ML	A204688	001	Dec 01, 2017	Jan DISC
>D>	AB	WOCKHARDT BIO AG	40MG/ML	A076721	001	Nov 01, 2004	Jan CAHN
>A>	AB	XTTRIUM LABS INC	40MG/ML	A076721	001	Nov 01, 2004	Jan CAHN

METOCLOPRAMIDE HYDROCHLORIDE

SOLUTION;ORAL
METOCLOPRAMIDE HYDROCHLORIDE

>D>	AA	! WOCKHARDT BIO AG	EQ 5MG BASE/5ML	A074703	001	Oct 31, 1997	Jan CAHN
>A>	AA	! XTTRIUM LABS INC	EQ 5MG BASE/5ML	A074703	001	Oct 31, 1997	Jan CAHN

METRONIDAZOLE

GEL;TOPICAL

METRONIDAZOLE

>A>	AB		COSETTE	1%	A216692	001	Jan 23, 2023	Jan NEWA

MILNACIPRAN HYDROCHLORIDE

TABLET;ORAL

SAVELLA

>A>		+	ABBVIE	12.5MG	N022256	001	Jan 14, 2009	Jan CAHN
>A>		+		25MG	N022256	002	Jan 14, 2009	Jan CAHN
>A>		+!		50MG	N022256	003	Jan 14, 2009	Jan CAHN
>A>		+		100MG	N022256	004	Jan 14, 2009	Jan CAHN
>D>		+	ALLERGAN	12.5MG	N022256	001	Jan 14, 2009	Jan CAHN
>D>		+		25MG	N022256	002	Jan 14, 2009	Jan CAHN
>D>		+!		50MG	N022256	003	Jan 14, 2009	Jan CAHN
>D>		+		100MG	N022256	004	Jan 14, 2009	Jan CAHN

MILRINONE LACTATE

INJECTABLE;INJECTION

MILRINONE LACTATE

>A>	AP		SHANDONG	EQ 1MG BASE/ML	A216373	001	Jan 23, 2023	Jan NEWA

MIRTAZAPINE

TABLET;ORAL

MIRTAZAPINE

>A>	AB		PRASCO	7.5MG	A216751	001	Jan 18, 2023	Jan NEWA
>A>	AB			15MG	A216751	002	Jan 18, 2023	Jan NEWA
>A>	AB			30MG	A216751	003	Jan 18, 2023	Jan NEWA
>A>	AB			45MG	A216751	004	Jan 18, 2023	Jan NEWA

MONTELUKAST SODIUM

TABLET, CHEWABLE;ORAL

MONTELUKAST SODIUM

>A>	AB		CHARTWELL MOLECULAR	EQ 4MG BASE	A207464	001	Dec 06, 2018	Jan CAHN
>A>	AB			EQ 5MG BASE	A207464	002	Dec 06, 2018	Jan CAHN
>D>	AB		CIPLA	EQ 4MG BASE	A207464	001	Dec 06, 2018	Jan CAHN
>D>	AB			EQ 5MG BASE	A207464	002	Dec 06, 2018	Jan CAHN

MORPHINE SULFATE

INJECTABLE;INJECTION

MORPHINE SULFATE

>A>	AP		HIKMA	2MG/ML	A211452	001	Jan 12, 2023	Jan NFTG
>A>	AP			4MG/ML	A211452	002	Jan 12, 2023	Jan NEWA
>A>	AP			8MG/ML	A211452	003	Jan 12, 2023	Jan NEWA
>A>	AP			10MG/ML	A211452	004	Jan 12, 2023	Jan NEWA
>A>				15MG/ML	A211452	005	Jan 12, 2023	Jan NFTG
>D>		+!	HOSPIRA INC	2MG/ML	N202515	001	Nov 14, 2011	Jan CFTG
>A>	AP	+!		2MG/ML	N202515	001	Nov 14, 2011	Jan CFTG

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

MOXIFLOXACIN HYDROCHLORIDE

>D>	AT1		AKORN	EQ 0.5% BASE	A202916	001	Nov 09, 2017	Jan DISC
>A>		@		EQ 0.5% BASE	A202916	001	Nov 09, 2017	Jan DISC

NAFCILLIN SODIUM

INJECTABLE;INJECTION

NAFCILLIN SODIUM

>D>	AP		EUGIA PHARMA SPECLTS	EQ 1GM BASE/VIAL	A091613	001	Dec 26, 2012	Jan CHRS
>A>	AP	!		EQ 1GM BASE/VIAL	A091613	001	Dec 26, 2012	Jan CHRS
>D>	AP			EQ 2GM BASE/VIAL	A091613	002	Dec 26, 2012	Jan CHRS
>A>	AP	!		EQ 2GM BASE/VIAL	A091613	002	Dec 26, 2012	Jan CHRS
>D>	AP			EQ 10GM BASE/VIAL	A091614	001	Dec 26, 2012	Jan CHRS
>A>	AP	!		EQ 10GM BASE/VIAL	A091614	001	Dec 26, 2012	Jan CHRS
>D>	AP	!	SANDOZ	EQ 1GM BASE/VIAL	A062527	002	Aug 02, 1984	Jan DISC
>A>		@		EQ 1GM BASE/VIAL	A062527	002	Aug 02, 1984	Jan DISC
>D>	AP	!		EQ 1GM BASE/VIAL	A062732	001	Dec 23, 1986	Jan DISC
>A>		@		EQ 1GM BASE/VIAL	A062732	001	Dec 23, 1986	Jan DISC
>D>	AP	!		EQ 2GM BASE/VIAL	A062527	003	Aug 02, 1984	Jan DISC
>A>		@		EQ 2GM BASE/VIAL	A062527	003	Aug 02, 1984	Jan DISC
>D>	AP	!		EQ 2GM BASE/VIAL	A062732	002	Dec 23, 1986	Jan DISC

		INJECTABLE;INJECTION						
		NAFCILLIN SODIUM						
>A>		@	EQ 2GM BASE/VIAL	A062732	002	Dec 23, 1986	Jan DISC
>D>	AP	!	EQ 10GM BASE/VIAL	A062527	004	Aug 02, 1984	Jan DISC
>A>		@	EQ 10GM BASE/VIAL	A062527	004	Aug 02, 1984	Jan DISC
		NALOXONE HYDROCHLORIDE						
		INJECTABLE;INJECTION						
		NALOXONE HYDROCHLORIDE						
>D>	AP	PAR STERILE PRODUCTS	1MG/ML	A215964	001	Jul 29, 2022	Jan DISC
>A>		@	1MG/ML	A215964	001	Jul 29, 2022	Jan DISC
		NITRIC OXIDE						
		GAS;INHALATION						
		GENOSYL						
>D>		+! VERO BIOTECH	800PPM	N202860	001	Dec 20, 2019	Jan CAHN
>A>		+! VERO BIOTECH INC	800PPM	N202860	001	Dec 20, 2019	Jan CAHN
		NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE						
		CAPSULE;ORAL						
		NITROFURANTOIN (MONOHYDRATE/MACROCRYSTALS)						
>D>	AB	ALVOGEN	75MG;25MG	A215002	001	Jul 20, 2022	Jan DISC
>A>		@	75MG;25MG	A215002	001	Jul 20, 2022	Jan DISC
		OLMESARTAN MEDOXOMIL						
		TABLET;ORAL						
		OLMESARTAN MEDOXOMIL						
>A>	AB	MSN	5MG	A217399	001	Jan 18, 2023	Jan NEWA
>A>	AB		20MG	A217399	002	Jan 18, 2023	Jan NEWA
>A>	AB		40MG	A217399	003	Jan 18, 2023	Jan NEWA
		ORPHENADRINE CITRATE						
		TABLET, EXTENDED RELEASE;ORAL						
		ORPHENADRINE CITRATE						
>D>	AB	ANDA REPOSITORY	100MG	A040249	001	Jan 29, 1999	Jan CAHN
>A>	AB	RISING	100MG	A040249	001	Jan 29, 1999	Jan CAHN
		OXYBUTYNIN CHLORIDE						
		TABLET;ORAL						
		OXYBUTYNIN CHLORIDE						
>A>		! APPCO	2.5MG	A209025	002	Feb 07, 2023	Jan NFTG
		PAROXETINE HYDROCHLORIDE						
		TABLET, EXTENDED RELEASE;ORAL						
		PAROXETINE HYDROCHLORIDE						
>A>		@ EPIC PHARMA LLC	EQ 12.5MG BASE	A213612	001	Aug 11, 2021	Jan CAHN
>A>		@	EQ 25MG BASE	A213612	002	Aug 11, 2021	Jan CAHN
>A>		@	EQ 37.5MG BASE	A213612	003	May 26, 2022	Jan CAHN
>D>		@ SINOTHERAPEUTICS INC	EQ 12.5MG BASE	A213612	001	Aug 11, 2021	Jan CAHN
>D>		@	EQ 25MG BASE	A213612	002	Aug 11, 2021	Jan CAHN
>D>		@	EQ 37.5MG BASE	A213612	003	May 26, 2022	Jan CAHN
		PEMETREXED DISODIUM						
		POWDER;INTRAVENOUS						
		PEMETREXED DISODIUM						
>D>	AP	HONG KONG	EQ 100MG BASE/VIAL	A215479	001	Dec 13, 2022	Jan CAHN
>D>	AP		EQ 500MG BASE/VIAL	A215479	002	Dec 13, 2022	Jan CAHN
>D>	AP		EQ 750MG BASE/VIAL	A215479	003	Dec 13, 2022	Jan CAHN
>D>	AP		EQ 1GM BASE/VIAL	A215479	004	Dec 13, 2022	Jan CAHN
>A>	AP	MEITHEAL	EQ 100MG BASE/VIAL	A215479	001	Dec 13, 2022	Jan CAHN
>A>	AP		EQ 500MG BASE/VIAL	A215479	002	Dec 13, 2022	Jan CAHN
>A>	AP		EQ 750MG BASE/VIAL	A215479	003	Dec 13, 2022	Jan CAHN
>A>	AP		EQ 1GM BASE/VIAL	A215479	004	Dec 13, 2022	Jan CAHN
		SOLUTION;INTRAVENOUS						
		PEMETREXED DISODIUM						
>D>		+! SANDOZ INC	EQ 100MG BASE/4ML (EQ 25MG BASE/MG)	N214657	001	May 26, 2022	Jan CMS1
>A>		+!	EQ 100MG BASE/4ML (EQ 25MG BASE/ML)	N214657	001	May 26, 2022	Jan CMS1

PENTAMIDINE ISETHIONATE

FOR SOLUTION;INHALATION

PENTAMIDINE ISETHIONATE

>A>	AN		X-GEN PHARMS INC	300MG/VIAL	A206983	001	Jan 20, 2023	Jan NEWA

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP;ORAL

PROMETHAZINE VC PLAIN

>D>			@ WOCKHARDT	5MG/5ML;6.25MG/5ML	A088897	001	Jan 04, 1985	Jan CAHN
>A>			@ XTTRIUM LABS INC	5MG/5ML;6.25MG/5ML	A088897	001	Jan 04, 1985	Jan CAHN

>A> PIRTOBRUTINIB

>A> TABLET;ORAL

>A> JAYPIRCA

>A>		+	LOXO ONCOL	50MG	N216059	001	Jan 27, 2023	Jan NEWA
>A>		+!		100MG	N216059	002	Jan 27, 2023	Jan NEWA

POMALIDOMIDE

CAPSULE;ORAL

POMALYST

>A>		+	BRISTOL	1MG	N204026	001	Feb 08, 2013	Jan CAHN
>A>		+		2MG	N204026	002	Feb 08, 2013	Jan CAHN
>A>		+		3MG	N204026	003	Feb 08, 2013	Jan CAHN
>A>		+!		4MG	N204026	004	Feb 08, 2013	Jan CAHN
>D>		+	CELGENE	1MG	N204026	001	Feb 08, 2013	Jan CAHN
>D>		+		2MG	N204026	002	Feb 08, 2013	Jan CAHN
>D>		+		3MG	N204026	003	Feb 08, 2013	Jan CAHN
>D>		+!		4MG	N204026	004	Feb 08, 2013	Jan CAHN

PREDNISOLONE

SYRUP;ORAL

PREDNISOLONE

>D>	AA		WOCKHARDT BIO AG	15MG/5ML	A040313	001	Sep 10, 2003	Jan CAHN
>A>	AA		XTTRIUM LABS INC	15MG/5ML	A040313	001	Sep 10, 2003	Jan CAHN

PREDNISOLONE ACETATE

SUSPENSION/DROPS;OPHTHALMIC

PRED FORTE

>A>	AB	+!	ABBVIE	1%	N017011	001		Jan CAHN
>D>	AB	+!	ALLERGAN	1%	N017011	001		Jan CAHN

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION;ORAL

PREDNISOLONE SODIUM PHOSPHATE

>A>	AA		EDENBRIDGE PHARMS	EQ 15MG BASE/5ML	A203559	003	Feb 06, 2023	Jan NEWA
>A>	AA			EQ 25MG BASE/5ML	A203559	004	Feb 06, 2023	Jan NEWA
>D>		!	MISSION PHARMA	EQ 25MG BASE/5ML	A091396	001	Sep 13, 2010	Jan CTEC
>A>	AA	!		EQ 25MG BASE/5ML	A091396	001	Sep 13, 2010	Jan CTEC
>D>	AA		WOCKHARDT BIO AG	EQ 5MG BASE/5ML	A075099	001	Jun 28, 2002	Jan CAHN
>D>	AA	!		EQ 15MG BASE/5ML	A076895	001	Oct 04, 2004	Jan CAHN
>A>	AA		XTTRIUM LABS INC	EQ 5MG BASE/5ML	A075099	001	Jun 28, 2002	Jan CAHN
>A>	AA	!		EQ 15MG BASE/5ML	A076895	001	Oct 04, 2004	Jan CAHN

PREDNISONE

SOLUTION;ORAL

PREDNISONE

>D>			@ WOCKHARDT	5MG/5ML	A089726	001	Aug 02, 1988	Jan CAHN
>A>			@ XTTRIUM LABS INC	5MG/5ML	A089726	001	Aug 02, 1988	Jan CAHN

TABLET;ORAL

PREDNISONE

>D>	AB	!	HIKMA	2.5MG	A087801	001	Apr 22, 1982	Jan CRLD
>A>	AB	+!		2.5MG	A087801	001	Apr 22, 1982	Jan CRLD
>D>	AB	!		5MG	A080352	001		Jan CRLD
>A>	AB	+!		5MG	A080352	001		Jan CRLD
>D>	AB	!		50MG	A084283	001		Jan CRLD
>A>	AB	+!		50MG	A084283	001		Jan CRLD

PREGABALIN

SOLUTION;ORAL

PREGABALIN

>D> AA	INVATECH	20MG/ML	A212604	001	Feb 18, 2022	Jan CAHN
>A> AA	PATRIN	20MG/ML	A212604	001	Feb 18, 2022	Jan CAHN

TABLET, EXTENDED RELEASE;ORAL

PREGABALIN

>D> AB	ZYDUS PHARMS	82.5MG	A215577	001	Aug 26, 2022	Jan DISC
>A>	@	82.5MG	A215577	001	Aug 26, 2022	Jan DISC
>D> AB		165MG	A215577	002	Aug 26, 2022	Jan DISC
>A>	@	165MG	A215577	002	Aug 26, 2022	Jan DISC
>D> AB		330MG	A215577	003	Aug 26, 2022	Jan DISC
>A>	@	330MG	A215577	003	Aug 26, 2022	Jan DISC

PROPOFOL

INJECTABLE;INJECTION

PROPOFOL

>A> AB	AVET LIFESCIENCES	10MG/ML	A206408	001	Oct 12, 2021	Jan CAHN
>D> AB	EMCURE PHARMS LTD	10MG/ML	A206408	001	Oct 12, 2021	Jan CAHN

RAMELTEON

TABLET;ORAL

RAMELTEON

>D> AB	ENALTEC	8MG	A215435	001	Aug 24, 2022	Jan CAHN
>A> AB	INNOGENIX	8MG	A215435	001	Aug 24, 2022	Jan CAHN

RANOLAZINE

TABLET, EXTENDED RELEASE;ORAL

>D> RANEXA

>D> AB +	GILEAD	500MG	N021526	002	Jan 27, 2006	Jan DISC
>A> + @		500MG	N021526	002	Jan 27, 2006	Jan DISC
>D> AB +!		1GM	N021526	001	Feb 12, 2007	Jan DISC
>A> + @		1GM	N021526	001	Feb 12, 2007	Jan DISC

RANOLAZINE

>D> AB	SUN PHARM	1GM	A211707	002	May 28, 2019	Jan CHRS
>A> AB !		1GM	A211707	002	May 28, 2019	Jan CHRS

REGADENOSON

SOLUTION;INTRAVENOUS

REGADENOSON

>A> AP	HIKMA	0.4MG/5ML (0.08MG/ML)	A215827	001	Feb 02, 2023	Jan NEWA

RISPERIDONE

>A> FOR SUSPENSION, EXTENDED RELEASE;INTRAMUSCULAR

>A> RYKINDO

>A> +!	SHANDONG LUYE	12.5MG	N212849	001	Jan 13, 2023	Jan NEWA
>A> +!		25MG	N212849	002	Jan 13, 2023	Jan NEWA
>A> +!		37.5MG	N212849	003	Jan 13, 2023	Jan NEWA
>A> +!		50MG	N212849	004	Jan 13, 2023	Jan NEWA

SIROLIMUS

SOLUTION;ORAL

SIROLIMUS

>A> AA	MSN	1MG/ML	A216728	001	Jan 19, 2023	Jan NEWA

SODIUM PHENYLBUTYRATE

POWDER;ORAL

BUPHENYL

>D> AB +!	HORIZON THERAP	3GM/TEASPOONFUL	N020573	001	Apr 30, 1996	Jan CAHN
>A> AB +!	HORIZON THERAP US	3GM/TEASPOONFUL	N020573	001	Apr 30, 1996	Jan CAHN

TABLET;ORAL

BUPHENYL

>D> AB +!	HORIZON THERAP	500MG	N020572	001	May 13, 1996	Jan CAHN
>A> AB +!	HORIZON THERAP US	500MG	N020572	001	May 13, 1996	Jan CAHN

STERILE WATER FOR INJECTION

LIQUID;N/A

STERILE WATER FOR INJECTION

>A>	AP	HIKMA	100%		A212735	001	Jan 31, 2023	Jan NEWA

SUCCINYLCHOLINE CHLORIDE

INJECTABLE;INJECTION

SUCCINYLCHOLINE CHLORIDE

>A>	AP	MANKIND PHARMA	20MG/ML		A216127	001	Feb 02, 2023	Jan NEWA

SULFACETAMIDE SODIUM

SOLUTION/DROPS;OPHTHALMIC

SULFACETAMIDE SODIUM

>D>	AT	AKORN	10%		A040215	001	May 25, 1999	Jan DISC
>A>		@	10%		A040215	001	May 25, 1999	Jan DISC

SULINDAC

TABLET;ORAL

SULINDAC

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

SUMATRIPTAN SUCCINATE

INJECTABLE;SUBCUTANEOUS

SUMATRIPTAN SUCCINATE

>A>	AP	BAXTER HLTHCARE CORP	EQ 6MG BASE/0.5ML EQ 12MG BASE/ML		A207101	001	Jan 19, 2023	Jan NEWA

TADALAFIL

TABLET;ORAL

TADALAFIL

>D>	BX	UNICHEM	2.5MG		A209250	001	Mar 26, 2019	Jan CTEC
>A>	AB1		2.5MG		A209250	001	Mar 26, 2019	Jan CTEC
>D>	BX		5MG		A209250	002	Mar 26, 2019	Jan CTEC
>A>	AB1		5MG		A209250	002	Mar 26, 2019	Jan CTEC
>D>	BX		10MG		A209250	003	Mar 26, 2019	Jan CTEC
>A>	AB1		10MG		A209250	003	Mar 26, 2019	Jan CTEC
>D>	BX		20MG		A209250	004	Mar 26, 2019	Jan CTEC
>A>	AB1		20MG		A209250	004	Mar 26, 2019	Jan CTEC

TASIMELTEON

CAPSULE;ORAL

TASIMELTEON

>A>	AB	APOTEX	20MG		A211607	001	Dec 20, 2022	Jan CAHN
>D>	AB	APOTEX CORP	20MG		A211607	001	Dec 20, 2022	Jan CAHN
>A>	AB	MSN	20MG		A211654	001	Jan 12, 2023	Jan NEWA

TECHNETIUM TC-99M MERTIATIDE KIT

POWDER;INTRAVENOUS

TECHNETIUM TC 99M MERTIATIDE KIT

>A>		+! JUBILANT DRAXIMAGE	N/A		N216820	001	Jan 30, 2023	Jan NEWA

TERIFLUNOMIDE

TABLET;ORAL

TERIFLUNOMIDE

>D>		@ APOTEX	7MG		A209601	001	Nov 02, 2018	Jan CMFD
>A>	AB		7MG		A209601	001	Nov 02, 2018	Jan CMFD
>D>		@	14MG		A209601	002	Nov 02, 2018	Jan CMFD
>A>	AB		14MG		A209601	002	Nov 02, 2018	Jan CMFD
>D>		@ AUROBINDO PHARMA	7MG		A209638	001	Oct 26, 2018	Jan CMFD
>A>	AB		7MG		A209638	001	Oct 26, 2018	Jan CMFD
>D>		@	14MG		A209638	002	Oct 26, 2018	Jan CMFD
>A>	AB		14MG		A209638	002	Oct 26, 2018	Jan CMFD
>D>		@ ZYDUS PHARMS	7MG		A209668	001	Nov 30, 2018	Jan CMFD
>A>	AB		7MG		A209668	001	Nov 30, 2018	Jan CMFD
>D>		@	14MG		A209668	002	Nov 30, 2018	Jan CMFD
>A>	AB		14MG		A209668	002	Nov 30, 2018	Jan CMFD

TESTOSTERONE

GEL, METERED;NASAL

NATESTO

>D>		ACERUS	5.5MG/0.122GM ACTUATION	N205488	001	May 28, 2014	Jan CHRS
>A>	+!		5.5MG/0.122GM ACTUATION	N205488	001	May 28, 2014	Jan CHRS

GEL, METERED;TRANSDERMAL

TESTOSTERONE

>D>	AB	DR REDDYS	1.62% (20.25MG/1.25GM ACTUATION)	A208620	001	Apr 10, 2019	Jan CAHN
>A>	AB	ENCUBE	1.62% (20.25MG/1.25GM ACTUATION)	A208620	001	Apr 10, 2019	Jan CAHN

TETRABENAZINE

TABLET;ORAL

TETRABENAZINE

>D>	AB	SUN PHARM	12.5MG	A206129	001	Aug 17, 2015	Jan DISC
>A>		@	12.5MG	A206129	001	Aug 17, 2015	Jan DISC
>D>	AB		25MG	A206129	002	Aug 17, 2015	Jan DISC
>A>		@	25MG	A206129	002	Aug 17, 2015	Jan DISC

THEOPHYLLINE

TABLET, EXTENDED RELEASE;ORAL

THEOPHYLLINE

>A>	AB	LEADING	300MG	A214950	001	Jan 30, 2023	Jan NEWA
>A>	AB		450MG	A214950	002	Jan 30, 2023	Jan NEWA

THIORIDAZINE HYDROCHLORIDE

TABLET;ORAL

THIORIDAZINE HYDROCHLORIDE

>A>		@ CHARTWELL RX	10MG	A088131	001	Aug 30, 1983	Jan CAHN
>A>		@	15MG	A088132	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>		@	150MG	A088136	001	Sep 17, 1986	Jan CAHN
>A>		@	200MG	A088137	001	Sep 17, 1986	Jan CAHN
>D>		@ FOSUN PHARMA	10MG	A088131	001	Aug 30, 1983	Jan CAHN
>D>		@	15MG	A088132	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>		@	150MG	A088136	001	Sep 17, 1986	Jan CAHN
>D>		@	200MG	A088137	001	Sep 17, 1986	Jan CAHN

TIMOLOL

SOLUTION/DROPS;OPHTHALMIC

BETIMOL

>D>	AT	+! THEA PHARMA	EQ 0.25% BASE	N020439	001	Mar 31, 1995	Jan CTEC
>A>		+!	EQ 0.25% BASE	N020439	001	Mar 31, 1995	Jan CTEC
>D>	AT	+!	EQ 0.5% BASE	N020439	002	Mar 31, 1995	Jan CTEC
>A>		+!	EQ 0.5% BASE	N020439	002	Mar 31, 1995	Jan CTEC

TIMOLOL

>D>	AT	AKORN	EQ 0.25% BASE	A205309	001	Sep 30, 2016	Jan DISC
>A>		@	EQ 0.25% BASE	A205309	001	Sep 30, 2016	Jan DISC
>D>	AT		EQ 0.5% BASE	A205309	002	Sep 30, 2016	Jan DISC
>A>		@	EQ 0.5% BASE	A205309	002	Sep 30, 2016	Jan DISC

TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC

TIMOLOL MALEATE

>D>	AT1	AKORN	EQ 0.5% BASE	A074466	001	Mar 25, 1997	Jan DISC
>A>		@	EQ 0.5% BASE	A074466	001	Mar 25, 1997	Jan DISC

TIROFIBAN HYDROCHLORIDE

SOLUTION;INTRAVENOUS

AGGRASTAT

>D>		+ MEDICURE	EQ 5MG BASE/100ML (EQ 0.05MG BASE/ML)	N020913	002	May 17, 2002	Jan CFTG
>A>	AP	+	EQ 5MG BASE/100ML (EQ 0.05MG BASE/ML)	N020913	002	May 17, 2002	Jan CFTG

TIROFIBAN HYDROCHLORIDE

>A>	AP	NEXUS PHARMS	EQ 5MG BASE/100ML (EQ 0.05MG BASE/ML)	A213947	001	Feb 07, 2023	Jan NFTG

TOBRAMYCIN SULFATE

INJECTABLE;INJECTION

TOBRAMYCIN SULFATE

>A>	AP		HAINAN POLY	EQ 1.2GM BASE/VIAL	A217029	001	Feb 01, 2023	Jan NEWA

TOPIRAMATE

CAPSULE, EXTENDED RELEASE;ORAL

TOPIRAMATE

>A>	AB1		ZYDUS	25MG	A207382	001	Nov 24, 2017	Jan CAHN
>A>	AB2			25MG	A208949	001	Nov 29, 2022	Jan CAHN
>A>	AB1			50MG	A207382	002	Nov 24, 2017	Jan CAHN
>A>	AB2			50MG	A208949	002	Nov 29, 2022	Jan CAHN
>A>	AB1			100MG	A207382	003	Nov 24, 2017	Jan CAHN
>A>	AB2			100MG	A208949	003	Nov 29, 2022	Jan CAHN
>A>	AB2			150MG	A208949	004	Nov 29, 2022	Jan CAHN
>A>	AB2			200MG	A208949	005	Nov 29, 2022	Jan CAHN
>D>	AB1		ZYDUS PHARMS	25MG	A207382	001	Nov 24, 2017	Jan CAHN
>D>	AB2			25MG	A208949	001	Nov 29, 2022	Jan CAHN
>D>	AB1			50MG	A207382	002	Nov 24, 2017	Jan CAHN
>D>	AB2			50MG	A208949	002	Nov 29, 2022	Jan CAHN
>D>	AB1			100MG	A207382	003	Nov 24, 2017	Jan CAHN
>D>	AB2			100MG	A208949	003	Nov 29, 2022	Jan CAHN
>D>	AB2			150MG	A208949	004	Nov 29, 2022	Jan CAHN
>D>	AB2			200MG	A208949	005	Nov 29, 2022	Jan CAHN
>A>	AB1			200MG	A216167	001	Feb 09, 2023	Jan NFTG

TROKENDI XR

>D>	BC	+!	SUPERNUS PHARMS	200MG	N201635	004	Aug 16, 2013	Jan CFTG
>A>	AB1	+!		200MG	N201635	004	Aug 16, 2013	Jan CFTG

TRAZODONE HYDROCHLORIDE

TABLET;ORAL

TRAZODONE HYDROCHLORIDE

>A>	AB		AUROBINDO PHARMA	50MG	A204852	001	Feb 05, 2020	Jan CAHN
>A>	AB			100MG	A204852	002	Feb 05, 2020	Jan CAHN
>A>	AB			150MG	A204852	003	Feb 05, 2020	Jan CAHN
>A>	AB			300MG	A204852	004	Feb 05, 2020	Jan CAHN
>D>	AB		AUROLIFE PHARMA LLC	50MG	A204852	001	Feb 05, 2020	Jan CAHN
>D>	AB			100MG	A204852	002	Feb 05, 2020	Jan CAHN
>D>	AB			150MG	A204852	003	Feb 05, 2020	Jan CAHN
>D>	AB			300MG	A204852	004	Feb 05, 2020	Jan CAHN

TRETINOIN

CREAM;TOPICAL

RETIN-A

>A>	AB	+!	BAUSCH	0.025%	N019049	001	Sep 16, 1988	Jan CAHN
>D>	AB	+!	VALEANT BERMUDA	0.025%	N019049	001	Sep 16, 1988	Jan CAHN

TRIAMCINOLONE ACETONIDE

OINTMENT;TOPICAL

TRIAMCINOLONE ACETONIDE

>A>	AT		GLASSHOUSE PHARMS	0.05%	A214532	001	Jan 27, 2023	Jan NEWA

TRIAMTERENE

CAPSULE;ORAL

TRIAMTERENE

>D>	AB		EYWA	50MG	A214768	001	Jul 06, 2022	Jan DISC
>A>		@		50MG	A214768	001	Jul 06, 2022	Jan DISC
>D>	AB			100MG	A214768	002	Jul 06, 2022	Jan DISC
>A>		@		100MG	A214768	002	Jul 06, 2022	Jan DISC

UBROGEPANT

TABLET;ORAL

UBRELVY

>A>		+	ABBVIE	50MG	N211765	001	Dec 23, 2019	Jan CAHN
>A>		+!		100MG	N211765	002	Dec 23, 2019	Jan CAHN
>D>		+	ALLERGAN	50MG	N211765	001	Dec 23, 2019	Jan CAHN
>D>		+!		100MG	N211765	002	Dec 23, 2019	Jan CAHN

URSODIOL

CAPSULE;ORAL

URSODIOL

>D>	AB		MYLAN	300MG	A090530	001	Feb 17, 2010	Jan DISC
>A>		@		300MG	A090530	001	Feb 17, 2010	Jan DISC

VALACYCLOVIR HYDROCHLORIDE

TABLET;ORAL

VALACYCLOVIR HYDROCHLORIDE

>A>	AB		CHARTWELL RX	EQ 500MG BASE	A090216	001	May 24, 2010	Jan CAHN
>A>	AB			EQ 1GM BASE	A090216	002	May 24, 2010	Jan CAHN
>D>	AB		WOCKHARDT BIO AG	EQ 500MG BASE	A090216	001	May 24, 2010	Jan CAHN
>D>	AB			EQ 1GM BASE	A090216	002	May 24, 2010	Jan CAHN

VALSARTAN

SOLUTION;ORAL

VALSARTAN

>D>			NOVITIUM PHARMA	20MG/5ML	A214102	001	Nov 02, 2021	Jan CHRS
>A>		!		20MG/5ML	A214102	001	Nov 02, 2021	Jan CHRS

VANCOMYCIN HYDROCHLORIDE

INJECTABLE;INJECTION

VANCOMYCIN HYDROCHLORIDE

>D>		@	HIKMA	EQ 1GM BASE/VIAL	A203300	002	Aug 11, 2020	Jan CMFD
>A>	AP			EQ 1GM BASE/VIAL	A203300	002	Aug 11, 2020	Jan CMFD

POWDER;INTRAVENOUS, ORAL

VANCOMYCIN HYDROCHLORIDE

>A>		+!	ZHEJIANG NOVUS PHARM	EQ 500MG BASE/VIAL	N210274	001	Jan 20, 2023	Jan NEWA
>A>		+!		EQ 1GM BASE/VIAL	N210274	002	Jan 20, 2023	Jan NEWA
>A>		+!		EQ 5GM BASE/VIAL	N210274	003	Jan 20, 2023	Jan NEWA
>A>		+!		EQ 10GM BASE/VIAL	N210274	004	Jan 20, 2023	Jan NEWA

VARENICLINE TARTRATE

TABLET;ORAL

VARENICLINE TARTRATE

>A>	AB		APOTEX	EQ 0.5MG BASE	A201962	001	Jan 25, 2023	Jan NEWA
>A>	AB			EQ 1MG BASE	A201962	002	Jan 25, 2023	Jan NEWA
>D>			PAR PHARM INC	EQ 0.5MG BASE	A201785	001	Aug 11, 2021	Jan CTEC
>A>	AB			EQ 0.5MG BASE	A201785	001	Aug 11, 2021	Jan CTEC
>D>		!		EQ 1MG BASE	A201785	002	Aug 11, 2021	Jan CTEC
>A>	AB	!		EQ 1MG BASE	A201785	002	Aug 11, 2021	Jan CTEC

VENLAFAXINE HYDROCHLORIDE

TABLET;ORAL

VENLAFAXINE HYDROCHLORIDE

>A>		@	CHARTWELL RX	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>		@	FOSUN PHARMA	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

VILAZODONE HYDROCHLORIDE

TABLET;ORAL

VIIBRYD

>A>	AB	+!	ABBVIE	10MG	N022567	001	Jan 21, 2011	Jan CAHN
>A>	AB	+		20MG	N022567	002	Jan 21, 2011	Jan CAHN
>A>	AB	+		40MG	N022567	003	Jan 21, 2011	Jan CAHN
>D>	AB	+!	ALLERGAN	10MG	N022567	001	Jan 21, 2011	Jan CAHN
>D>	AB	+		20MG	N022567	002	Jan 21, 2011	Jan CAHN
>D>	AB	+		40MG	N022567	003	Jan 21, 2011	Jan CAHN

VORICONAZOLE

INJECTABLE;INTRAVENOUS

VORICONAZOLE

>A>	AP		EUGIA PHARMA	200MG/VIAL	A212162	001	Feb 02, 2023	Jan NEWA

>A> XENON XE-129 HYPERPOLARIZED

>A> GAS;INHALATION

>A> XENOVIEW

>A>		+!	POLAREAN	N/A	N214375	001	Dec 23, 2022	Jan NEWA

ZILEUTON

TABLET, EXTENDED RELEASE;ORAL

>D> ZILEUTON

>D>	BX		LUPIN LTD	600MG	A211972	001	Nov 05, 2019	Jan DISC
>A>		@		600MG	A211972	001	Nov 05, 2019	Jan DISC
>D>	AB		RISING	600MG	A204929	001	Mar 17, 2017	Jan CHRS
>A>	AB	!		600MG	A204929	001	Mar 17, 2017	Jan CHRS

ZYFLO CR

>D>	AB	+!	CHIESI	600MG	N022052	001	May 30, 2007	Jan DISC
>A>		+ @		600MG	N022052	001	May 30, 2007	Jan DISC

ZOLMITRIPTAN

SPRAY;NASAL

ZOMIG

>A>	AB	+	AMNEAL	2.5MG/SPRAY	N021450	003	Sep 16, 2013	Jan CAHN
>A>	AB	+!		5MG/SPRAY	N021450	004	Sep 30, 2003	Jan CAHN
>D>	AB	+	ASTRAZENECA	2.5MG/SPRAY	N021450	003	Sep 16, 2013	Jan CAHN
>D>	AB	+!		5MG/SPRAY	N021450	004	Sep 30, 2003	Jan CAHN

OLOPATADINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

OLOPATADINE HYDROCHLORIDE

>D>	AKORN	EQ 0.1% BASE	A204532	001	Jan 10, 2017	Jan	DISC
>A>	@	EQ 0.1% BASE	A204532	001	Jan 10, 2017	Jan	DISC
>D>		EQ 0.2% BASE	A204723	001	Dec 05, 2017	Jan	DISC
>A>	@	EQ 0.2% BASE	A204723	001	Dec 05, 2017	Jan	DISC

TRIAMCINOLONE ACETONIDE

SPRAY, METERED;NASAL

TRIAMCINOLONE ACETONIDE

>A>	APOTEX	0.055MG/SPRAY	A214615	001	Jan 19, 2023	Jan	NEWA

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 2023

NO JANUARY 2023 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of Orphan Designations and Approvals is available at:

https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products.

DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

NO JANUARY 2023 APPROVALS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2023

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ADAGRASIB - KRAZATI							
N 216340	001					>A> NCE	Dec 12, 2027
ALBUTEROL SULFATE; BUDESONIDE - AIRSUPRA							
N 214070	001	>A> 9415009	May 28, 2030	U-3509		>A> NP	Jan 10, 2026
ALPELISIB - VIJOICE							
N 215039	001					>A> ODE-396	Apr 05, 2029
ALPELISIB - VIJOICE							
N 215039	002					>A> ODE-396	Apr 05, 2029
ALPELISIB - VIJOICE							
N 215039	003					>A> ODE-396	Apr 05, 2029
AMINOLEVULINIC ACID HYDROCHLORIDE - AMELUZ							
N 208081	001	>A> 11540981	Feb 07, 2028	DP			
ANGIOTENSIN II ACETATE - GIAPREZA							
N 209360	001	>A> 11559559	Dec 18, 2034	U-3514			
ANGIOTENSIN II ACETATE - GIAPREZA							
N 209360	002	>A> 11559559	Dec 18, 2034	U-3514			
ANGIOTENSIN II ACETATE - GIAPREZA							
N 209360	003	>A> 11559559	Dec 18, 2034	U-3514			
APALUTAMIDE - ERLEADA							
N 210951	001	10052314	Sep 23, 2033	U-2381	Y		
		10052314	Sep 23, 2033	U-2382	Y		
		>A> RE49353	Sep 23, 2033	U-2381			
BENDAMUSTINE HYDROCHLORIDE - TREANDA							
N 022249	001	>A> 9533955	Mar 26, 2029	DP U-1949			
		>A> 9533955	Mar 26, 2029	DP U-1952			
		>A> 9533955*PED	Sep 26, 2029				
BENDAMUSTINE HYDROCHLORIDE - TREANDA							
N 022249	002	>A> 9533955	Mar 26, 2029	DP U-1949			
		>A> 9533955	Mar 26, 2029	DP U-1952			
		>A> 9533955*PED	Sep 26, 2029				
BENZOYL PEROXIDE - EPSOLAY							
N 214510	001	>A> 11541026	Feb 19, 2040	U-3356			
BUDESONIDE - TARPEYO							
N 215935	001					>A> ODE-389	Dec 15, 2028
BUPROPION HYDROCHLORIDE; DEXTROMETHORPHAN HYDROBROMIDE - AUVELITY							
N 215430	001	>A> 11534414	Nov 05, 2034	DP U-3419			
		>A> 11541021	Nov 05, 2034	U-3419			
		>A> 11541048	Nov 05, 2034	U-3419			
CALCIUM OXYBATE; MAGNESIUM OXYBATE; POTASSIUM OXYBATE; SODIUM OXYBATE - XYWAV							
N 212690	001	>A> 11554102	Jan 11, 2033	DP			
CARBAMAZEPINE - CARNEXIV							
N 206030	001	>A> 11529357	Jan 31, 2040	DP			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2023

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
CARIPRAZINE HYDROCHLORIDE - VRAYLAR						
N 204370 001	>A> 7737142	Sep 17, 2029	DS DP U-1750		>A> I-904	Dec 16, 2025
	>A> 7737142	Sep 17, 2029	DS DP U-2543			
	>A> 7737142	Sep 17, 2029	DS DP U-2544			
	>A> 7737142	Sep 17, 2029	DS DP U-2545			
	>A> 7737142	Sep 17, 2029	DS DP U-3503			
	>A> RE47350	Jul 16, 2029	U-1750			
	>A> RE47350	Jul 16, 2029	U-2543			
	>A> RE47350	Jul 16, 2029	U-2544			
	>A> RE47350	Jul 16, 2029	U-2545			
	>A> RE47350	Jul 16, 2029	U-3503			
	>A> RE49110	Jul 16, 2029	U-2543			
	>A> RE49110	Jul 16, 2029	U-2544			
	>A> RE49110	Jul 16, 2029	U-2545			
	>A> RE49110	Jul 16, 2029	U-3503			
	>A> RE49302	Jul 16, 2029	U-2543			
	>A> RE49302	Jul 16, 2029	U-2544			
	>A> RE49302	Jul 16, 2029	U-2545			
	>A> RE49302	Jul 16, 2029	U-3503			
CARIPRAZINE HYDROCHLORIDE - VRAYLAR						
N 204370 002	>A> 7737142	Sep 17, 2029	DS DP U-1750		>A> I-904	Dec 16, 2025
	>A> 7737142	Sep 17, 2029	DS DP U-2543			
	>A> 7737142	Sep 17, 2029	DS DP U-2544			
	>A> 7737142	Sep 17, 2029	DS DP U-2545			
	>A> 7737142	Sep 17, 2029	DS DP U-3503			
	>A> RE49110	Jul 16, 2029	U-2543			
	>A> RE49110	Jul 16, 2029	U-2544			
	>A> RE49110	Jul 16, 2029	U-2545			
	>A> RE49110	Jul 16, 2029	U-3503			
	>A> RE49302	Jul 16, 2029	U-2543			
	>A> RE49302	Jul 16, 2029	U-2544			
	>A> RE49302	Jul 16, 2029	U-2545			
	>A> RE49302	Jul 16, 2029	U-3503			
CARIPRAZINE HYDROCHLORIDE - VRAYLAR						
N 204370 003	>A> RE49302	Jul 16, 2029	U-2543		>A> I-904	Dec 16, 2025
	>A> RE49302	Jul 16, 2029	U-2544			
	>A> RE49302	Jul 16, 2029	U-2545			
	>A> RE49302	Jul 16, 2029	U-3503			
CARIPRAZINE HYDROCHLORIDE - VRAYLAR						
N 204370 004	>A> RE49302	Jul 16, 2029	U-2543		>A> I-904	Dec 16, 2025
	>A> RE49302	Jul 16, 2029	U-2544			
	>A> RE49302	Jul 16, 2029	U-2545			
	>A> RE49302	Jul 16, 2029	U-3503			
CHLOROPROCAINE HYDROCHLORIDE - IHEEZO						
N 216227 001					>A> NP	Sep 27, 2025
CLASCOTERONE - WINLEVI						
N 213433 001	>A> 8143240	Jan 12, 2024	U-2942			
CLOBAZAM - SYMPAZAN						
N 210833 001	>A> 11541002	Jan 31, 2040	DP U-724			
CLOBAZAM - SYMPAZAN						
N 210833 002	>A> 11541002	Jan 31, 2040	DP U-724			
CLOBAZAM - SYMPAZAN						
N 210833 003	>A> 11541002	Jan 31, 2040	DP U-724			
DALBAVANCIN HYDROCHLORIDE - DALVANCE						
N 021883 001	>A> 6900175	May 23, 2028	U-3499			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2023

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX						
N 021038 001					>A> NPP	Dec 16, 2025
DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX						
N 021038 002					>A> NPP	Dec 16, 2025
DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX						
N 021038 003					>A> NPP	Dec 16, 2025
DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX						
N 021038 004					>A> NPP	Dec 16, 2025
DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX						
N 021038 005					>A> NPP	Dec 16, 2025
ELAGOLIX SODIUM - ORILISSA						
N 210450 001	>A> 11542239	Jul 23, 2039	DS DP			
ELAGOLIX SODIUM - ORILISSA						
N 210450 002	>A> 11542239	Jul 23, 2039	DS DP			
ELAGOLIX SODIUM,ESTRADIOL,NORETHINDRONE ACETATE; ELAGOLIX SODIUM - ORIAHNN (COPACKAGED)						
N 213388 001	>A> 11542239	Jul 23, 2039	DS DP			
ENCORAFENIB - BRAFTOVI						
N 210496 002	>A> 8501758	Aug 27, 2030	DS DP			
FENFLURAMINE HYDROCHLORIDE - FINTEPLA						
N 212102 001					>A> ODE-393	Mar 25, 2029
					>A> PED	Sep 25, 2029
FLUTICASONE PROPIONATE - XHANCE						
N 209022 001	>A> 8327844	Oct 24, 2023	U-2133			
FOSNETUPITANT CHLORIDE HYDROCHLORIDE; PALONOSETRON HYDROCHLORIDE - AKYNZEO						
N 210493 001	>A> 11529362	Jun 02, 2037	DP			
FOSNETUPITANT CHLORIDE HYDROCHLORIDE; PALONOSETRON HYDROCHLORIDE - AKYNZEO						
N 210493 002	>A> 11529362	Jun 02, 2037	DP			
GANAXOLONE - ZTALMY						
N 215904 001					>A> ODE-395	Jun 01, 2029
IBREXAFUNGERP CITRATE - BREXAFEMME						
N 214900 001	>A> 11534433	Jun 10, 2039	U-3159		>A> I-903	Nov 30, 2025
	>A> 11534433	Jun 10, 2039	U-3508			
IBRUTINIB - IMBRUVICA						
N 205552 001					>A> ODE-109	Mar 04, 2023
					>A> ODE-117	May 06, 2023
					>A> ODE-128	Jan 18, 2024
					>A> ODE-152	Aug 02, 2024
IBRUTINIB - IMBRUVICA						
N 205552 002					>A> ODE*	Mar 04, 2023
					>A> ODE*	May 06, 2023
					>A> ODE*	Jan 18, 2024
					>A> ODE*	Aug 02, 2024
IBRUTINIB - IMBRUVICA						
N 210563 001					>A> ODE*	Mar 04, 2023
					>A> ODE*	May 06, 2023
					>A> ODE*	Jan 18, 2024

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2023

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
IBRUTINIB - IMBRUVICA						
N 210563 001					>A> ODE*	Aug 02, 2024
IBRUTINIB - IMBRUVICA						
N 210563 002					>A> ODE*	Mar 04, 2023
					>A> ODE*	May 06, 2023
					>A> ODE*	Jan 18, 2024
					>A> ODE*	Aug 02, 2024
IBRUTINIB - IMBRUVICA						
N 210563 003					>A> ODE*	Mar 04, 2023
					>A> ODE*	May 06, 2023
					>A> ODE*	Jan 18, 2024
					>A> ODE*	Aug 02, 2024
IBRUTINIB - IMBRUVICA						
N 210563 004					>A> ODE*	Mar 04, 2023
					>A> ODE*	May 06, 2023
					>A> ODE*	Jan 18, 2024
					>A> ODE*	Aug 02, 2024
LENACAPAVIR SODIUM - SUNLENCA						
N 215973 001	>A> 10071985	Aug 17, 2037	DS DP			
	>A> 10654827	Aug 17, 2037	U-3507			
	>A> 11267799	Aug 16, 2038	DS			
	>A> 9951043	Feb 28, 2034	DS DP U-3507			
LENACAPAVIR SODIUM - SUNLENCA						
N 215974 001	>A> 10071985	Aug 17, 2037	DS DP			
	>A> 10654827	Aug 17, 2037	U-3507			
	>A> 11267799	Aug 16, 2038	DS			
	>A> 9951043	Feb 28, 2034	DS DP U-3507			
LEVOKETOCONAZOLE - RECORLEV						
N 214133 001					>A> ODE-385	Dec 30, 2028
LEVOLEUCOVORIN - KHAPZORY						
N 211226 001	>A> 11541012	Mar 25, 2039	DP			
LEVOLEUCOVORIN - KHAPZORY						
N 211226 002	>A> 11541012	Mar 25, 2039	DP			
LOTEPREDNOL ETABONATE - LOTEMAX SM						
N 208219 001	>A> 11534395	Jan 26, 2036	DP U-2764			
MARIBAVIR - LIVTENCITY						
N 215596 001					>A> ODE-388	Nov 23, 2028
MITAPIVAT SULFATE - PYRUKYND						
N 216196 001					>A> ODE-392	Feb 17, 2029
MITAPIVAT SULFATE - PYRUKYND						
N 216196 002					>A> ODE-392	Feb 17, 2029
MITAPIVAT SULFATE - PYRUKYND						
N 216196 003					>A> ODE-392	Feb 17, 2029
NICARDIPINE HYDROCHLORIDE - CARDENE IN 4.8% DEXTROSE IN PLASTIC CONTAINER						
N 019734 002	>A> 11547758	Apr 18, 2027	U-1029			
NICARDIPINE HYDROCHLORIDE - CARDENE IN 0.86% SODIUM CHLORIDE IN PLASTIC CONTAINER						
N 019734 003	>A> 11547758	Apr 18, 2027	U-1029			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2023

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
NICARDIPINE HYDROCHLORIDE - CARDENE IN 0.83% SODIUM CHLORIDE IN PLASTIC CONTAINER							
N 019734	004	>A> 11547758	Apr 18, 2027	U-1029			
NIMODIPINE - NYMALIZE							
N 203340	002	>A> 11517563	Apr 16, 2038	DP	Y		
NITRIC OXIDE - GENOSYL							
N 202860	001	>A> 11511252	Sep 21, 2029	DP			
OLUTASIDENIB - REZLIDHIA							
N 215814	001					>A> NCE	Dec 01, 2027
PAFOLACIANINE SODIUM - CYTALUX							
N 214907	001					>A> I-905	Dec 16, 2025
						>A> ODE-390	Nov 29, 2028
PHENTOLAMINE MESYLATE - ORAVERSE							
N 022159	001	>A> 7229630	Jul 31, 2023	DP			
		>A> 7575757	Jul 31, 2023	DP			
PHENYLEPHRINE HYDROCHLORIDE - PHENYLEPHRINE HYDROCHLORIDE							
A 216496	001					>A> CGT	Jul 17, 2023
RIFAXIMIN - XIFAXAN							
N 021361	002	>A> 11564912	Feb 26, 2029	U-3511			
		>A> 11564912	Feb 26, 2029	U-3512			
RIPRETINIB - QINLOCK							
N 213973	001	>A> 11529336	Aug 12, 2040	U-3382			
		>A> 11534432	Aug 12, 2040	U-3442			
RISPERIDONE - RYKINDO							
N 212849	001	>A> 10098882	Apr 10, 2032	DP U-3513			
		>A> 10406161	Apr 10, 2032	DP U-3513			
		>A> 11110094	Apr 10, 2032	DP			
		>A> 9446135	Apr 10, 2032	DP U-3513			
		>A> 9532991	Apr 10, 2032	DP U-3513			
RISPERIDONE - RYKINDO							
N 212849	002	>A> 10098882	Apr 10, 2032	DP U-3513			
		>A> 10406161	Apr 10, 2032	DP U-3513			
		>A> 11110094	Apr 10, 2032	DP			
		>A> 9446135	Apr 10, 2032	DP U-3513			
		>A> 9532991	Apr 10, 2032	DP U-3513			
RISPERIDONE - RYKINDO							
N 212849	003	>A> 10098882	Apr 10, 2032	DP U-3513			
		>A> 10406161	Apr 10, 2032	DP U-3513			
		>A> 11110094	Apr 10, 2032	DP			
		>A> 9446135	Apr 10, 2032	DP U-3513			
		>A> 9532991	Apr 10, 2032	DP U-3513			
RISPERIDONE - RYKINDO							
N 212849	004	>A> 10098882	Apr 10, 2032	DP U-3513			
		>A> 10406161	Apr 10, 2032	DP U-3513			
		>A> 11110094	Apr 10, 2032	DP			
		>A> 9446135	Apr 10, 2032	DP U-3513			
		>A> 9532991	Apr 10, 2032	DP U-3513			
RUXOLITINIB PHOSPHATE - JAKAFI							
N 202192	001					>A> M-285	Dec 19, 2025
						>A> PED	Jun 19, 2026

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
RUXOLITINIB PHOSPHATE - JAKAFI						
N 202192 002					>A> M-285	Dec 19, 2025
					>A> PED	Jun 19, 2026
RUXOLITINIB PHOSPHATE - JAKAFI						
N 202192 003					>A> M-285	Dec 19, 2025
					>A> PED	Jun 19, 2026
RUXOLITINIB PHOSPHATE - JAKAFI						
N 202192 004					>A> M-285	Dec 19, 2025
					>A> PED	Jun 19, 2026
RUXOLITINIB PHOSPHATE - JAKAFI						
N 202192 005					>A> M-285	Dec 19, 2025
					>A> PED	Jun 19, 2026
RUXOLITINIB PHOSPHATE - OPZELURA						
N 215309 001	>A> 11510923	Sep 04, 2040	U-3505			
SEMAGLUTIDE - WEGOVY						
N 215256 001					>A> NPP	Dec 23, 2025
SEMAGLUTIDE - WEGOVY						
N 215256 002					>A> NPP	Dec 23, 2025
SEMAGLUTIDE - WEGOVY						
N 215256 003					>A> NPP	Dec 23, 2025
SEMAGLUTIDE - WEGOVY						
N 215256 004					>A> NPP	Dec 23, 2025
SEMAGLUTIDE - WEGOVY						
N 215256 005					>A> NPP	Dec 23, 2025
SIROLIMUS - FYARRO						
N 213312 001					>A> ODE-386	Nov 22, 2028
SIROLIMUS - HYFTOR						
N 213478 001					>A> ODE-391	Mar 22, 2029
SODIUM PHENYLBUTYRATE - OLPRUVA						
N 214860 001	>A> 11154521	Oct 17, 2036	DP			
	>A> 11202767	Oct 17, 2036	U-3502			
	>A> 11433041	Oct 17, 2036	DP			
SODIUM PHENYLBUTYRATE - OLPRUVA						
N 214860 002	>A> 11154521	Oct 17, 2036	DP			
	>A> 11202767	Oct 17, 2036	U-3502			
	>A> 11433041	Oct 17, 2036	DP			
SODIUM PHENYLBUTYRATE - OLPRUVA						
N 214860 003	>A> 11154521	Oct 17, 2036	DP			
	>A> 11202767	Oct 17, 2036	U-3502			
	>A> 11433041	Oct 17, 2036	DP			
SODIUM PHENYLBUTYRATE - OLPRUVA						
N 214860 004	>A> 11154521	Oct 17, 2036	DP			
	>A> 11202767	Oct 17, 2036	U-3502			
	>A> 11433041	Oct 17, 2036	DP			
SODIUM PHENYLBUTYRATE - OLPRUVA						
N 214860 005	>A> 11154521	Oct 17, 2036	DP			
	>A> 11202767	Oct 17, 2036	U-3502			

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APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
SODIUM PHENYLBUTYRATE - OLPRUVA							
N 214860	005	>A> 11433041	Oct 17, 2036	DP			
SODIUM PHENYLBUTYRATE - OLPRUVA							
N 214860	006	>A> 11154521	Oct 17, 2036	DP			
		>A> 11202767	Oct 17, 2036	U-3502			
		>A> 11433041	Oct 17, 2036	DP			
SODIUM THIOSULFATE - PEDMARK							
N 212937	001					>A> ODE-384	Sep 20, 2029
TRILACICLIB DIHYDROCHLORIDE - COSELA							
N 214200	001	>A> 11529352	Jul 23, 2039	U-3504			
TUCATINIB - TUKYSA							
N 213411	001	>A> 11207324	Apr 27, 2038	U-3510			
TUCATINIB - TUKYSA							
N 213411	002	>A> 11207324	Apr 27, 2038	U-3510			
UPADACITINIB - RINVOQ							
N 211675	001	>A> 11524964	Oct 17, 2036	U-3371			
		>A> 11535624	Oct 17, 2036	U-3255			
		>A> 11535625	Oct 17, 2036	U-3298			
UPADACITINIB - RINVOQ							
N 211675	002	>A> 11535626	Oct 17, 2036	U-3298			
VOSORITIDE - VOXZOGO							
N 214938	001					>A> ODE-387	Nov 19, 2028
VOSORITIDE - VOXZOGO							
N 214938	002					>A> ODE-387	Nov 19, 2028
VOSORITIDE - VOXZOGO							
N 214938	003					>A> ODE-387	Nov 19, 2028
VOXELOTOR - OXBRYTA							
N 213137	001					>A> ODE-394	Dec 17, 2028
VOXELOTOR - OXBRYTA							
N 213137	002					>A> ODE-394	Dec 17, 2028
VOXELOTOR - OXBRYTA							
N 216157	001					>A> ODE-394	Dec 17, 2028
XENON XE-129 HYPERPOLARIZED - XENOVIEW							
N 214375	001	>A> 10583205	Feb 20, 2035	DP		>A> NCE	Dec 23, 2027
		>A> 11052161	Dec 29, 2035	DP			
ZANUBRUTINIB - BRUKINSA							
N 213217	001	>A> 10570139	Apr 22, 2034	U-1745			
		>A> 10570139	Apr 22, 2034	U-2145			
		>A> 10570139	Apr 22, 2034	U-2537			
		>A> 10570139	Apr 22, 2034	U-2666			
		>A> 10570139	Apr 22, 2034	U-3063			
		>A> 10570139	Apr 22, 2034	U-3486			
		>A> 11142528	Apr 22, 2034	DP U-1745			
		>A> 11142528	Apr 22, 2034	DP U-2145			
		>A> 11142528	Apr 22, 2034	DP U-2537			
		>A> 11142528	Apr 22, 2034	DP U-2666			
		>A> 11142528	Apr 22, 2034	DP U-3063			
		>A> 11142528	Apr 22, 2034	DP U-3486			
		>A> 9447106	Apr 22, 2034	DS DP U-1745			

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APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ZANUBRUTINIB - BRUKINSA							
N 213217	001	>A> 9447106	Apr 22, 2034	DS DP U-2145			
		>A> 9447106	Apr 22, 2034	DS DP U-2537			
		>A> 9447106	Apr 22, 2034	DS DP U-2666			
		>A> 9447106	Apr 22, 2034	DS DP U-3063			
		>A> 9447106	Apr 22, 2034	DS DP U-3486			

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, 43rd Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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

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