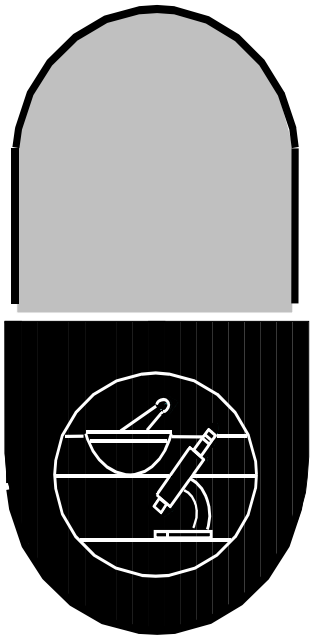
CUMULATIVE SUPPLEMENT 1
January 2025



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

45th 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

2025

Prepared By
Food and Drug Administration
Office of Medical Products and Tobacco
Center for Drug Evaluation and Research
Office of Generic Drugs
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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for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.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.
  o 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)
ACI HEALTHCARE LTD (ACI)	STRIDES PHARMA GLOBAL PTE LTD (STRIDES PHARMA)
AKORN OPERATING CO LLC (AKORN)	EPIC PHARMA LLC (EPIC PHARMA LLC)
AKORN OPERATING CO LLC (AKORN)	SCIEGEN PHARMACEUTICALS INC (SCIEGEN PHARMS INC)
CADILA HEALTHCARE LTD (CADILA)	ZYDUS LIFESCIENCES LTD (ZYDUS LIFESCIENCES)
EXTROVIS AG (EXTROVIS)	RISING PHARMA HOLDINGS INC (RISING)
GLAXOSMITHKLINE (GLAXOSMITHKLINE)	HALEON US HOLDINGS LLC (HALEON US HOLDINGS)

GLAXOSMITHKLINE CONSUMER HEALTHCARE (GLAXOSMITHKLINE CONS)	HALEON US HOLDINGS LLC (HALEON US HOLDINGS)
GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS US LLC (GLAXOSMITHKLINE)	HALEON US HOLDINGS LLC (HALEON US HOLDINGS)
GLENMARK GENERICS INC USA (GLENMARK GENERICS)	GLENMARK PHARMACEUTICALS INC USA (GLENMARK PHARMS INC)
GLENMARK GENERICS LIMITED (GLENMARK GENERICS)	GLENMARK PHARMACEUTICALS LTD (GLENMARK PHARMS LTD)
GLENMARK GENERICS LTD (GLENMARK GENERICS)	GLENMARK PHARMACEUTICALS INC USA (GLENMARK PHARMS INC)
GLENMARK GENERICS LTD (GLENMARK GENERICS)	GLENMARK PHARMACEUTICALS LTD (GLENMARK PHARMS LTD)
GLENMARK GENERICS LTD INDIA (GLENMARK GENERICS)	GLENMARK PHARMACEUTICALS LTD (GLENMARK PHARMS LTD)
GLENMARK PHARMACEUTICALS SA (GLENMARK PHARMS)	GLENMARK SPECIALTY SA (GLENMARK SPECLT)
GLENMARK PHARMACEUTICALS SA SWITZERLAND (GLENMARK PHARMS SA)	GLENMARK SPECIALTY SA (GLENMARK SPECLT)
JOHNSON AND JOHNSON CONSUMER INC (JOHNSON AND JOHNSON)	KENVUE BRANDS LLC (KENVUE BRANDS)
JOHNSON AND JOHNSON CONSUMER INC MCNEIL CONSUMER HEALTHCARE DIV (J AND J CONSUMER INC)	KENVUE BRANDS LLC (KENVUE BRANDS)
LUPIN LTD (LUPIN LTD)	CHARTWELL RX SCIENCES LLC (CHARTWELL RX)
MYLAN INSTITUTIONAL LLC (MYLAN INSTITUTIONAL)	NORVIUM BIOSCIENCE LLC (NORVIUM BIOSCIENCE)
MYLAN LABORATORIES LTD (MYLAN LABS LTD)	NORVIUM BIOSCIENCE LLC (NORVIUM BIOSCIENCE)
MYLAN LABORATORIES LTD (MYLAN LABS LTD)	XIROMED LLC (XIROMED)
MYLAN PHARMACEUTICALS INC (MYLAN)	NATCO PHARMA LTD (NATCO)

MYLAN PHARMACEUTICALS INC (MYLAN)	NATCO PHARMA LTD (NATCO PHARMA)
MYLAN PHARMACEUTICALS INC (MYLAN)	NORVIUM BIOSCIENCE LLC (NORVIUM BIOSCIENCE)
MYLAN PHARMACEUTICALS INC (MYLAN PHARMS INC)	NATCO PHARMA LTD (NATCO PHARMA)
MYLAN PHARMACEUTICALS INC (MYLAN PHARMS INC)	NORVIUM BIOSCIENCE LLC (NORVIUM BIOSCIENCE)
MYLAN TECHNOLOGIES INC (MYLAN TECHNOLOGIES)	NORVIUM BIOSCIENCE LLC (NORVIUM BIOSCIENCE)
PAR PHARMACEUTICAL (PAR PHARM)	ENDO OPERATIONS LTD (ENDO OPERATIONS)
PAR PHARMACEUTICAL INC (PAR PHARM)	ENDO OPERATIONS LTD (ENDO OPERATIONS)
PAR PHARMACEUTICAL INC (PAR PHARM INC)	ENDO OPERATIONS LTD (ENDO OPERATIONS)
PAR STERILE PRODUCTS LLC (PAR STERILE PRODUCTS)	ENDO OPERATIONS LTD (ENDO OPERATIONS)
SAPTALIS PHARMACEUTICALS LLC (SAPTALIS PHARMS)	SCIEGEN PHARMACEUTICALS INC (SCIEGEN PHARMS INC)
STERISCIENCE PTE LTD (STERISCIENCE)	STERISCIENCE SPECIALITIES PTE LTD (STERISCIENCE SPECLTS)
STRIDES PHARMA GLOBAL PTE LTD (STRIDES PHARMA)	ESJAY PHARMA LLC (ESJAY PHARMA)
STRIDES PHARMA GLOBAL PTE LTD (STRIDES PHARMA)	STRIDES SOFTGELS PTE LTD (STRIDES SOFTGELS)
TARO PHARMACEUTICALS USA INC (TARO)	TARO PHARMACEUTICALS INC (TARO)
VERTICE PHARMA MANAGEMENT CORP (VERTICE)	ENCUBE ETHICALS PRIVATE LTD (ENCUBE)
ZYDUS WORLDWIDE DMCC (ZYDUS)	ZYDUS LIFESCIENCES GLOBAL FZE (ZYDUS LIFESCIENCES)

1.4 LEVOTHYROXINE SODIUM[1]

[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

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

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.

[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

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.

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.

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

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).

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 2024	MAR 2025	JUN 2025	SEP 2025	DEC 2025
DRUG PRODUCTS	23856				
LISTED SINGLE SOURCE	2772 (11.8%)				
MULTISOURCE	20814 (88.2%)				
THERAPEUTICALLY EQUIVALENT	20741 (87.9%)				
NOT THERAPEUTICALLY EQUIVALENT	73 (0.3%)				
EXCEPTIONS[4]	47 (0.2%)				
NEW MOLECULAR ENTITIES APPROVED	43				
NUMBER OF APPLICANTS	1197				

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,

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

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.
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.

[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.

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET;ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D>	AA		RHODES PHARMS	300MG;5MG	A207808	001	Mar 30, 2018	Jan DISC
>A>		@		300MG;5MG	A207808	001	Mar 30, 2018	Jan DISC
>D>	AA			300MG;7.5MG	A207808	002	Mar 30, 2018	Jan DISC
>A>		@		300MG;7.5MG	A207808	002	Mar 30, 2018	Jan DISC
>D>	AA			300MG;10MG	A207808	003	Mar 30, 2018	Jan DISC
>A>		@		300MG;10MG	A207808	003	Mar 30, 2018	Jan DISC

ACETYLCYSTEINE

SOLUTION;INHALATION, ORAL

ACETYLCYSTEINE

>A>	AN		SOMERSET THERAPS LLC	10%	A219194	001	Feb 12, 2025	Jan NEWA
>A>	AN			20%	A219194	002	Feb 12, 2025	Jan NEWA

ACYCLOVIR

OINTMENT;TOPICAL

ACYCLOVIR

>D>	AB		APOTEX	5%	A210774	001	Sep 06, 2019	Jan DISC
>A>		@		5%	A210774	001	Sep 06, 2019	Jan DISC

ALBUTEROL SULFATE

SYRUP;ORAL

ALBUTEROL SULFATE

>D>	AA		COSETTE	EQ 2MG BASE/5ML	A074454	001	Sep 25, 1995	Jan DISC
>A>		@		EQ 2MG BASE/5ML	A074454	001	Sep 25, 1995	Jan DISC

AMINOCAPROIC ACID

SOLUTION;ORAL

AMINOCAPROIC ACID

>A>	AA		AJENAT PHARMS	0.25GM/ML	A213825	001	Apr 08, 2021	Jan CAHN
>D>	AA		BELCHER	0.25GM/ML	A213825	001	Apr 08, 2021	Jan CAHN

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET;ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>D>		@	CEDIPROF INC	1.25MG;1.25MG;1.25MG;1.25MG	A210754	001	Jul 05, 2022	Jan CMFD
>A>	AB			1.25MG;1.25MG;1.25MG;1.25MG	A210754	001	Jul 05, 2022	Jan CMFD
>D>		@		2.5MG;2.5MG;2.5MG;2.5MG	A210754	002	Jul 05, 2022	Jan CMFD
>A>	AB			2.5MG;2.5MG;2.5MG;2.5MG	A210754	002	Jul 05, 2022	Jan CMFD
>D>		@		3.75MG;3.75MG;3.75MG;3.75MG	A210754	003	Jul 05, 2022	Jan CMFD
>A>	AB			3.75MG;3.75MG;3.75MG;3.75MG	A210754	003	Jul 05, 2022	Jan CMFD
>D>		@		5MG;5MG;5MG;5MG	A210754	004	Jul 05, 2022	Jan CMFD
>A>	AB			5MG;5MG;5MG;5MG	A210754	004	Jul 05, 2022	Jan CMFD
>D>		@		7.5MG;7.5MG;7.5MG;7.5MG	A210754	005	Jul 05, 2022	Jan CMFD
>A>	AB			7.5MG;7.5MG;7.5MG;7.5MG	A210754	005	Jul 05, 2022	Jan CMFD

AMPHETAMINE SULFATE

TABLET;ORAL

AMPHETAMINE SULFATE

>D>	AA		RHODES PHARMS	5MG	A213852	001	Sep 07, 2021	Jan DISC
>A>		@		5MG	A213852	001	Sep 07, 2021	Jan DISC
>D>	AA			10MG	A213852	002	Sep 07, 2021	Jan DISC
>A>		@		10MG	A213852	002	Sep 07, 2021	Jan DISC

ARFORMOTEROL TARTRATE

SOLUTION;INHALATION

ARFORMOTEROL TARTRATE

>A>	AN		AUCTA	EQ 0.015MG BASE/2ML	A218380	001	Feb 03, 2025	Jan NEWA

ARIPIPRAZOLE

FOR SUSPENSION, EXTENDED RELEASE;INTRAMUSCULAR

ABILIFY MAINTENA KIT

>D>	AP	+	OTSUKA PHARM CO LTD	300MG/VIAL	N202971	001	Feb 28, 2013	Jan CTEC
>A>		+		300MG/VIAL	N202971	001	Feb 28, 2013	Jan CTEC
>D>	AP	+!		400MG/VIAL	N202971	002	Feb 28, 2013	Jan CTEC
>A>		+!		400MG/VIAL	N202971	002	Feb 28, 2013	Jan CTEC

		FOR SUSPENSION, EXTENDED RELEASE;INTRAMUSCULAR						
		ARIPIPRAZOLE						
>D>	AP	MYLAN	300MG/VIAL		A216608	001	Dec 03, 2024	Jan DISC
>A>		@	300MG/VIAL		A216608	001	Dec 03, 2024	Jan DISC
>D>	AP		400MG/VIAL		A216608	002	Dec 03, 2024	Jan DISC
>A>		@	400MG/VIAL		A216608	002	Dec 03, 2024	Jan DISC
		SOLUTION;ORAL						
		ARIPIPRAZOLE						
>D>	AA	VISTAPHARM	1MG/ML		A212870	001	Dec 26, 2019	Jan CAHN
>A>	AA	VISTAPHARM LLC	1MG/ML		A212870	001	Dec 26, 2019	Jan CAHN
		ARMODAFINIL						
		TABLET;ORAL						
		NUVIGIL						
>D>	AB	+ CEPHALON	50MG		N021875	001	Jun 15, 2007	Jan CAHN
>D>		+ @	100MG		N021875	002	Mar 26, 2009	Jan CAHN
>D>	AB	+	150MG		N021875	003	Jun 15, 2007	Jan CAHN
>D>	AB	+	200MG		N021875	005	Mar 26, 2009	Jan CAHN
>D>	AB	+!	250MG		N021875	004	Jun 15, 2007	Jan CAHN
>A>	AB	+ NUVO PHARMS	50MG		N021875	001	Jun 15, 2007	Jan CAHN
>A>		+ @	100MG		N021875	002	Mar 26, 2009	Jan CAHN
>A>	AB	+	150MG		N021875	003	Jun 15, 2007	Jan CAHN
>A>	AB	+	200MG		N021875	005	Mar 26, 2009	Jan CAHN
>A>	AB	+!	250MG		N021875	004	Jun 15, 2007	Jan CAHN
		AZELASTINE HYDROCHLORIDE						
		SPRAY, METERED;NASAL						
		ASTEPRO						
>D>		+ @ MYLAN SPECIALITY LP	0.137MG/SPRAY		N022203	001	Oct 15, 2008	Jan CAHN
>D>		@	0.2055MG/SPRAY		N022203	002	Aug 31, 2009	Jan CAHN
>A>		+ @ NORVIUM BIOSCIENCE	0.137MG/SPRAY		N022203	001	Oct 15, 2008	Jan CAHN
>A>		@	0.2055MG/SPRAY		N022203	002	Aug 31, 2009	Jan CAHN
		AZELASTINE HYDROCHLORIDE						
>D>	AB	BIONPHARMA	0.137MG/SPRAY		A090176	001	Jul 28, 2015	Jan DISC
>A>		@	0.137MG/SPRAY		A090176	001	Jul 28, 2015	Jan DISC
		AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE						
		TABLET;ORAL						
>A>		AZILSARTAN MEDOXOMIL AND CHLORTHALIDONE						
>A>	AB	ALKEM LABS LTD	EQ 40MG MEDOXOMIL;12.5MG		A217490	001	Jan 21, 2025	Jan NFTG
>A>	AB		EQ 40MG MEDOXOMIL;25MG		A217490	002	Jan 21, 2025	Jan NFTG
		EDARBYCLOR						
>D>		+ AZURITY	EQ 40MG MEDOXOMIL;12.5MG		N202331	001	Dec 20, 2011	Jan CFTG
>A>	AB	+	EQ 40MG MEDOXOMIL;12.5MG		N202331	001	Dec 20, 2011	Jan CFTG
>D>		+!	EQ 40MG MEDOXOMIL;25MG		N202331	002	Dec 20, 2011	Jan CFTG
>A>	AB	+!	EQ 40MG MEDOXOMIL;25MG		N202331	002	Dec 20, 2011	Jan CFTG
		BACLOFEN						
		TABLET;ORAL						
		BACLOFEN						
>A>	AB	APPCO	5MG		A090334	003	Jan 31, 2025	Jan NEWA
		BENZTROPINE MESYLATE						
		TABLET;ORAL						
		BENZTROPINE MESYLATE						
>A>	AA	QUAGEN	0.5MG		A212694	001	Feb 11, 2025	Jan NEWA
>A>	AA		1MG		A212694	002	Feb 11, 2025	Jan NEWA
>A>	AA		2MG		A212694	003	Feb 11, 2025	Jan NEWA
		BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE						
		SUSPENSION;TOPICAL						
		CALCIPOTRIENE AND BETHAMETHASONE DIPROPIONATE						
>D>	AB	PADAGIS ISRAEL	0.064%;0.005%		A212367	001	Sep 11, 2020	Jan DISC
>A>		@	0.064%;0.005%		A212367	001	Sep 11, 2020	Jan DISC
		BEXAROTENE						
		CAPSULE;ORAL						
		BEXAROTENE						
>D>	AB	CIPLA	75MG		A210352	001	Dec 10, 2024	Jan DISC
>A>		@	75MG		A210352	001	Dec 10, 2024	Jan DISC

BOSENTAN

TABLET, FOR SUSPENSION;ORAL

BOSENTAN

>A>	AB		NATCO PHARMA LTD	32MG	A213154	001	Feb 05, 2025	Jan NFTG

TRACLEER

>D>		+!	ACTELION	32MG	N209279	001	Sep 05, 2017	Jan CFTG
>A>	AB	+!		32MG	N209279	001	Sep 05, 2017	Jan CFTG

>D> BREXANOLONE

>D> SOLUTION;INTRAVENOUS

>D> ZULRESSO

>D>		+!	SAGE THERAP	100MG/20ML (5MG/ML)	N211371	001	Jun 17, 2019	Jan DISC
>A>		+ @		100MG/20ML (5MG/ML)	N211371	001	Jun 17, 2019	Jan DISC

BREXPIPRAZOLE

TABLET;ORAL

BREXPIPRAZOLE

>A>	AB		ALEMBIC	0.25MG	A213683	001	Jan 13, 2025	Jan NEWA
>A>	AB			0.5MG	A213683	002	Jan 13, 2025	Jan NEWA
>A>	AB			1MG	A213683	003	Jan 13, 2025	Jan NEWA
>A>	AB			2MG	A213683	004	Jan 13, 2025	Jan NEWA
>A>	AB			3MG	A213683	005	Jan 13, 2025	Jan NEWA
>A>	AB			4MG	A213683	006	Jan 13, 2025	Jan NEWA

REXULTI

>D>		+	OTSUKA	0.25MG	N205422	001	Jul 10, 2015	Jan CTEC
>A>	AB	+		0.25MG	N205422	001	Jul 10, 2015	Jan CTEC
>D>		+		0.5MG	N205422	002	Jul 10, 2015	Jan CTEC
>A>	AB	+		0.5MG	N205422	002	Jul 10, 2015	Jan CTEC
>D>		+		1MG	N205422	003	Jul 10, 2015	Jan CTEC
>A>	AB	+		1MG	N205422	003	Jul 10, 2015	Jan CTEC
>D>		+!		2MG	N205422	004	Jul 10, 2015	Jan CTEC
>A>	AB	+!		2MG	N205422	004	Jul 10, 2015	Jan CTEC
>D>		+		3MG	N205422	005	Jul 10, 2015	Jan CTEC
>A>	AB	+		3MG	N205422	005	Jul 10, 2015	Jan CTEC
>D>		+		4MG	N205422	006	Jul 10, 2015	Jan CTEC
>A>	AB	+		4MG	N205422	006	Jul 10, 2015	Jan CTEC

BRIMONIDINE TARTRATE; TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC

BRIMONIDINE TARTRATE AND TIMOLOL MALEATE

>D>	AB		AMNEAL	0.2%;EQ 0.5% BASE	A217288	001	Dec 30, 2024	Jan DISC
>A>		@		0.2%;EQ 0.5% BASE	A217288	001	Dec 30, 2024	Jan DISC

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE;INJECTION

BUPRENORPHINE HYDROCHLORIDE

>A>	AP		SOMERSET THERAPS LLC	EQ 0.3MG BASE/ML	A219302	001	Jan 30, 2025	Jan NEWA

BUSULFAN

INJECTABLE;INJECTION

BUSULFAN

>D>	AP		APOTEX	6MG/ML	A210448	001	May 07, 2019	Jan DISC
>A>		@		6MG/ML	A210448	001	May 07, 2019	Jan DISC

CANDESARTAN CILEXETIL

TABLET;ORAL

CANDESARTAN CILEXETIL

>D>			@ ZYDUS LIFESCIENCES	4MG	A091390	001	Aug 23, 2017	Jan CMFD
>A>	AB			4MG	A091390	001	Aug 23, 2017	Jan CMFD
>D>			@	8MG	A091390	002	Aug 23, 2017	Jan CMFD
>A>	AB			8MG	A091390	002	Aug 23, 2017	Jan CMFD
>D>			@	16MG	A091390	003	Aug 23, 2017	Jan CMFD
>A>	AB			16MG	A091390	003	Aug 23, 2017	Jan CMFD
>D>			@	32MG	A091390	004	Aug 23, 2017	Jan CMFD
>A>	AB			32MG	A091390	004	Aug 23, 2017	Jan CMFD

CARBAMAZEPINE

TABLET, EXTENDED RELEASE;ORAL

CARBAMAZEPINE

>A> AB	ALKEM LABS LTD	100MG	A217277	001	Jan 14, 2025	Jan NEWA
>A> AB		200MG	A217277	002	Jan 14, 2025	Jan NEWA
>A> AB		400MG	A217277	003	Jan 14, 2025	Jan NEWA
>A> AB	TORRENT	100MG	A212524	001	Jan 13, 2025	Jan NEWA
>A> AB		200MG	A212524	002	Jan 13, 2025	Jan NEWA
>A> AB		400MG	A212524	003	Jan 13, 2025	Jan NEWA
>A> AB	YICHANG HUMANWELL	100MG	A219072	001	Jan 16, 2025	Jan NEWA
>A> AB		200MG	A219072	002	Jan 16, 2025	Jan NEWA
>A> AB		400MG	A219072	003	Jan 16, 2025	Jan NEWA

CARBIDOPA; LEVODOPA

TABLET;ORAL

CARBIDOPA AND LEVODOPA

>A> AB	ASCENT PHARMS INC	10MG;100MG	A218939	001	Jan 14, 2025	Jan NEWA
>A> AB		25MG;100MG	A218939	002	Jan 14, 2025	Jan NEWA
>A> AB		25MG;250MG	A218939	003	Jan 14, 2025	Jan NEWA

CARBINOXAMINE MALEATE

TABLET;ORAL

CARBINOXAMINE MALEATE

>D>	@ INVAGEN PHARMS	4MG	A090435	001	Apr 15, 2010	Jan CAHN
>A>	@ SENORES PHARMS	4MG	A090435	001	Apr 15, 2010	Jan CAHN

CARISOPRODOL

TABLET;ORAL

CARISOPRODOL

>A> AA	FOSUN WANBANG	350MG	A081025	001	Apr 13, 1989	Jan CAHN
>D> AA	WANBANG BIOPHARMS	350MG	A081025	001	Apr 13, 1989	Jan CAHN

CEFAZOLIN SODIUM

INJECTABLE;INJECTION

CEFAZOLIN SODIUM

>D>	QILU	EQ 3GM BASE/VIAL	A203661	003	Jan 24, 2024	Jan CAHN
>D> AP		EQ 1GM BASE/VIAL	A203661	001	Dec 28, 2015	Jan CAHN
>D>		EQ 2GM BASE/VIAL	A203661	002	Mar 11, 2022	Jan CAHN
>D> AP !		EQ 10GM BASE/VIAL	A209217	001	Oct 17, 2018	Jan CAHN
>A>	QILU ANTIBIOTICS	EQ 3GM BASE/VIAL	A203661	003	Jan 24, 2024	Jan CAHN
>A> AP		EQ 1GM BASE/VIAL	A203661	001	Dec 28, 2015	Jan CAHN
>A>		EQ 2GM BASE/VIAL	A203661	002	Mar 11, 2022	Jan CAHN
>A> AP !		EQ 10GM BASE/VIAL	A209217	001	Oct 17, 2018	Jan CAHN

CEFEPIME HYDROCHLORIDE

INJECTABLE;INJECTION

CEFEPIME HYDROCHLORIDE

>D> !	QILU	EQ 500MG BASE/VIAL	A203704	001	Feb 01, 2016	Jan CAHN
>D> AP !		EQ 1GM BASE/VIAL	A203704	002	Feb 01, 2016	Jan CAHN
>D> AP !		EQ 2GM BASE/VIAL	A203704	003	Feb 01, 2016	Jan CAHN
>A> !	QILU ANTIBIOTICS	EQ 500MG BASE/VIAL	A203704	001	Feb 01, 2016	Jan CAHN
>A> AP !		EQ 1GM BASE/VIAL	A203704	002	Feb 01, 2016	Jan CAHN
>A> AP !		EQ 2GM BASE/VIAL	A203704	003	Feb 01, 2016	Jan CAHN

CEFTRIAXONE SODIUM

INJECTABLE;INJECTION

CEFTRIAXONE

>D> AP	QILU	EQ 10GM BASE/VIAL	A209218	001	Oct 17, 2018	Jan CAHN
>A> AP	QILU ANTIBIOTICS	EQ 10GM BASE/VIAL	A209218	001	Oct 17, 2018	Jan CAHN

INJECTABLE;INTRAMUSCULAR, INTRAVENOUS

CEFTRIAXONE

>D> AP	QILU	EQ 250MG BASE/VIAL	A203702	001	Jun 29, 2016	Jan CAHN
>D> AP		EQ 500MG BASE/VIAL	A203702	002	Jun 29, 2016	Jan CAHN
>D> AP		EQ 1GM BASE/VIAL	A203702	003	Jun 29, 2016	Jan CAHN
>D> AP		EQ 2GM BASE/VIAL	A203702	004	Jun 29, 2016	Jan CAHN
>A> AP	QILU ANTIBIOTICS	EQ 250MG BASE/VIAL	A203702	001	Jun 29, 2016	Jan CAHN
>A> AP		EQ 500MG BASE/VIAL	A203702	002	Jun 29, 2016	Jan CAHN
>A> AP		EQ 1GM BASE/VIAL	A203702	003	Jun 29, 2016	Jan CAHN
>A> AP		EQ 2GM BASE/VIAL	A203702	004	Jun 29, 2016	Jan CAHN

CHLORTHALIDONE

TABLET;ORAL

CHLORTHALIDONE

>A>		@ AIPING PHARM INC	25MG	A087380	001		Jan CAHN
>A>		@	50MG	A087381	001		Jan CAHN
>D>		@ SANDOZ	25MG	A087380	001		Jan CAHN
>D>		@	50MG	A087381	001		Jan CAHN

CHLORZOXAZONE

TABLET;ORAL

CHLORZOXAZONE

>A>	AA	AJENAT PHARMS	250MG	A215540	001	Jan 24, 2023	Jan CAHN
>D>	AA	BELCHER	250MG	A215540	001	Jan 24, 2023	Jan CAHN

CINACALCET HYDROCHLORIDE

TABLET;ORAL

CINACALCET HYDROCHLORIDE

>A>	AB	PIRAMAL	EQ 30MG BASE	A210207	001	Aug 01, 2018	Jan CAHN
>A>	AB		EQ 60MG BASE	A210207	002	Aug 01, 2018	Jan CAHN
>A>	AB		EQ 90MG BASE	A210207	003	Aug 01, 2018	Jan CAHN
>D>	AB	SLATE RUN PHARMA	EQ 30MG BASE	A210207	001	Aug 01, 2018	Jan CAHN
>D>	AB		EQ 60MG BASE	A210207	002	Aug 01, 2018	Jan CAHN
>D>	AB		EQ 90MG BASE	A210207	003	Aug 01, 2018	Jan CAHN

CLOBAZAM

SUSPENSION;ORAL

CLOBAZAM

>D>		@ VISTAPHARM	2.5MG/ML	A210746	001	Jul 10, 2019	Jan CAHN
>A>		@ VISTAPHARM LLC	2.5MG/ML	A210746	001	Jul 10, 2019	Jan CAHN

CLOBETASOL PROPIONATE

LOTION;TOPICAL

IMPEKLO

>D>	+	@ MYLAN	0.05%	N213691	001	May 19, 2020	Jan CAHN
>A>	+	@ NORVIUM BIOSCIENCE	0.05%	N213691	001	May 19, 2020	Jan CAHN

CLONAZEPAM

TABLET, ORALLY DISINTEGRATING;ORAL

CLONAZEPAM

>D>	AB	SUN PHARM INDS INC	0.125MG	A078654	001	Aug 27, 2014	Jan DISC
>A>		@	0.125MG	A078654	001	Aug 27, 2014	Jan DISC
>D>	AB		0.25MG	A078654	002	Aug 27, 2014	Jan DISC
>A>		@	0.25MG	A078654	002	Aug 27, 2014	Jan DISC
>D>	AB		0.5MG	A078654	003	Aug 27, 2014	Jan DISC
>A>		@	0.5MG	A078654	003	Aug 27, 2014	Jan DISC
>D>	AB		1MG	A078654	004	Aug 27, 2014	Jan DISC
>A>		@	1MG	A078654	004	Aug 27, 2014	Jan DISC
>D>	AB		2MG	A078654	005	Aug 27, 2014	Jan DISC
>A>		@	2MG	A078654	005	Aug 27, 2014	Jan DISC

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP;ORAL

PROMETHAZINE WITH CODEINE

>D>	AA	PHARM ASSOC	10MG/5ML;6.25MG/5ML	A040650	001	Jan 31, 2006	Jan DISC
>A>		@	10MG/5ML;6.25MG/5ML	A040650	001	Jan 31, 2006	Jan DISC

COPPER CU-64 DOTATATE

SOLUTION;INTRAVENOUS

DETECTNET

>A>	+!	CURIUM	4mL (1mCi/ML)	N213227	001	Sep 03, 2020	Jan CAHN
>D>	+!	RADIOMEDIX	4mL (1mCi/ML)	N213227	001	Sep 03, 2020	Jan CAHN

CUPRIC SULFATE

INJECTABLE;INJECTION

CUPRIC SULFATE

>D>	AP !	AM REGENT	EQ 0.4MG COPPER/ML	A216324	001	Dec 16, 2022	Jan CTEC
>A>	!		EQ 0.4MG COPPER/ML	A216324	001	Dec 16, 2022	Jan CTEC
>D>	AP	APOTEX CORP	EQ 0.4MG COPPER/ML	A218745	001	Aug 19, 2024	Jan DISC
>A>		@	EQ 0.4MG COPPER/ML	A218745	001	Aug 19, 2024	Jan DISC

CYANOCOBALAMIN

INJECTABLE;INJECTION

DODEX

>D>	AP		ACCORD HLTHCARE	1MG/ML	A083022	001		Jan DISC
>A>		@		1MG/ML	A083022	001		Jan DISC

DABIGATRAN ETEXILATE MESYLATE

CAPSULE;ORAL

DABIGATRAN ETEXILATE MESYLATE

>A>	AB		DR REDDYS	EQ 75MG BASE	A208048	001	Jan 28, 2025	Jan NEWA
>A>	AB			EQ 110MG BASE	A208048	002	Jan 28, 2025	Jan NEWA
>A>	AB			EQ 150MG BASE	A208048	003	Jan 28, 2025	Jan NEWA
>A>	AB		MYLAN	EQ 75MG BASE	A208067	001	Feb 03, 2025	Jan NEWA
>A>	AB			EQ 150MG BASE	A208067	002	Feb 03, 2025	Jan NEWA

DAPTOMYCIN

POWDER;INTRAVENOUS

DAPTOMYCIN

>D>	AP		FRESENIUS KABI USA	350MG/VIAL	A213396	001	Aug 01, 2024	Jan DISC
>A>		@		350MG/VIAL	A213396	001	Aug 01, 2024	Jan DISC

DARUNAVIR

TABLET;ORAL

DARUNAVIR

>A>	AB		ANNORA PHARMA	600MG	A216168	001	Jan 21, 2025	Jan NEWA
>A>	AB			800MG	A216168	002	Jan 21, 2025	Jan NEWA

DASATINIB

TABLET;ORAL

PHYRAGO

>A>		+	HANDA THERAP	20MG	N216099	001	Dec 05, 2023	Jan CAHN
>A>		+		50MG	N216099	002	Dec 05, 2023	Jan CAHN
>A>		+		70MG	N216099	003	Dec 05, 2023	Jan CAHN
>A>		+		80MG	N216099	004	Dec 05, 2023	Jan CAHN
>A>		+!		100MG	N216099	005	Dec 05, 2023	Jan CAHN
>A>		+		140MG	N216099	006	Dec 05, 2023	Jan CAHN
>D>		+	NANOCOPOEIA	20MG	N216099	001	Dec 05, 2023	Jan CAHN
>D>		+		50MG	N216099	002	Dec 05, 2023	Jan CAHN
>D>		+		70MG	N216099	003	Dec 05, 2023	Jan CAHN
>D>		+		80MG	N216099	004	Dec 05, 2023	Jan CAHN
>D>		+!		100MG	N216099	005	Dec 05, 2023	Jan CAHN
>D>		+		140MG	N216099	006	Dec 05, 2023	Jan CAHN

DESLORATADINE

TABLET;ORAL

DESLORATADINE

>A>	AB		AJENAT PHARMS	5MG	A078355	001	Apr 19, 2012	Jan CAHN
>D>	AB		BELCHER PHARMS	5MG	A078355	001	Apr 19, 2012	Jan CAHN

DESVENLAFAXINE SUCCINATE

TABLET, EXTENDED RELEASE;ORAL

DESVENLAFAXINE SUCCINATE

>A>	AB		MACLEODS PHARMS LTD	EQ 50MG BASE	A211427	001	Jan 15, 2025	Jan NEWA
>A>	AB			EQ 100MG BASE	A211427	002	Jan 15, 2025	Jan NEWA

DEUTETRABENAZINE

TABLET;ORAL

AUSTEDO

>D>	AB	+	TEVA BRANDED PHARM	6MG	N208082	001	Apr 03, 2017	Jan CTEC
>A>		+		6MG	N208082	001	Apr 03, 2017	Jan CTEC
>D>	AB	+		9MG	N208082	002	Apr 03, 2017	Jan CTEC
>A>		+		9MG	N208082	002	Apr 03, 2017	Jan CTEC
>D>	AB	+!		12MG	N208082	003	Apr 03, 2017	Jan CTEC
>A>		+!		12MG	N208082	003	Apr 03, 2017	Jan CTEC

DEUTETRABENAZINE

>D>	AB		AUROBINDO PHARMA LTD	6MG	A215971	001	Dec 26, 2024	Jan DISC
>A>		@		6MG	A215971	001	Dec 26, 2024	Jan DISC
>D>	AB			9MG	A215971	002	Dec 26, 2024	Jan DISC
>A>		@		9MG	A215971	002	Dec 26, 2024	Jan DISC
>D>	AB			12MG	A215971	003	Dec 26, 2024	Jan DISC
>A>		@		12MG	A215971	003	Dec 26, 2024	Jan DISC

DEXMETHYLPHENIDATE HYDROCHLORIDE

TABLET;ORAL

DEXMETHYLPHENIDATE HYDROCHLORIDE

>D>	AB		RHODES PHARMS	2.5MG	A208756	001	Nov 20, 2017	Jan DISC
>A>		@		2.5MG	A208756	001	Nov 20, 2017	Jan DISC
>D>	AB			5MG	A208756	002	Nov 20, 2017	Jan DISC
>A>		@		5MG	A208756	002	Nov 20, 2017	Jan DISC
>D>	AB			10MG	A208756	003	Nov 20, 2017	Jan DISC
>A>		@		10MG	A208756	003	Nov 20, 2017	Jan DISC

DICLOFENAC POTASSIUM

FOR SOLUTION;ORAL

DICLOFENAC POTASSIUM

>A>	AB		TORRENT	50MG	A215891	001	Jan 22, 2025	Jan NEWA

DIFLUPREDNATE

EMULSION;OPHTHALMIC

DIFLUPREDNATE

>A>	AB		UPSHER SMITH LABS	0.05%	A218191	001	Feb 11, 2025	Jan NEWA

DIHYDROERGOTAMINE MESYLATE

INJECTABLE;INJECTION

DIHYDROERGOTAMINE MESYLATE

>D>	AP		CIPLA	1MG/ML	A212334	001	Sep 20, 2024	Jan DISC
>A>		@		1MG/ML	A212334	001	Sep 20, 2024	Jan DISC

DORZOLAMIDE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

DORZOLAMIDE HYDROCHLORIDE

>A>	AT		SOMERSET THERAPS LLC	EQ 2% BASE	A215004	001	Feb 11, 2025	Jan NEWA

DOXEPIN HYDROCHLORIDE

CAPSULE;ORAL

DOXEPIN HYDROCHLORIDE

>D>	AB		ADAPTIS	EQ 150MG BASE	A213796	001	Apr 19, 2022	Jan DISC
>A>		@		EQ 150MG BASE	A213796	001	Apr 19, 2022	Jan DISC

DOXYCYCLINE

CAPSULE;ORAL

DOXYCYCLINE

>A>	AB		PRINSTON INC	40MG	A217098	001	Jan 27, 2025	Jan NEWA

DOXYCYCLINE HYCLATE

INJECTABLE;INJECTION

DOXYCYCLINE HYCLATE

>D>	AP		AMNEAL	EQ 100MG BASE/VIAL	A217487	001	Dec 04, 2024	Jan DISC
>A>		@		EQ 100MG BASE/VIAL	A217487	001	Dec 04, 2024	Jan DISC

ELIGLUSTAT TARTRATE

CAPSULE;ORAL

ELIGLUSTAT TARTRATE

>D>	AB		APOTEX	EQ 84MG BASE	A212425	001	Jul 10, 2024	Jan DISC
>A>		@		EQ 84MG BASE	A212425	001	Jul 10, 2024	Jan DISC

ELTROMBOPAG OLAMINE

TABLET;ORAL

ELTROMBOPAG OLAMINE

>A>	AB		HETERO LABS LTD V	EQ 12.5MG ACID	A206788	001	Jan 17, 2025	Jan NFTG
>A>	AB			EQ 25MG ACID	A206788	002	Jan 17, 2025	Jan NFTG
>A>	AB			EQ 50MG ACID	A206788	003	Jan 17, 2025	Jan NFTG
>A>	AB			EQ 75MG ACID	A206788	004	Jan 17, 2025	Jan NFTG

PROMACTA

>D>		+	NOVARTIS	EQ 12.5MG ACID	N022291	004	Oct 20, 2011	Jan CFTG
>A>	AB	+		EQ 12.5MG ACID	N022291	004	Oct 20, 2011	Jan CFTG
>D>		+		EQ 25MG ACID	N022291	001	Nov 20, 2008	Jan CFTG
>A>	AB	+		EQ 25MG ACID	N022291	001	Nov 20, 2008	Jan CFTG
>D>		+		EQ 50MG ACID	N022291	002	Nov 20, 2008	Jan CFTG
>A>	AB	+		EQ 50MG ACID	N022291	002	Nov 20, 2008	Jan CFTG
>D>		+!		EQ 75MG ACID	N022291	003	Sep 08, 2009	Jan CFTG
>A>	AB	+!		EQ 75MG ACID	N022291	003	Sep 08, 2009	Jan CFTG

EPHEDRINE SULFATE

SOLUTION;INTRAVENOUS

EMERPHED

>D>		+!	NEXUS	50MG/10ML (5MG/ML)	N213407	001	Apr 17, 2020	Jan CFTG
>A>	AP	+!		50MG/10ML (5MG/ML)	N213407	001	Apr 17, 2020	Jan CFTG

EPHEDRINE SULFATE

>A>	AP		GLAND PHARMA LTD	50MG/10ML (5MG/ML)	A218211	001	Jan 16, 2025	Jan NFTG

EPINEPHRINE

SOLUTION;INTRAMUSCULAR, INTRAOCULAR, SUBCUTANEOUS

EPINEPHRINE

>A>	AP		GLAND PHARMA LTD	10MG/10ML (1MG/ML)	A219239	001	Feb 06, 2025	Jan NFTG

SOLUTION;INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS

EPINEPHRINE

>D>		+!	BPI LABS	10MG/10ML (1MG/ML)	N205029	002	Feb 04, 2022	Jan CFTG
>A>	AP	+!		10MG/10ML (1MG/ML)	N205029	002	Feb 04, 2022	Jan CFTG

ERLOTINIB HYDROCHLORIDE

TABLET;ORAL

ERLOTINIB HYDROCHLORIDE

>D>	AB		APOTEX	EQ 25MG BASE	A208396	001	Nov 05, 2019	Jan DISC
>A>		@		EQ 25MG BASE	A208396	001	Nov 05, 2019	Jan DISC
>D>	AB			EQ 100MG BASE	A208396	002	Nov 05, 2019	Jan DISC
>A>		@		EQ 100MG BASE	A208396	002	Nov 05, 2019	Jan DISC
>D>	AB			EQ 150MG BASE	A208396	003	Nov 05, 2019	Jan DISC
>A>		@		EQ 150MG BASE	A208396	003	Nov 05, 2019	Jan DISC
>D>	AB		SUN PHARM	EQ 25MG BASE	A210300	001	Nov 05, 2019	Jan DISC
>A>		@		EQ 25MG BASE	A210300	001	Nov 05, 2019	Jan DISC
>D>	AB			EQ 150MG BASE	A210300	003	Nov 05, 2019	Jan DISC
>A>		@		EQ 150MG BASE	A210300	003	Nov 05, 2019	Jan DISC

ERTUGLIFLOZIN

TABLET;ORAL

ERTUGLIFLOZIN

>A>	AB		HIKMA	5MG	A216842	001	Jan 21, 2025	Jan NEWA
>A>	AB			15MG	A216842	002	Jan 21, 2025	Jan NEWA

ESOMEPRAZOLE SODIUM

INJECTABLE;INTRAVENOUS

ESOMEPRAZOLE SODIUM

>A>	AP		YANGTZE	EQ 40MG BASE/VIAL	A214046	001	Jan 08, 2025	Jan NEWA

ESTRADIOL

CREAM;VAGINAL

ESTRADIOL

>D>	AB		ALVOGEN	0.01%	A209767	001	Mar 05, 2018	Jan CAHN
>A>	AB		ENCUBE	0.01%	A209767	001	Mar 05, 2018	Jan CAHN

EVEROLIMUS

TABLET, FOR SUSPENSION;ORAL

EVEROLIMUS

>A>	AB		AMNEAL	2MG	A218863	001	Jan 10, 2025	Jan NEWA
>A>	AB			3MG	A218863	002	Jan 10, 2025	Jan NEWA
>A>	AB			5MG	A218863	003	Jan 10, 2025	Jan NEWA
>A>	AB		NATCO	2MG	A217640	001	Jan 28, 2025	Jan NEWA
>A>	AB			3MG	A217640	002	Jan 28, 2025	Jan NEWA
>A>	AB			5MG	A217640	003	Jan 28, 2025	Jan NEWA

EZETIMIBE; SIMVASTATIN

TABLET;ORAL

EZETIMIBE AND SIMVASTATIN

>A>	AB		TORRENT	10MG;10MG	A209461	001	Jan 27, 2025	Jan NEWA
>A>	AB			10MG;20MG	A209461	002	Jan 27, 2025	Jan NEWA
>A>	AB			10MG;40MG	A209461	003	Jan 27, 2025	Jan NEWA
>A>	AB			10MG;80MG	A209461	004	Jan 27, 2025	Jan NEWA

FEBUXOSTAT

TABLET;ORAL

FEBUXOSTAT

>D>	BX	MSN	40MG	A210461	001	Dec 30, 2019	Jan	CTEC
>A>	AB		40MG	A210461	001	Dec 30, 2019	Jan	CTEC
>D>	BX		80MG	A210461	002	Dec 30, 2019	Jan	CTEC
>A>	AB		80MG	A210461	002	Dec 30, 2019	Jan	CTEC

FENOFIBRATE

TABLET;ORAL

FENOFIBRATE

>D>	AB	SUN PHARM	48MG	A200884	001	Sep 07, 2017	Jan	DISC
>A>		@	48MG	A200884	001	Sep 07, 2017	Jan	DISC

FLUOROURACIL

CREAM;TOPICAL

FLUOROURACIL

>A>	AB	ENCUBE	5%	A216942	001	Feb 12, 2025	Jan	NEWA

INJECTABLE;INJECTION

FLUOROURACIL

>A>	AP	KINDOS	5GM/100ML (50MG/ML)	A215699	001	Feb 06, 2025	Jan	NEWA

FORMOTEROL FUMARATE

SOLUTION;INHALATION

FORMOTEROL FUMARATE

>A>	AN	DEVA HOLDING AS	0.02MG/2ML	A218308	001	Feb 11, 2025	Jan	NEWA
>A>	AN	DR REDDYS	0.02MG/2ML	A215907	001	Jan 30, 2025	Jan	NEWA

FOSAPREPITANT DIMEGLUMINE

POWDER;INTRAVENOUS

FOSAPREPITANT DIMEGLUMINE

>D>		@ ARTHUR GRP	EQ 150MG BASE/VIAL	A213199	001	Oct 04, 2021	Jan	CAHN
>A>		@ PRAXGEN	EQ 150MG BASE/VIAL	A213199	001	Oct 04, 2021	Jan	CAHN

GABAPENTIN

SOLUTION;ORAL

GABAPENTIN

>A>	AA	AJENAT PHARMS	250MG/5ML	A091286	001	Mar 14, 2016	Jan	CAHN
>D>	AA	BELCHER	250MG/5ML	A091286	001	Mar 14, 2016	Jan	CAHN

GADOTERIDOL

INJECTABLE;INJECTION

>A>		GADOTERIDOL						
>A>	AP	HAINAN POLY	279.3MG/ML	A218749	001	Feb 11, 2025	Jan	NFTG
		PROHANCE						
>D>		+! BRACCO	279.3MG/ML	N020131	001	Nov 16, 1992	Jan	CFTG
>A>	AP	+!	279.3MG/ML	N020131	001	Nov 16, 1992	Jan	CFTG

GLIPIZIDE

TABLET;ORAL

GLIPIZIDE

>A>		@ AIPING PHARM INC	5MG	A074305	001	Apr 07, 1995	Jan	CAHN
>A>		@	10MG	A074305	002	Apr 07, 1995	Jan	CAHN
>D>		@ SANDOZ	5MG	A074305	001	Apr 07, 1995	Jan	CAHN
>D>		@	10MG	A074305	002	Apr 07, 1995	Jan	CAHN

GLYCOPYRROLATE

INJECTABLE;INJECTION

GLYCOPYRROLATE

>D>	AP	XIROMED	0.2MG/ML	A212227	001	Mar 04, 2021	Jan	DISC
>A>		@	0.2MG/ML	A212227	001	Mar 04, 2021	Jan	DISC

GUANFACINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

GUANFACINE HYDROCHLORIDE

>A>		@ FOSUN WANBANG	EQ 1MG BASE	A217638	001	Jun 12, 2024	Jan	CAHN
>A>		@	EQ 2MG BASE	A217638	002	Jun 12, 2024	Jan	CAHN
>A>		@	EQ 3MG BASE	A217638	003	Jun 12, 2024	Jan	CAHN
>A>		@	EQ 4MG BASE	A217638	004	Jun 12, 2024	Jan	CAHN
>D>		@ WANBANG BIOPHARMS	EQ 1MG BASE	A217638	001	Jun 12, 2024	Jan	CAHN
>D>		@	EQ 2MG BASE	A217638	002	Jun 12, 2024	Jan	CAHN

TABLET, EXTENDED RELEASE;ORAL
GUANFACINE HYDROCHLORIDE

>D>		@	EQ 3MG BASE	A217638	003	Jun 12, 2024	Jan CAHN
>D>		@	EQ 4MG BASE	A217638	004	Jun 12, 2024	Jan CAHN

HALCINONIDE
SOLUTION;TOPICAL
HALCINONIDE

>D>		ENCUBE	0.1%	A217671	001	May 29, 2024	Jan DISC
>A>		@	0.1%	A217671	001	May 29, 2024	Jan DISC

HALOBETASOL PROPIONATE
LOTION;TOPICAL
ULTRAVATE

>A>	+ @	LACER PHARMA	0.05%	N208183	001	Nov 06, 2015	Jan CAHN
>D>	+ @	MICAL PHARMS	0.05%	N208183	001	Nov 06, 2015	Jan CAHN

HEPARIN SODIUM
INJECTABLE;INJECTION
HEPARIN SODIUM

>D> AP		B BRAUN MEDICAL INC	5,000 UNITS/0.5ML	A208827	001	Nov 19, 2018	Jan DISC
>A>		@	5,000 UNITS/0.5ML	A208827	001	Nov 19, 2018	Jan DISC
>D> AP		HIKMA	5,000 UNITS/0.5ML	N017037	013	Apr 07, 1986	Jan CTEC
>A>			5,000 UNITS/0.5ML	N017037	013	Apr 07, 1986	Jan CTEC

HYDROCHLOROTHIAZIDE
FOR SUSPENSION;ORAL
INZIRQO

>A>							
>A>	+!	NOVITIUM PHARMA	10MG/ML	N219141	001	Jan 28, 2025	Jan NEWA

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE
TABLET;ORAL
METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE

>A> AB		SENORES PHARMS	25MG;50MG	A215789	001	Jan 08, 2025	Jan NEWA
>A> AB			25MG;100MG	A215789	002	Jan 08, 2025	Jan NEWA

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE
TABLET;ORAL
QUINAPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>D> AB		APOTEX	12.5MG;EQ 10MG BASE	A091524	001	Mar 12, 2013	Jan DISC
>A>		@	12.5MG;EQ 10MG BASE	A091524	001	Mar 12, 2013	Jan DISC
>D> AB			12.5MG;EQ 20MG BASE	A091524	002	Mar 12, 2013	Jan DISC
>A>		@	12.5MG;EQ 20MG BASE	A091524	002	Mar 12, 2013	Jan DISC
>D> AB			25MG;EQ 20MG BASE	A091524	003	Mar 12, 2013	Jan DISC
>A>		@	25MG;EQ 20MG BASE	A091524	003	Mar 12, 2013	Jan DISC

HYDROCHLOROTHIAZIDE; TRIAMTERENE
CAPSULE;ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

>A> AB		MACLEODS PHARMS LTD	25MG;37.5MG	A214611	001	Jan 28, 2025	Jan NEWA

HYDROCORTISONE ACETATE
CREAM;TOPICAL
MICORT-HC

>A>		@ LEGACY PHARMA	2%	A040398	001	Mar 29, 2002	Jan CAHN
>D>		@ SEBELA IRELAND LTD	2%	A040398	001	Mar 29, 2002	Jan CAHN

IPRATROPIUM BROMIDE
SPRAY, METERED;NASAL
IPRATROPIUM BROMIDE

>A> AB		LUPIN	0.021MG/SPRAY	A217912	001	Feb 07, 2025	Jan NEWA
>A> AB			0.042MG/SPRAY	A217886	001	Jan 27, 2025	Jan NEWA
>A> AB		RUBICON	0.021MG/SPRAY	A219222	001	Jan 14, 2025	Jan NEWA

IVERMECTIN
TABLET;ORAL
IVERMECTIN

>A> AB		RUBICON	3MG	A215922	001	Jan 22, 2025	Jan NEWA
>A>			6MG	A215922	002	Jan 22, 2025	Jan NFTG

LACTULOSE

SOLUTION;ORAL

LACTULOSE

>D>		@ VISTAPHARM	10GM/15ML	A074138	001	Sep 30, 1992	Jan CAHN
>A>		@ VISTAPHARM LLC	10GM/15ML	A074138	001	Sep 30, 1992	Jan CAHN

LAMOTRIGINE

TABLET;ORAL

LAMOTRIGINE

>A>		@ AIPING PHARM INC	25MG	A078645	001	Jan 27, 2009	Jan CAHN
>A>		@	100MG	A078645	002	Jan 27, 2009	Jan CAHN
>A>		@	150MG	A078645	003	Jan 27, 2009	Jan CAHN
>A>		@	200MG	A078645	004	Jan 27, 2009	Jan CAHN
>D>		@ SANDOZ	25MG	A078645	001	Jan 27, 2009	Jan CAHN
>D>		@	100MG	A078645	002	Jan 27, 2009	Jan CAHN
>D>		@	150MG	A078645	003	Jan 27, 2009	Jan CAHN
>D>		@	200MG	A078645	004	Jan 27, 2009	Jan CAHN

LEFLUNOMIDE

TABLET;ORAL

LEFLUNOMIDE

>A>	AB	FOSUN WANBANG	10MG	A077087	001	Sep 13, 2005	Jan CAHN
>A>	AB		20MG	A077087	002	Sep 13, 2005	Jan CAHN
>D>	AB	WANBANG BIOPHARMS	10MG	A077087	001	Sep 13, 2005	Jan CAHN
>D>	AB		20MG	A077087	002	Sep 13, 2005	Jan CAHN

LENALIDOMIDE

CAPSULE;ORAL

LENALIDOMIDE

>A>	AB	AMNEAL	2.5MG	A216213	001	Jan 31, 2025	Jan NEWA
>A>	AB		5MG	A216213	002	Jan 31, 2025	Jan NEWA
>A>	AB		10MG	A216213	003	Jan 31, 2025	Jan NEWA
>A>	AB		15MG	A216213	004	Jan 31, 2025	Jan NEWA
>A>	AB		20MG	A216213	005	Jan 31, 2025	Jan NEWA
>A>	AB		25MG	A216213	006	Jan 31, 2025	Jan NEWA

LEVETIRACETAM

INJECTABLE;INTRAVENOUS

LEVETIRACETAM IN SODIUM CHLORIDE

>A>	AP	CAPLIN	500MG/100ML (5MG/ML)	A219562	001	Jan 16, 2025	Jan NEWA
>A>	AP		1GM/100ML (10MG/ML)	A219562	002	Jan 16, 2025	Jan NEWA
>A>	AP		1.5GM/100ML (15MG/ML)	A219562	003	Jan 16, 2025	Jan NEWA

SOLUTION;ORAL

LEVETIRACETAM

>A>	AA	AJENAT PHARMS	100MG/ML	A090461	001	Sep 30, 2010	Jan CAHN
>D>	AA	BELCHER	100MG/ML	A090461	001	Sep 30, 2010	Jan CAHN

TABLET;ORAL

LEVETIRACETAM

>A>		@ CHINA RESOURCES	500MG	A205102	004	Dec 16, 2015	Jan CAHN
>A>		@	1GM	A205102	003	Dec 16, 2015	Jan CAHN
>D>		@ SECAN PHARMS	500MG	A205102	004	Dec 16, 2015	Jan CAHN
>D>		@	1GM	A205102	003	Dec 16, 2015	Jan CAHN

LEVOTHYROXINE SODIUM **

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

TABLET;ORAL

LEVOTHYROXINE SODIUM

>D>	AB2	AUROBINDO PHARMA	0.137MG	A216414	001	Jul 16, 2024	Jan DISC
>A>		@	0.137MG	A216414	001	Jul 16, 2024	Jan DISC
>D>	AB2		0.15MG	A216414	002	Jul 16, 2024	Jan DISC
>A>		@	0.15MG	A216414	002	Jul 16, 2024	Jan DISC
>D>	AB2		0.175MG	A216414	003	Jul 16, 2024	Jan DISC
>A>		@	0.175MG	A216414	003	Jul 16, 2024	Jan DISC
>D>	AB2		0.2MG	A216414	004	Jul 16, 2024	Jan DISC
>A>		@	0.2MG	A216414	004	Jul 16, 2024	Jan DISC
>D>	AB2		0.3MG	A216414	005	Jul 16, 2024	Jan DISC
>A>		@	0.3MG	A216414	005	Jul 16, 2024	Jan DISC

LISDEXAMFETAMINE DIMESYLATE

CAPSULE;ORAL

LISDEXAMFETAMINE DIMESYLATE

>A>	AB	GRANULES	10MG	A218987	001	Jan 29, 2025	Jan NEWA
>A>	AB		20MG	A218987	002	Jan 29, 2025	Jan NEWA
>A>	AB		30MG	A218987	003	Jan 29, 2025	Jan NEWA
>A>	AB		40MG	A218987	004	Jan 29, 2025	Jan NEWA
>A>	AB		50MG	A218987	005	Jan 29, 2025	Jan NEWA
>A>	AB		60MG	A218987	006	Jan 29, 2025	Jan NEWA
>A>	AB		70MG	A218987	007	Jan 29, 2025	Jan NEWA
>D>		@ SANDOZ	20MG	A202836	001	Jul 26, 2024	Jan CMFD
>A>	AB		20MG	A202836	001	Jul 26, 2024	Jan CMFD
>D>		@	30MG	A202836	002	Jul 26, 2024	Jan CMFD
>A>	AB		30MG	A202836	002	Jul 26, 2024	Jan CMFD
>D>		@	40MG	A202836	003	Jul 26, 2024	Jan CMFD
>A>	AB		40MG	A202836	003	Jul 26, 2024	Jan CMFD
>D>		@	50MG	A202836	004	Jul 26, 2024	Jan CMFD
>A>	AB		50MG	A202836	004	Jul 26, 2024	Jan CMFD
>D>		@	60MG	A202836	005	Jul 26, 2024	Jan CMFD
>A>	AB		60MG	A202836	005	Jul 26, 2024	Jan CMFD
>D>		@	70MG	A202836	006	Jul 26, 2024	Jan CMFD
>A>	AB		70MG	A202836	006	Jul 26, 2024	Jan CMFD

LOSARTAN POTASSIUM

TABLET;ORAL

LOSARTAN POTASSIUM

>D>	AB	APOTEX	25MG	A218551	001	Jun 04, 2024	Jan DISC
>A>		@	25MG	A218551	001	Jun 04, 2024	Jan DISC
>D>	AB		50MG	A218551	002	Jun 04, 2024	Jan DISC
>A>		@	50MG	A218551	002	Jun 04, 2024	Jan DISC
>D>	AB		100MG	A218551	003	Jun 04, 2024	Jan DISC
>A>		@	100MG	A218551	003	Jun 04, 2024	Jan DISC

LOTEPREDNOL ETABONATE

SUSPENSION/DROPS;OPHTHALMIC

LOTEPREDNOL ETABONATE

>A>	AB	PADAGIS US	0.5%	A215204	001	Jan 29, 2025	Jan NEWA

LURASIDONE HYDROCHLORIDE

TABLET;ORAL

LURASIDONE HYDROCHLORIDE

>A>	AB	TORRENT	60MG	A208055	005	Jan 13, 2025	Jan NEWA

MEFENAMIC ACID

CAPSULE;ORAL

MEFENAMIC ACID

>A>	AB	AJENAT PHARMS	250MG	A091608	001	Jun 02, 2014	Jan CAHN
>D>	AB	BELCHER	250MG	A091608	001	Jun 02, 2014	Jan CAHN

>A> MELOXICAM; RIZATRIPTAN BENZOATE

>A> TABLET;ORAL

>A> SYMBRAVO

>A>		+! AXSOME	20MG;EQ 10MG BASE	N215431	001	Jan 30, 2025	Jan NEWA

MESNA

TABLET;ORAL

MESNA

>A>	AB	RICONPHARMA LLC	400MG	A218871	001	Jan 13, 2025	Jan NFTG

MESNEX

>D>		+! BAXTER HLTHCARE	400MG	N020855	001	Mar 21, 2002	Jan CFTG
>A>	AB	+!	400MG	N020855	001	Mar 21, 2002	Jan CFTG

METFORMIN HYDROCHLORIDE

SOLUTION;ORAL

METFORMIN HYDROCHLORIDE

>D>	AB	VISTAPHARM	500MG/5ML	A212677	001	Aug 19, 2022	Jan CAHN
>A>	AB	VISTAPHARM LLC	500MG/5ML	A212677	001	Aug 19, 2022	Jan CAHN

TABLET, EXTENDED RELEASE;ORAL

METFORMIN HYDROCHLORIDE

>D>	AB3	SUN PHARM	500MG	A202917	001	Aug 01, 2016	Jan DISC
>A>		@	500MG	A202917	001	Aug 01, 2016	Jan DISC

TABLET, EXTENDED RELEASE;ORAL
METFORMIN HYDROCHLORIDE

>D> AB3		1GM	A202917	002	Aug 01, 2016	Jan DISC
>A>	@	1GM	A202917	002	Aug 01, 2016	Jan DISC

METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

>D>		METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE				
>D> AB		DR REDDYS LABS SA	500MG;EQ 5MG BASE	A207678	001	Aug 09, 2023	Jan CTNA
>D> AB			1GM;EQ 2.5MG BASE	A207678	002	Aug 09, 2023	Jan CTNA
>D> AB	!		1GM;EQ 5MG BASE	A207678	003	Aug 09, 2023	Jan CTNA
>A>		SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE				
>A> AB		DR REDDYS LABS SA	500MG;EQ 5MG BASE	A207678	001	Aug 09, 2023	Jan CTNA
>A> AB			1GM;EQ 2.5MG BASE	A207678	002	Aug 09, 2023	Jan CTNA
>A> AB	!		1GM;EQ 5MG BASE	A207678	003	Aug 09, 2023	Jan CTNA

METHADONE HYDROCHLORIDE

TABLET, FOR SUSPENSION;ORAL
METHADONE HYDROCHLORIDE

>D> AA		VISTAPHARM	40MG	A075082	001	Mar 25, 1998	Jan CAHN
>A> AA		VISTAPHARM LLC	40MG	A075082	001	Mar 25, 1998	Jan CAHN

METHIMAZOLE

TABLET;ORAL
METHIMAZOLE

>A> AB		SQUARE PHARMS PLC	5MG	A218830	001	Feb 05, 2025	Jan NEWA
>A> AB			10MG	A218830	002	Feb 05, 2025	Jan NEWA

METHYLENE BLUE

SOLUTION;INTRAVENOUS
METHYLENE BLUE

>A> AP		HIKMA	50MG/10ML (5MG/ML)	A216959	001	Dec 17, 2024	Jan CAHN
>A> AP		MEITHEAL	50MG/10ML (5MG/ML)	A217380	001	Jan 23, 2025	Jan CAHN
>A> AP		NANJING KING-FRIEND	50MG/10ML (5MG/ML)	A217380	001	Jan 23, 2025	Jan NEWA
>D> AP		RK PHARMA	50MG/10ML (5MG/ML)	A216959	001	Dec 17, 2024	Jan CAHN

METOCLOPRAMIDE HYDROCHLORIDE

SOLUTION;ORAL
METOCLOPRAMIDE HYDROCHLORIDE

>D>	@	VISTAPHARM	EQ 5MG BASE/5ML	A075051	001	Jan 26, 2001	Jan CAHN
>A>	@	VISTAPHARM LLC	EQ 5MG BASE/5ML	A075051	001	Jan 26, 2001	Jan CAHN

METOPROLOL TARTRATE

TABLET;ORAL
METOPROLOL TARTRATE

>A> AB		SCIEGEN PHARMS INC	25MG	A208955	001	Feb 05, 2020	Jan CAHN
>A> AB			50MG	A208955	002	Feb 05, 2020	Jan CAHN
>A> AB			100MG	A208955	003	Feb 05, 2020	Jan CAHN
>D> AB		YOUNGTECH PHARMS INC	25MG	A208955	001	Feb 05, 2020	Jan CAHN
>D> AB			50MG	A208955	002	Feb 05, 2020	Jan CAHN
>D> AB			100MG	A208955	003	Feb 05, 2020	Jan CAHN

METRONIDAZOLE

GEL;VAGINAL

>D>		METRONIDAZOLE				
>D> AB		ENCUBE	1.3%	A216795	001	Mar 18, 2024	Jan DISC
>A>	@		1.3%	A216795	001	Mar 18, 2024	Jan DISC
		NUVESSA				
>D> AB	+!	CHEMO RESEARCH SL	1.3%	N205223	001	Mar 24, 2014	Jan CTEC
>A>	+!		1.3%	N205223	001	Mar 24, 2014	Jan CTEC

MITOMYCIN

INJECTABLE;INJECTION
MITOMYCIN

>D> AP	!	ACCORD HLTHCARE	20MG/VIAL	A064144	002	Apr 30, 1998	Jan DISC
>A>	@		20MG/VIAL	A064144	002	Apr 30, 1998	Jan DISC
>D> AP		MEITHEAL	20MG/VIAL	A214505	002	Sep 08, 2022	Jan CHRS
>A> AP	!		20MG/VIAL	A214505	002	Sep 08, 2022	Jan CHRS

MODAFINIL

TABLET;ORAL

PROVIGIL

>D>	AB	+	CEPHALON	100MG	N020717	001	Dec 24, 1998	Jan CAHN
>D>	AB	+!		200MG	N020717	002	Dec 24, 1998	Jan CAHN
>A>	AB	+	NUVO PHARMS	100MG	N020717	001	Dec 24, 1998	Jan CAHN
>A>	AB	+!		200MG	N020717	002	Dec 24, 1998	Jan CAHN

MORPHINE SULFATE

SOLUTION;ORAL

MORPHINE SULFATE

>D>	AA		RHODES PHARMS	10MG/5ML	A206308	001	Jun 22, 2017	Jan DISC
>A>		@		10MG/5ML	A206308	001	Jun 22, 2017	Jan DISC
>D>	AA			20MG/5ML	A206420	001	Jul 12, 2016	Jan DISC
>A>		@		20MG/5ML	A206420	001	Jul 12, 2016	Jan DISC
>D>	AA			100MG/5ML	A206308	002	Jun 22, 2017	Jan DISC
>A>		@		100MG/5ML	A206308	002	Jun 22, 2017	Jan DISC

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

MOXIFLOXACIN HYDROCHLORIDE

>A>	AT1		MANKIND PHARMA	EQ 0.5% BASE	A217988	001	Jan 27, 2025	Jan NEWA

MYCOPHENOLATE MOFETIL

FOR SUSPENSION;ORAL

MYCOPHENOLATE MOFETIL

>D>	AB		VISTAPHARM	200MG/ML	A210370	001	Feb 12, 2019	Jan CAHN
>A>	AB		VISTAPHARM LLC	200MG/ML	A210370	001	Feb 12, 2019	Jan CAHN

MYCOPHENOLIC SODIUM

TABLET, DELAYED RELEASE;ORAL

MYCOPHENOLIC SODIUM

>A>	AB		FOSUN WANBANG	EQ 180MG BASE	A216637	001	May 29, 2024	Jan CAHN
>A>	AB			EQ 360MG BASE	A216637	002	May 29, 2024	Jan CAHN
>D>	AB		WANBANG BIOPHARMS	EQ 180MG BASE	A216637	001	May 29, 2024	Jan CAHN
>D>	AB			EQ 360MG BASE	A216637	002	May 29, 2024	Jan CAHN

NALMEFENE HYDROCHLORIDE

SOLUTION;INTRAMUSCULAR, SUBCUTANEOUS

ZURNAI (AUTOINJECTOR)

>D>		+!	PURDUE PHARMA LP	EQ 1.5MG BASE/0.5ML (EQ 1.5MG BASE/0.5ML)	N218590	001	Aug 07, 2024	Jan DISC
>A>		+	@	EQ 1.5MG BASE/0.5ML (EQ 1.5MG BASE/0.5ML)	N218590	001	Aug 07, 2024	Jan DISC

NEBIVOLOL HYDROCHLORIDE

TABLET;ORAL

NEBIVOLOL HYDROCHLORIDE

>A>	AB		MACLEODS PHARMS LTD	EQ 2.5MG BASE	A212661	001	Jan 28, 2025	Jan NEWA
>A>	AB			EQ 5MG BASE	A212661	002	Jan 28, 2025	Jan NEWA
>A>	AB			EQ 10MG BASE	A212661	003	Jan 28, 2025	Jan NEWA
>A>	AB			EQ 20MG BASE	A212661	004	Jan 28, 2025	Jan NEWA

NICARDIPINE HYDROCHLORIDE

INJECTABLE;INJECTION

NICARDIPINE HYDROCHLORIDE

>D>	AP		AMNEAL	25MG/10ML (2.5MG/ML)	A215406	001	Oct 31, 2024	Jan DISC
>A>		@		25MG/10ML (2.5MG/ML)	A215406	001	Oct 31, 2024	Jan DISC

NIMODIPINE

SOLUTION;ORAL

NIMODIPINE

>A>	AB		ALKEM LABS LTD	6MG/ML	A213409	001	Jan 22, 2025	Jan NFTG

NYMALIZE

>D>		+!	AZURITY	6MG/ML	N203340	002	Apr 08, 2020	Jan CFTG
>A>	AB	+!		6MG/ML	N203340	002	Apr 08, 2020	Jan CFTG

NITAZOXANIDE

TABLET;ORAL

NITAZOXANIDE

>D>		!	RISING	500MG	A213820	001	Nov 27, 2020	Jan CTEC
>A>	AB	!		500MG	A213820	001	Nov 27, 2020	Jan CTEC
>A>	AB		ZENARA	500MG	A214844	001	Feb 03, 2025	Jan NEWA

NITROFURANTOIN

SUSPENSION;ORAL

NITROFURANTOIN

>A>	AB		APPCO	25MG/5ML	A208909	001	Jan 14, 2025	Jan NEWA

NOREPINEPHRINE BITARTRATE

INJECTABLE;INJECTION

NOREPINEPHRINE BITARTRATE

>A>	AP		ASPIRO	EQ 1MG BASE/ML	A219163	001	Jan 31, 2025	Jan NEWA

NYSTATIN

SUSPENSION;ORAL

NYSTATIN

>D>	AA		WOCKHARDT BIO AG	100,000 UNITS/ML	A062512	001	Oct 29, 1984	Jan CAHN
>A>	AA		XTTRIUM LABS INC	100,000 UNITS/ML	A062512	001	Oct 29, 1984	Jan CAHN

>D> OLICERIDINE

>D> SOLUTION;INTRAVENOUS

>D> OLINVYK

>D>		+!	TREVENA	1MG/ML (1MG/ML)	N210730	001	Oct 30, 2020	Jan DISC
>A>		+ @		1MG/ML (1MG/ML)	N210730	001	Oct 30, 2020	Jan DISC
>D>		+!		2MG/2ML (1MG/ML)	N210730	002	Oct 30, 2020	Jan DISC
>A>		+ @		2MG/2ML (1MG/ML)	N210730	002	Oct 30, 2020	Jan DISC

OMAVELOXOLONE

CAPSULE;ORAL

SKYCLARYS

>A>		+!	BIOGEN US	50MG	N216718	001	Feb 28, 2023	Jan CAHN
>D>		+!	REATA PHARMS	50MG	N216718	001	Feb 28, 2023	Jan CAHN

OXALIPLATIN

INJECTABLE;INTRAVENOUS

OXALIPLATIN

>A>	AP		HETERO LABS LTD VI	50MG/10ML (5MG/ML)	A217925	001	Jan 27, 2025	Jan NEWA
>A>	AP			100MG/20ML (5MG/ML)	A217925	002	Jan 27, 2025	Jan NEWA

OXYCODONE HYDROCHLORIDE

SOLUTION;ORAL

OXYCODONE HYDROCHLORIDE

>D>			@ VISTAPHARM	100MG/5ML	A202537	001	Jul 30, 2012	Jan CAHN
>A>			@ VISTAPHARM LLC	100MG/5ML	A202537	001	Jul 30, 2012	Jan CAHN

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE;ORAL

PANTOPRAZOLE SODIUM

>A>	AB		GRAVITI PHARMS	EQ 20MG BASE	A219087	001	Jan 16, 2025	Jan NEWA
>A>	AB			EQ 40MG BASE	A219087	002	Jan 16, 2025	Jan NEWA
>D>	AB		INGENUS PHARMS LLC	EQ 40MG BASE	A211368	001	Mar 01, 2019	Jan DISC
>A>		@		EQ 40MG BASE	A211368	001	Mar 01, 2019	Jan DISC

PHENYTOIN

SUSPENSION;ORAL

PHENYTOIN

>D>			@ VISTAPHARM	125MG/5ML	A040342	001	Jan 31, 2001	Jan CAHN
>D>			@	125MG/5ML	A040342	002	Aug 18, 2005	Jan CAHN
>A>			@ VISTAPHARM LLC	125MG/5ML	A040342	001	Jan 31, 2001	Jan CAHN
>A>			@	125MG/5ML	A040342	002	Aug 18, 2005	Jan CAHN

POMALIDOMIDE

CAPSULE;ORAL

POMALIDOMIDE

>D>	AB		APOTEX	1MG	A210164	001	Jun 11, 2024	Jan DISC
>A>		@		1MG	A210164	001	Jun 11, 2024	Jan DISC
>D>	AB			2MG	A210164	002	Jun 11, 2024	Jan DISC

CAPSULE;ORAL
POMALIDOMIDE

>A>		@	2MG	A210164	002	Jun 11, 2024	Jan DISC
>D>	AB		3MG	A210164	003	Jun 11, 2024	Jan DISC
>A>		@	3MG	A210164	003	Jun 11, 2024	Jan DISC
>D>	AB		4MG	A210164	004	Jun 11, 2024	Jan DISC
>A>		@	4MG	A210164	004	Jun 11, 2024	Jan DISC

POTASSIUM CHLORIDE

FOR SOLUTION;ORAL
POTASSIUM CHLORIDE

>A>	AA	AJENAT PHARMS	20MEQ	A212183	001	May 06, 2019	Jan CAHN
>D>	AA	BELCHER	20MEQ	A212183	001	May 06, 2019	Jan CAHN
>D>	AA +	GENUS	20MEQ	N208019	001	Aug 19, 2015	Jan CHRS
>A>	AA +!		20MEQ	N208019	001	Aug 19, 2015	Jan CHRS
>D>	+!		40MEQ	N208019	003	Aug 25, 2023	Jan DISC
>A>	+ @		40MEQ	N208019	003	Aug 25, 2023	Jan DISC

SOLUTION;ORAL
POTASSIUM CHLORIDE

>A>	AA	AJENAT PHARMS	20MEQ/15ML	A216156	001	Mar 07, 2023	Jan CAHN
>A>	AA		40MEQ/15ML	A216156	002	Mar 07, 2023	Jan CAHN
>D>	AA	BELCHER	20MEQ/15ML	A216156	001	Mar 07, 2023	Jan CAHN
>D>	AA		40MEQ/15ML	A216156	002	Mar 07, 2023	Jan CAHN

POTASSIUM PHOSPHATE, DIBASIC; POTASSIUM PHOSPHATE, MONOBASIC

SOLUTION;INTRAVENOUS
POTASSIUM PHOSPHATES

>A>	AP	CIPLA	1.18GM/5ML (236MG/ML);1.12GM/5ML (224MG/ML)	A217892	001	Jan 24, 2025	Jan NEWA
>A>	AP		3.54GM/15ML (236MG/ML);3.36GM/15ML (224MG/ML)	A217892	002	Jan 24, 2025	Jan NEWA
>A>	AP		11.8GM/50ML (236MG/ML);11.2GM/50ML (224MG/ML)	A217892	003	Jan 24, 2025	Jan NEWA

PREDNISONE

TABLET;ORAL
PREDNISONE

>A>		@ AIPING PHARM INC	5MG	A080336	002		Jan CAHN
>D>		@ SANDOZ	5MG	A080336	002		Jan CAHN

PREGABALIN

TABLET, EXTENDED RELEASE;ORAL
PREGABALIN

>D>	AB	APOTEX	165MG	A213313	001	Apr 13, 2021	Jan DISC
>A>		@	165MG	A213313	001	Apr 13, 2021	Jan DISC
>D>	AB		330MG	A213313	002	Apr 13, 2021	Jan DISC
>A>		@	330MG	A213313	002	Apr 13, 2021	Jan DISC
>A>	AB	HQ PHARMA	330MG	A217857	001	Jan 28, 2025	Jan NEWA

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE;INJECTION
PROCAINAMIDE HYDROCHLORIDE

>A>	AP	CAPLIN	100MG/ML	A218674	001	Feb 04, 2025	Jan NEWA
>A>	AP		500MG/ML	A218674	002	Feb 04, 2025	Jan NEWA

RALTEGRAVIR POTASSIUM

TABLET;ORAL
ISENTRESS

>D>	AB +!	MSD SUB MERCK	EQ 400MG BASE	N022145	001	Oct 12, 2007	Jan CTEC
>A>	+!		EQ 400MG BASE	N022145	001	Oct 12, 2007	Jan CTEC
>D>		RALTEGRAVIR POTASSIUM					
>D>	AB	HETERO LABS LTD III	EQ 400MG BASE	A203540	001	Dec 19, 2024	Jan DISC
>A>		@	EQ 400MG BASE	A203540	001	Dec 19, 2024	Jan DISC

RANOLAZINE

TABLET, EXTENDED RELEASE;ORAL
RANOLAZINE

>A>	AB	ARTHUR GRP	500MG	A212781	001	Mar 23, 2020	Jan CAHN
>A>	AB		1GM	A212781	002	Mar 23, 2020	Jan CAHN
>D>	AB	PRAXGEN	500MG	A212781	001	Mar 23, 2020	Jan CAHN
>D>	AB		1GM	A212781	002	Mar 23, 2020	Jan CAHN
>A>	AB	TORRENT	500MG	A210407	001	Feb 04, 2025	Jan NEWA
>A>	AB		1GM	A210407	002	Feb 04, 2025	Jan NEWA

REGORAFENIB

TABLET;ORAL

>A>			REGORAFENIB					
>A>	AB		ACTAVIS LABS FL	40MG	A209728	001	Jan 13, 2025	Jan NFTG
			STIVARGA					
>D>		+!	BAYER HLTHCARE	40MG	N203085	001	Sep 27, 2012	Jan CFTG
>A>	AB	+!		40MG	N203085	001	Sep 27, 2012	Jan CFTG

ROFLUMILAST

TABLET;ORAL

			ROFLUMILAST					
>A>	AB		AUROBINDO PHARMA LTD	250MCG	A213298	002	Jan 31, 2025	Jan NEWA

ROSUVASTATIN CALCIUM

TABLET;ORAL

			CRESTOR					
>A>	AB	+	ASTRAZENECA	EQ 5MG BASE	N021366	002	Aug 12, 2003	Jan CAHN
>A>	AB	+		EQ 10MG BASE	N021366	003	Aug 12, 2003	Jan CAHN
>A>	AB	+		EQ 20MG BASE	N021366	004	Aug 12, 2003	Jan CAHN
>A>	AB	+!		EQ 40MG BASE	N021366	005	Aug 12, 2003	Jan CAHN
>D>	AB	+	IPR	EQ 5MG BASE	N021366	002	Aug 12, 2003	Jan CAHN
>D>	AB	+		EQ 10MG BASE	N021366	003	Aug 12, 2003	Jan CAHN
>D>	AB	+		EQ 20MG BASE	N021366	004	Aug 12, 2003	Jan CAHN
>D>	AB	+!		EQ 40MG BASE	N021366	005	Aug 12, 2003	Jan CAHN

SACUBITRIL; VALSARTAN

TABLET;ORAL

			SACUBITRIL AND VALSARTAN					
>A>	AB		DR REDDYS	24MG;26MG	A213627	001	Jan 13, 2025	Jan NEWA
>A>	AB			49MG;51MG	A213627	002	Jan 13, 2025	Jan NEWA
>A>	AB			97MG;103MG	A213627	003	Jan 13, 2025	Jan NEWA
>A>	AB		LUPIN	24MG;26MG	A213808	001	Jan 08, 2025	Jan NEWA
>A>	AB			49MG;51MG	A213808	002	Jan 08, 2025	Jan NEWA
>A>	AB			97MG;103MG	A213808	003	Jan 08, 2025	Jan NEWA

SELENIOUS ACID

SOLUTION;INTRAVENOUS

			SELENIOUS ACID					
>D>		+!	AM REGENT	EQ 60MCG SELENIUM/ML (EQ 60MCG SELENIUM/ML)	N209379	002	Jan 25, 2021	Jan CFTG
>A>	AP	+!		EQ 60MCG SELENIUM/ML (EQ 60MCG SELENIUM/ML)	N209379	002	Jan 25, 2021	Jan CFTG
>A>	AP		FRESENIUS KABI USA	EQ 60MCG SELENIUM/ML (EQ 60MCG SELENIUM/ML)	A218779	001	Feb 10, 2025	Jan NFTG

SELPERCATINIB

CAPSULE;ORAL

			RETEVMO					
>A>		+	ELI LILLY AND CO	40MG	N213246	001	May 08, 2020	Jan CAHN
>A>		+!		80MG	N213246	002	May 08, 2020	Jan CAHN
>D>		+	LOXO ONCOL ELI LILLY	40MG	N213246	001	May 08, 2020	Jan CAHN
>D>		+!		80MG	N213246	002	May 08, 2020	Jan CAHN

TABLET;ORAL

			RETEVMO					
>A>		+	ELI LILLY AND CO	40MG	N218160	001	Apr 10, 2024	Jan CAHN
>A>		+		80MG	N218160	002	Apr 10, 2024	Jan CAHN
>A>		+		120MG	N218160	003	Apr 10, 2024	Jan CAHN
>A>		+!		160MG	N218160	004	Apr 10, 2024	Jan CAHN
>D>		+	LOXO ONCOL ELI LILLY	40MG	N218160	001	Apr 10, 2024	Jan CAHN
>D>		+		80MG	N218160	002	Apr 10, 2024	Jan CAHN
>D>		+		120MG	N218160	003	Apr 10, 2024	Jan CAHN
>D>		+!		160MG	N218160	004	Apr 10, 2024	Jan CAHN

SEVELAMER CARBONATE

FOR SUSPENSION;ORAL

			SEVELAMER CARBONATE					
>D>	AB		INVAGEN PHARMS	800MG/PACKET	A206234	001	Jul 12, 2024	Jan DISC
>A>		@		800MG/PACKET	A206234	001	Jul 12, 2024	Jan DISC
>D>	AB			2.4GM/PACKET	A206234	002	Jul 12, 2024	Jan DISC
>A>		@		2.4GM/PACKET	A206234	002	Jul 12, 2024	Jan DISC

SEVELAMER HYDROCHLORIDE

TABLET;ORAL

SEVELAMER HYDROCHLORIDE

>A> AB	NAVINTA LLC	800MG	A218966	001	Feb 03, 2025	Jan NEWA

SILODOSIN

CAPSULE;ORAL

SILODOSIN

>A> AB	TORRENT	4MG	A210396	001	Feb 10, 2025	Jan NEWA
>A> AB		8MG	A210396	002	Feb 10, 2025	Jan NEWA

SITAGLIPTIN HYDROCHLORIDE

>A> SOLUTION;ORAL

>A> BRYNOVIN

>A>	+! AZURITY	EQ 25MG BASE/ML	N219122	001	Jan 16, 2025	Jan NEWA

SODIUM NITROPRUSSIDE

INJECTABLE;INJECTION

SODIUM NITROPRUSSIDE

>D> AP	XIROMED	25MG/ML	A211277	001	Oct 29, 2020	Jan DISC
>A>	@	25MG/ML	A211277	001	Oct 29, 2020	Jan DISC

SODIUM POLYSTYRENE SULFONATE

POWDER;ORAL, RECTAL

SODIUM POLYSTYRENE SULFONATE

>A> AA	AJENAT PHARMS	454GM/BOT	A205727	001	Feb 23, 2016	Jan CAHN
>D> AA	BELCHER	454GM/BOT	A205727	001	Feb 23, 2016	Jan CAHN

SORAFENIB TOSYLATE

TABLET;ORAL

SORAFENIB TOSYLATE

>A> AB	APOTEX	EQ 200MG BASE	A212228	001	Jan 27, 2025	Jan NEWA

SPIRONOLACTONE

TABLET;ORAL

SPIRONOLACTONE

>A> AB	GRAVITI PHARMS	25MG	A219494	001	Jan 23, 2025	Jan NEWA
>A> AB		50MG	A219494	002	Jan 23, 2025	Jan NEWA
>A> AB		100MG	A219494	003	Jan 23, 2025	Jan NEWA

SUCCINYLCHOLINE CHLORIDE

SOLUTION;INTRAMUSCULAR, INTRAVENOUS

SUCCINYLCHOLINE CHLORIDE

>A> AP	FRESENIUS KABI USA	100MG/5ML (20MG/ML)	A217884	001	Feb 11, 2025	Jan NEWA

SUNITINIB MALATE

CAPSULE;ORAL

SUNITINIB MALATE

>A> AB	FOSUN WANBANG	EQ 12.5MG BASE	A218012	001	Aug 21, 2023	Jan CAHN
>A> AB		EQ 25MG BASE	A218012	002	Aug 21, 2023	Jan CAHN
>A> AB		EQ 37.5MG BASE	A218012	003	Aug 21, 2023	Jan CAHN
>A> AB		EQ 50MG BASE	A218012	004	Aug 21, 2023	Jan CAHN
>D> AB	WANBANG BIOPHARMS	EQ 12.5MG BASE	A218012	001	Aug 21, 2023	Jan CAHN
>D> AB		EQ 25MG BASE	A218012	002	Aug 21, 2023	Jan CAHN
>D> AB		EQ 37.5MG BASE	A218012	003	Aug 21, 2023	Jan CAHN
>D> AB		EQ 50MG BASE	A218012	004	Aug 21, 2023	Jan CAHN

>A> SUZETRIGINE

>A> TABLET;ORAL

>A> JOURNAVX

>A>	+! VERTEX PHARMS INC	50MG	N219209	001	Jan 30, 2025	Jan NEWA

TACROLIMUS

CAPSULE;ORAL

TACROLIMUS

>A> AB	AJENAT PHARMS	EQ 0.5MG BASE	A206651	001	Nov 30, 2017	Jan CAHN
>A> AB		EQ 1MG BASE	A206651	002	Nov 30, 2017	Jan CAHN
>A> AB		EQ 5MG BASE	A206651	003	Nov 30, 2017	Jan CAHN
>D> AB	BELCHER	EQ 0.5MG BASE	A206651	001	Nov 30, 2017	Jan CAHN
>D> AB		EQ 1MG BASE	A206651	002	Nov 30, 2017	Jan CAHN
>D> AB		EQ 5MG BASE	A206651	003	Nov 30, 2017	Jan CAHN

INJECTABLE;INJECTION
PROGRAF

>D>		+!	ASTELLAS	EQ 5MG BASE/ML	N050709	001	Apr 08, 1994	Jan CFTG
>A>	AP	+!		EQ 5MG BASE/ML	N050709	001	Apr 08, 1994	Jan CFTG

TACROLIMUS

>A>	AP		NEXUS	EQ 5MG BASE/ML	A217108	001	Feb 12, 2025	Jan NFTG

TELMISARTAN

TABLET;ORAL
TELMISARTAN

>A>	AB		MACLEODS PHARMS LTD	20MG	A203986	001	Jan 15, 2025	Jan NEWA
>A>	AB			40MG	A203986	002	Jan 15, 2025	Jan NEWA
>A>	AB			80MG	A203986	003	Jan 15, 2025	Jan NEWA

TESTOSTERONE

SOLUTION, METERED;TRANSDERMAL
TESTOSTERONE

>D>	AT		ENCUBE	30MG/1.5ML ACTUATION	A212301	001	Jan 11, 2021	Jan DISC
>A>		@		30MG/1.5ML ACTUATION	A212301	001	Jan 11, 2021	Jan DISC

THEOPHYLLINE

TABLET, EXTENDED RELEASE;ORAL
THEOPHYLLINE

>A>	AB		AJANTA PHARMA LTD	450MG	A218401	001	Jan 13, 2025	Jan NEWA
>D>	AB		RHODES PHARMS	300MG	A214113	001	May 11, 2023	Jan DISC
>A>		@		300MG	A214113	001	May 11, 2023	Jan DISC

TRAMADOL HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
TRAMADOL HYDROCHLORIDE

>D>		!	LUPIN LTD	100MG	A200503	001	Aug 29, 2011	Jan CTEC
>A>	AB1	!		100MG	A200503	001	Aug 29, 2011	Jan CTEC
>D>				200MG	A200503	002	Aug 29, 2011	Jan CTEC
>A>	AB1			200MG	A200503	002	Aug 29, 2011	Jan CTEC
>D>				300MG	A200503	003	Aug 29, 2011	Jan CTEC
>A>	AB1			300MG	A200503	003	Aug 29, 2011	Jan CTEC
>A>	AB1		MACLEODS PHARMS LTD	100MG	A209404	001	Jan 31, 2025	Jan NEWA
>A>	AB1			200MG	A209404	002	Jan 31, 2025	Jan NEWA
>A>	AB1			300MG	A209404	003	Jan 31, 2025	Jan NEWA

TRANEXAMIC ACID

INJECTABLE;INJECTION
TRANEXAMIC ACID

>D>	AP		FRESENIUS KABI USA	100MG/ML	A091596	001	Mar 02, 2012	Jan DISC
>A>		@		100MG/ML	A091596	001	Mar 02, 2012	Jan DISC

TREOSULFAN

POWDER;INTRAVENOUS
GRAFAPEX

>A>		+!	MEDEXUS	1GM/VIAL	N214759	001	Jan 21, 2025	Jan CAHN
>A>		+!		5GM/VIAL	N214759	002	Jan 21, 2025	Jan CAHN
>A>		+!	MGFKSMB	1GM/VIAL	N214759	001	Jan 21, 2025	Jan NEWA
>A>		+!		5GM/VIAL	N214759	002	Jan 21, 2025	Jan NEWA

TREPROSTINIL

POWDER;INHALATION
TYVASO DPI

>D>		+	UNITED THERAP	0.032MG/INH	N214324	002	May 23, 2022	Jan CHRS
>A>		+!		0.032MG/INH	N214324	002	May 23, 2022	Jan CHRS
>D>		+		0.048MG/INH	N214324	003	May 23, 2022	Jan CHRS
>A>		+!		0.048MG/INH	N214324	003	May 23, 2022	Jan CHRS
>D>		+		0.08MG/INH	N214324	005	Oct 24, 2024	Jan CHRS
>A>		+!		0.08MG/INH	N214324	005	Oct 24, 2024	Jan CHRS

TRETINOIN

GEL;TOPICAL
RETIN-A

>A>	AB	+!	BAUSCH	0.01%	N017955	001		Jan CAHN
>D>	AB	+!	VALEANT INTL	0.01%	N017955	001		Jan CAHN

TRETINOIN

>A>	AB		AUROBINDO PHARMA LTD	0.01%	A218246	001	Jan 13, 2025	Jan NEWA

VALSARTAN

TABLET;ORAL

VALSARTAN

>A> AB	RENATA	40MG	A218169	001	Aug 05, 2024	Jan	CAHN
>A> AB		80MG	A218169	002	Aug 05, 2024	Jan	CAHN
>A> AB		160MG	A218169	003	Aug 05, 2024	Jan	CAHN
>A> AB		320MG	A218169	004	Aug 05, 2024	Jan	CAHN
>D> AB	RYAN LABS	40MG	A218169	001	Aug 05, 2024	Jan	CAHN
>D> AB		80MG	A218169	002	Aug 05, 2024	Jan	CAHN
>D> AB		160MG	A218169	003	Aug 05, 2024	Jan	CAHN
>D> AB		320MG	A218169	004	Aug 05, 2024	Jan	CAHN

VANCOMYCIN HYDROCHLORIDE

INJECTABLE;INJECTION

VANCOMYCIN HYDROCHLORIDE

>D>	@ MEDIMETRIKS PHARMS	EQ 500MG BASE/VIAL	A065401	001	Jun 30, 2008	Jan	CMFD
>A> AP		EQ 500MG BASE/VIAL	A065401	001	Jun 30, 2008	Jan	CMFD
>D>	@	EQ 1GM BASE/VIAL	A065401	002	Jun 30, 2008	Jan	CMFD
>A> AP		EQ 1GM BASE/VIAL	A065401	002	Jun 30, 2008	Jan	CMFD

VENLAFAXINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

VENLAFAXINE HYDROCHLORIDE

>A> AB	ABON PHARMS LLC	EQ 150MG BASE	A217841	001	Feb 07, 2025	Jan	NEWA
>A> AB		EQ 225MG BASE	A217841	002	Feb 07, 2025	Jan	NEWA
>A> AB	TORRENT	EQ 37.5MG BASE	A218180	001	Jan 28, 2025	Jan	NEWA
>A> AB		EQ 75MG BASE	A218180	002	Jan 28, 2025	Jan	NEWA
>A> AB		EQ 150MG BASE	A218180	003	Jan 28, 2025	Jan	NEWA
>A> AB		EQ 225MG BASE	A218180	004	Jan 28, 2025	Jan	NEWA

VIGABATRIN

TABLET;ORAL

VIGABATRIN

>D> AB	RYAN LABS	500MG	A215519	001	Apr 28, 2023	Jan	DISC
>A>	@	500MG	A215519	001	Apr 28, 2023	Jan	DISC

ZINC ACETATE

CAPSULE;ORAL

GALZIN

>A>	+ ETON	EQ 25MG ZINC	N020458	001	Jan 28, 1997	Jan	CAHN
>A>	+!	EQ 50MG ZINC	N020458	002	Jan 28, 1997	Jan	CAHN
>D>	+ TEVA	EQ 25MG ZINC	N020458	001	Jan 28, 1997	Jan	CAHN
>D>	+!	EQ 50MG ZINC	N020458	002	Jan 28, 1997	Jan	CAHN

ZOLPIDEM TARTRATE

TABLET;ORAL

AMBIEN

>A> AB	+ COSETTE	5MG	N019908	001	Dec 16, 1992	Jan	CAHN
>A> AB	+!	10MG	N019908	002	Dec 16, 1992	Jan	CAHN
>D> AB	+ SANOFI AVENTIS US	5MG	N019908	001	Dec 16, 1992	Jan	CAHN
>D> AB	+!	10MG	N019908	002	Dec 16, 1992	Jan	CAHN

TABLET, EXTENDED RELEASE;ORAL

AMBIEN CR

>A> AB	+ COSETTE	6.25MG	N021774	002	Sep 02, 2005	Jan	CAHN
>A> AB	+!	12.5MG	N021774	001	Sep 02, 2005	Jan	CAHN
>D> AB	+ SANOFI AVENTIS US	6.25MG	N021774	002	Sep 02, 2005	Jan	CAHN
>D> AB	+!	12.5MG	N021774	001	Sep 02, 2005	Jan	CAHN

ACETAMINOPHEN; IBUPROFEN

TABLET;ORAL

ACETAMINOPHEN AND IBUPROFEN

>A>	STRIDES PHARMA	250MG;125MG	A217241	001	Jan 17, 2025	Jan NEWA

AZELASTINE HYDROCHLORIDE

SPRAY, METERED;NASAL

AZELASTINE HYDROCHLORIDE ALLERGY

>A>	AUROBINDO PHARMA	0.2055MG/SPRAY	A216561	001	Jan 27, 2025	Jan NEWA

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET;ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

>D>	APOTEX	5MG	A211443	001	Apr 21, 2021	Jan DISC
>A>	@	5MG	A211443	001	Apr 21, 2021	Jan DISC

OMEPRAZOLE

TABLET, DELAYED RELEASE;ORAL

OMEPRAZOLE

>D>	APOTEX	20MG	A210070	001	Feb 11, 2019	Jan DISC
>A>	@	20MG	A210070	001	Feb 11, 2019	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 2025

NO JANUARY 2025 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 2025 APPROVALS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2025

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ACALABRUTINIB - CALQUENCE						
N 210259 001	>A> 10272083	Jan 21, 2035	U-2519			
	>A> 10272083	Jan 21, 2035	U-2682			
	>A> 10272083	Jan 21, 2035	U-2683			
	>A> 10272083	Jan 21, 2035	U-2684			
	>A> 10272083	Jan 21, 2035	U-2685			
	>A> 10272083	Jan 21, 2035	U-2686			
	>A> 10272083	Jan 21, 2035	U-2687			
	>A> 10272083	Jan 21, 2035	U-4109			
	>A> 9796721	Jul 01, 2036	DS DP U-2145			
	>A> 9796721	Jul 01, 2036	DS DP U-2666			
	>A> 9796721	Jul 01, 2036	DS DP U-2667			
	>A> 9796721	Jul 01, 2036	DS DP U-2668			
	>A> 9796721	Jul 01, 2036	DS DP U-2669			
	>A> 9796721	Jul 01, 2036	DS DP U-2670			
	>A> 9796721	Jul 01, 2036	DS DP U-2671			
	>A> 9796721	Jul 01, 2036	DS DP U-4108			
ACALABRUTINIB MALEATE - CALQUENCE						
N 216387 001	>A> 10272083	Jan 21, 2035	U-2519			
	>A> 10272083	Jan 21, 2035	U-2682			
	>A> 10272083	Jan 21, 2035	U-2683			
	>A> 10272083	Jan 21, 2035	U-2684			
	>A> 10272083	Jan 21, 2035	U-2685			
	>A> 10272083	Jan 21, 2035	U-2686			
	>A> 10272083	Jan 21, 2035	U-2687			
	>A> 10272083	Jan 21, 2035	U-4109			
	>A> 11059829	Jul 01, 2036	DS DP U-2145			
	>A> 11059829	Jul 01, 2036	DS DP U-2666			
	>A> 11059829	Jul 01, 2036	DS DP U-2667			
	>A> 11059829	Jul 01, 2036	DS DP U-2668			
	>A> 11059829	Jul 01, 2036	DS DP U-2669			
	>A> 11059829	Jul 01, 2036	DS DP U-2670			
	>A> 11059829	Jul 01, 2036	DS DP U-2671			
	>A> 11059829	Jul 01, 2036	DS DP U-4108			
ACORAMIDIS HYDROCHLORIDE - ATTRUBY						
N 216540 001	>A> 9913826	May 05, 2031	U-4046		>A> ODE-506	Nov 22, 2031
AMIKACIN SULFATE - ARIKAYCE KIT						
N 207356 001	>A> 12168021	May 15, 2035	U-2414			
	>A> 12168022	May 15, 2035	U-2414			
AMISULPRIDE - BARHEMSYS						
N 209510 001	>A> 12005042	Feb 09, 2038	U-1744			
	>A> 12005042	Feb 09, 2038	U-2754			
	>A> 12005042	Feb 09, 2038	U-3467			
	>A> 12194022	Mar 10, 2031	U-1744			
	>A> 12194022	Mar 10, 2031	U-3467			
AMISULPRIDE - BARHEMSYS						
N 209510 002	>A> 12005042	Feb 09, 2038	U-1744			
	>A> 12005042	Feb 09, 2038	U-2754			
	>A> 12005042	Feb 09, 2038	U-3467			
	>A> 12194022	Mar 10, 2031	U-1744			
	>A> 12194022	Mar 10, 2031	U-3467			
BACLOFEN - BACLOFEN						
A 214445 001					>A> PC	Jul 14, 2025
BENDAMUSTINE HYDROCHLORIDE - BELRAPZO						
N 205580 001	>A> 12138248	Jan 28, 2031	DP			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
BENDAMUSTINE HYDROCHLORIDE - BENDEKA						
N 208194 001	>A> 12138248	Jan 28, 2031	DP			
BENDAMUSTINE HYDROCHLORIDE - VIVIMUSTA						
N 212209 001	>A> 12208086	Jul 29, 2042	DP			
BICTEGRAVIR SODIUM; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - BIKTARVY						
N 210251 001	>A> 7390791	Jan 07, 2025	DS DP			
	>A> 7390791*PED	Jul 07, 2025				
BICTEGRAVIR SODIUM; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - BIKTARVY						
N 210251 002	>A> 7390791	Jan 07, 2025	DS DP			
	>A> 7390791*PED	Jul 07, 2025				
BUDESONIDE - TARPEYO						
N 215935 001	>A> 12171882	Jan 23, 2043	U-4085			
	>A> 12171882	Jan 23, 2043	U-4086			
	>A> 12171883	Jan 23, 2043	DP			
BUPRENORPHINE - BRIXADI						
N 210136 001	>A> 12161640	Jul 26, 2032	DP U-4100			
BUPRENORPHINE - BRIXADI						
N 210136 002	>A> 12161640	Jul 26, 2032	DP U-4100			
BUPRENORPHINE - BRIXADI						
N 210136 003	>A> 12161640	Jul 26, 2032	DP U-4100			
BUPRENORPHINE - BRIXADI						
N 210136 004	>A> 12161640	Jul 26, 2032	DP U-4100			
BUPRENORPHINE - BRIXADI						
N 210136 005	>A> 12161640	Jul 26, 2032	DP U-4100			
BUPRENORPHINE - BRIXADI						
N 210136 006	>A> 12161640	Jul 26, 2032	DP U-4100			
BUPRENORPHINE - BRIXADI						
N 210136 007	>A> 12161640	Jul 26, 2032	DP U-4100			
CABOTEGRAVIR; RILPIVIRINE - CABENUVA KIT						
N 212888 001	>A> 12178815	Jul 18, 2038	U-3348			
CABOTEGRAVIR; RILPIVIRINE - CABENUVA KIT						
N 212888 002	>A> 12178815	Jul 18, 2038	U-3348			
CANAGLIFLOZIN - INVOKANA						
N 204042 001					>A> NPP	Dec 18, 2027
					>A> PED	Jun 18, 2028
CANAGLIFLOZIN - INVOKANA						
N 204042 002					>A> NPP	Dec 18, 2027
					>A> PED	Jun 18, 2028
CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET						
N 204353 001					>A> NPP	Dec 18, 2027
					>A> PED	Jun 18, 2028
CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET						
N 204353 002					>A> NPP	Dec 18, 2027
					>A> PED	Jun 18, 2028

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2025

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET						
N 204353 003					>A> NPP	Dec 18, 2027
					>A> PED	Jun 18, 2028
CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET						
N 204353 004					>A> NPP	Dec 18, 2027
					>A> PED	Jun 18, 2028
CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR						
N 205879 001					>A> NPP	Dec 18, 2027
					>A> PED	Jun 18, 2028
CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR						
N 205879 002					>A> NPP	Dec 18, 2027
					>A> PED	Jun 18, 2028
CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR						
N 205879 003					>A> NPP	Dec 18, 2027
					>A> PED	Jun 18, 2028
CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR						
N 205879 004					>A> NPP	Dec 18, 2027
					>A> PED	Jun 18, 2028
CAPMATINIB HYDROCHLORIDE - TABRECTA						
N 213591 001	>A> 10596178	Jul 22, 2035	DP			
	>A> 12208101	Jul 22, 2035	DP			
CAPMATINIB HYDROCHLORIDE - TABRECTA						
N 213591 002	>A> 10596178	Jul 22, 2035	DP			
	>A> 12208101	Jul 22, 2035	DP			
CARBIDOPA; LEVODOPA - CREXONT						
N 217186 001	>A> 12194150	Dec 21, 2041	U-219			
	>A> 12201596	Dec 21, 2041	U-1649			
	>A> 12201596	Dec 21, 2041	U-4004			
	>A> 12201596	Dec 21, 2041	U-4005			
CARBIDOPA; LEVODOPA - CREXONT						
N 217186 002	>A> 12194150	Dec 21, 2041	U-219			
	>A> 12201596	Dec 21, 2041	U-1649			
	>A> 12201596	Dec 21, 2041	U-4004			
	>A> 12201596	Dec 21, 2041	U-4005			
CARBIDOPA; LEVODOPA - CREXONT						
N 217186 003	>A> 12194150	Dec 21, 2041	U-219			
	>A> 12201596	Dec 21, 2041	U-1649			
	>A> 12201596	Dec 21, 2041	U-4004			
	>A> 12201596	Dec 21, 2041	U-4005			
CARBIDOPA; LEVODOPA - CREXONT						
N 217186 004	>A> 12194150	Dec 21, 2041	U-219			
	>A> 12201596	Dec 21, 2041	U-1649			
	>A> 12201596	Dec 21, 2041	U-4004			
	>A> 12201596	Dec 21, 2041	U-4005			
CEDAZURIDINE; DECITABINE - INQOVI						
N 212576 001	>A> 12195496	Oct 07, 2040	DP			
CHLOROPROCAINE HYDROCHLORIDE - IHEEZO						
N 216227 001	>A> 11969403	May 14, 2039	DP			

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COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - GENVOYA							
N 207561	001	>A> 7390791	Jan 07, 2025	DS DP			
		>A> 7390791*PED	Jul 07, 2025				
CRINECERFONT - CRENESSITY							
N 218808	001	>A> 10905690	Jan 21, 2035	U-4049		>A> NCE	Dec 13, 2029
		>A> 11311544	Jan 21, 2035	U-4049			
		>A> 11730739	Jan 21, 2035	U-4049			
		>A> 12128033	Jun 09, 2041	DS U-4049			
CRINECERFONT - CRENESSITY							
N 218808	002	>A> 10905690	Jan 21, 2035	U-4049		>A> NCE	Dec 13, 2029
		>A> 11311544	Jan 21, 2035	U-4049			
		>A> 11730739	Jan 21, 2035	U-4049			
		>A> 12128033	Jun 09, 2041	DS U-4049			
CRINECERFONT - CRENESSITY							
N 218808	003	>A> 10905690	Jan 21, 2035	U-4049		>A> NCE	Dec 13, 2029
		>A> 11311544	Jan 21, 2035	U-4049			
		>A> 11730739	Jan 21, 2035	U-4049			
		>A> 12128033	Jun 09, 2041	DS U-4049			
CRINECERFONT - CRENESSITY							
N 218820	001	>A> 10905690	Jan 21, 2035	U-4049		>A> NCE	Dec 13, 2029
		>A> 11311544	Jan 21, 2035	U-4049			
		>A> 11730739	Jan 21, 2035	U-4049			
		>A> 12128033	Jun 09, 2041	DS U-4049			
DARIDOREXANT HYDROCHLORIDE - QUVIVIQ							
N 214985	001					>A> M-200	Sep 30, 2027
DARIDOREXANT HYDROCHLORIDE - QUVIVIQ							
N 214985	002					>A> M-200	Sep 30, 2027
DEOXYCHOLIC ACID - KYBELLA							
N 206333	001	>A> 12161653	Feb 17, 2032	U-1940			
DEUTIVACAFTOR; TEZACAFTOR; VANZACAFTOR CALCIUM - ALYFTREK							
N 218730	001	>A> 10022352	Apr 09, 2027	DP U-4081		>A> NCE	Dec 20, 2029
		>A> 10047053	May 17, 2032	DS			
		>A> 10081621	Mar 25, 2031	DP U-4087			
		>A> 10239867	Apr 09, 2027	DS DP U-4090			
		>A> 10646481	Aug 13, 2029	DP			
		>A> 11066417	Feb 14, 2039	DS DP			
		>A> 11564916	Aug 13, 2029	U-4095			
		>A> 11578062	Mar 25, 2031	DP U-4096			
		>A> 11639347	Apr 09, 2027	DS DP U-4090			
		>A> 11866450	Feb 14, 2039	U-4082			
		>A> 11873300	Aug 13, 2040	DS DP U-4083			
		>A> 7495103	May 20, 2027	DS DP			
		>A> 7645789	May 01, 2027	DS DP			
		>A> 7776905	Jun 03, 2027	DS DP			
		>A> 8324242	Aug 05, 2027	U-4090			
		>A> 8354427	Jul 06, 2026	U-4091			
		>A> 8410274	Dec 28, 2026	DP			
		>A> 8415387	Nov 12, 2027	U-4082			
		>A> 8598181	May 01, 2027	U-4090			
		>A> 8623905	May 01, 2027	DS DP			
		>A> 8629162	Jun 24, 2025	U-4084			
		>A> 8754224	Dec 28, 2026	DS DP			
		>A> 8865902	May 17, 2032	DS DP			
		>A> 9181192	May 17, 2032	DS DP U-4094			
		>A> 9512079	May 17, 2032	DS DP U-4098			
		>A> 9670163	Dec 28, 2026	DP U-4080			
		>A> 9931334	Dec 28, 2026	DP U-4080			
		>A> 9974781	Apr 09, 2027	DP U-4082			

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DEUTIVACAFTOR; TEZACAFTOR; VANZACAFTOR CALCIUM - ALYFTREK							
N 218730	001	>A> 10022352	Apr 09, 2027		DP U-4081	>A> NCE	Dec 20, 2029
		>A> 10047053	May 17, 2032	DS			
		>A> 10081621	Mar 25, 2031		DP U-4087		
		>A> 10239867	Apr 09, 2027	DS	DP U-4090		
		>A> 10646481	Aug 13, 2029		DP		
		>A> 11066417	Feb 14, 2039	DS	DP		
		>A> 11564916	Aug 13, 2029		U-4095		
		>A> 11578062	Mar 25, 2031		DP U-4096		
		>A> 11639347	Apr 09, 2027	DS	DP U-4090		
		>A> 11866450	Feb 14, 2039		U-4082		
		>A> 11873300	Aug 13, 2040	DS	DP U-4083		
		>A> 7495103	May 20, 2027	DS	DP		
		>A> 7645789	May 01, 2027	DS	DP		
		>A> 7776905	Jun 03, 2027	DS	DP		
		>A> 8324242	Aug 05, 2027		U-4090		
		>A> 8354427	Jul 06, 2026		U-4091		
		>A> 8410274	Dec 28, 2026		DP		
		>A> 8415387	Nov 12, 2027		U-4082		
		>A> 8598181	May 01, 2027		U-4090		
		>A> 8623905	May 01, 2027	DS	DP		
		>A> 8629162	Jun 24, 2025		U-4084		
		>A> 8754224	Dec 28, 2026	DS	DP		
		>A> 8865902	May 17, 2032	DS	DP		
		>A> 9181192	May 17, 2032	DS	DP U-4094		
		>A> 9512079	May 17, 2032	DS	DP U-4098		
		>A> 9670163	Dec 28, 2026		DP U-4080		
		>A> 9931334	Dec 28, 2026		DP U-4080		
		>A> 9974781	Apr 09, 2027		DP U-4082		
DEUTIVACAFTOR; TEZACAFTOR; VANZACAFTOR CALCIUM - ALYFTREK							
N 218730	002	>A> 10022352	Apr 09, 2027		DP U-4081	>A> NCE	Dec 20, 2029
		>A> 10047053	May 17, 2032	DS			
		>A> 10058546	Jul 15, 2033		U-4093		
		>A> 10081621	Mar 25, 2031		DP U-4087		
		>A> 10206877	Apr 14, 2035		DP U-4092		
		>A> 10239867	Apr 09, 2027	DS	DP U-4090		
		>A> 10646481	Aug 13, 2029		DP		
		>A> 11066417	Feb 14, 2039	DS	DP		
		>A> 11564916	Aug 13, 2029		U-4095		
		>A> 11578062	Mar 25, 2031		DP U-4096		
		>A> 11639347	Apr 09, 2027	DS	DP U-4090		
		>A> 11866450	Feb 14, 2039		U-4082		
		>A> 11873300	Aug 13, 2040	DS	DP U-4083		
		>A> 11951212	Apr 14, 2035		DP U-4089		
		>A> 12186306	Jan 10, 2043		U-4088		
		>A> 7495103	May 20, 2027	DS	DP		
		>A> 7645789	May 01, 2027	DS	DP		
		>A> 7776905	Jun 03, 2027	DS	DP		
		>A> 8324242	Aug 05, 2027		U-4090		
		>A> 8354427	Jul 06, 2026		U-4091		
		>A> 8410274	Dec 28, 2026		DP		
		>A> 8415387	Nov 12, 2027		U-4082		
		>A> 8598181	May 01, 2027		U-4090		
		>A> 8623905	May 01, 2027	DS	DP		
		>A> 8629162	Jun 24, 2025		U-4084		
		>A> 8754224	Dec 28, 2026	DS	DP		
		>A> 8865902	May 17, 2032	DS	DP		
		>A> 9012496	Jul 15, 2033		U-4097		
		>A> 9181192	May 17, 2032	DS	DP U-4094		
		>A> 9512079	May 17, 2032	DS	DP U-4098		
		>A> 9670163	Dec 28, 2026		DP U-4080		
		>A> 9931334	Dec 28, 2026		DP U-4080		
		>A> 9974781	Apr 09, 2027		DP U-4082		
DONEPEZIL HYDROCHLORIDE - ADLARITY							
N 212304	001	>A> 12161767	Dec 30, 2036	DS	DP U-3334		
		>A> 12168075	Dec 30, 2036		U-3334		

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DONEPEZIL HYDROCHLORIDE - ADLARITY							
N 212304	001	>A> 12161767	Dec 30, 2036	DS DP U-3334			
		>A> 12168075	Dec 30, 2036	U-3334			
DONEPEZIL HYDROCHLORIDE - ADLARITY							
N 212304	002	>A> 12161767	Dec 30, 2036	DS DP U-3334			
		>A> 12168075	Dec 30, 2036	U-3334			
DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - MEMANTINE HYDROCHLORIDE AND DONEPEZIL HYDROCHLORIDE							
A 208328	001					>A> PC	Jul 15, 2025
DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - MEMANTINE HYDROCHLORIDE AND DONEPEZIL HYDROCHLORIDE							
A 208328	002					>A> PC	Jul 15, 2025
DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE							
N 212516	001	>A> 12171742	Apr 13, 2037	DP			
DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE							
N 212516	002	>A> 12171742	Apr 13, 2037	DP			
DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE							
N 212516	003	>A> 12171742	Apr 13, 2037	DP			
DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE							
N 212516	004	>A> 12171742	Apr 13, 2037	DP			
EDARAVONE - RADICAVA ORS							
N 215446	001	>A> 12194025	Nov 12, 2041	U-4111			
ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)							
N 212273	001	>A> 10081621	Mar 25, 2031	DP U-3032			
		>A> 10081621	Mar 25, 2031	DP U-3157			
		>A> 10081621	Mar 25, 2031	DP U-4075			
		>A> 10239867	Apr 09, 2027	DS DP U-3033			
		>A> 10239867	Apr 09, 2027	DS DP U-3158			
		>A> 10758534	Oct 06, 2035	DS DP U-3028			
		>A> 10758534	Oct 06, 2035	DS DP U-3144			
		>A> 10758534	Oct 06, 2035	DS DP U-4073			
		>A> 10793547	Dec 08, 2037	DS DP U-3028			
		>A> 10793547	Dec 08, 2037	DS DP U-3144			
		>A> 10793547	Dec 08, 2037	DS DP U-4073			
		>A> 11179367	Dec 08, 2037	DP U-3253			
		>A> 11179367	Dec 08, 2037	DP U-4071			
		>A> 11426407	Oct 06, 2035	DS DP U-3425			
		>A> 11426407	Oct 06, 2035	DS DP U-4070			
		>A> 11517564	Dec 08, 2037	DP U-3498			
		>A> 11517564	Dec 08, 2037	DP U-4067			
		>A> 11564916	Aug 13, 2029	U-3525			
		>A> 11564916	Aug 13, 2029	U-4063			
		>A> 11578062	Mar 25, 2031	DP U-3544			
		>A> 11578062	Mar 25, 2031	DP U-4054			
		>A> 11639347	Apr 09, 2027	DS DP U-3587			
		>A> 11639347	Apr 09, 2027	DS DP U-4056			
		>A> 8324242	Aug 05, 2027	U-3028			
		>A> 8324242	Aug 05, 2027	U-3144			
		>A> 8324242	Aug 05, 2027	U-4073			
		>A> 8415387	Nov 12, 2027	U-3028			
		>A> 8415387	Nov 12, 2027	U-3144			
		>A> 8415387	Nov 12, 2027	U-4073			
		>A> 8598181	May 01, 2027	U-3028			
		>A> 8598181	May 01, 2027	U-3144			
		>A> 8598181	May 01, 2027	U-4056			
		>A> 8629162	Jun 24, 2025	U-3030			
		>A> 8629162	Jun 24, 2025	U-3146			
		>A> 8629162	Jun 24, 2025	U-4079			
		>A> 9670163	Dec 28, 2026	DP U-3031			

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APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)							
N 212273	001	>A> 9670163	Dec 28, 2026			DP U-3155	
		>A> 9670163	Dec 28, 2026			DP U-4078	
		>A> 9931334	Dec 28, 2026			DP U-3031	
		>A> 9931334	Dec 28, 2026			DP U-3155	
		>A> 9931334	Dec 28, 2026			DP U-4078	
		>A> 9974781	Apr 09, 2027			DP U-3028	
		>A> 9974781	Apr 09, 2027			DP U-3144	
		>A> 9974781	Apr 09, 2027			DP U-4073	
ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)							
N 212273	002	>A> 10081621	Mar 25, 2031			DP U-3157	
		>A> 10081621	Mar 25, 2031			DP U-4075	
		>A> 10239867	Apr 09, 2027		DS	DP U-3158	
		>A> 10239867	Apr 09, 2027		DS	DP U-4056	
		>A> 10758534	Oct 06, 2035		DS	DP U-3144	
		>A> 10758534	Oct 06, 2035		DS	DP U-4073	
		>A> 10793547	Dec 08, 2037		DS	DP U-3144	
		>A> 10793547	Dec 08, 2037		DS	DP U-4073	
		>A> 11179367	Dec 08, 2037			DP U-3253	
		>A> 11179367	Dec 08, 2037			DP U-4071	
		>A> 11426407	Oct 06, 2035		DS	DP U-3425	
		>A> 11426407	Oct 06, 2035		DS	DP U-4070	
		>A> 11517564	Dec 08, 2037			DP U-3498	
		>A> 11517564	Dec 08, 2037			DP U-4069	
		>A> 11564916	Aug 13, 2029			U-3525	
		>A> 11564916	Aug 13, 2029			U-4063	
		>A> 11578062	Mar 25, 2031			DP U-3544	
		>A> 11578062	Mar 25, 2031			DP U-4054	
		>A> 11639347	Apr 09, 2027		DS	DP U-3587	
		>A> 11639347	Apr 09, 2027		DS	DP U-4056	
		>A> 8324242	Aug 05, 2027			U-3144	
		>A> 8324242	Aug 05, 2027			U-4073	
		>A> 8415387	Nov 12, 2027			U-3144	
		>A> 8415387	Nov 12, 2027			U-4073	
		>A> 8598181	May 01, 2027			U-3144	
		>A> 8598181	May 01, 2027			U-4056	
		>A> 8629162	Jun 24, 2025			U-3146	
		>A> 8629162	Jun 24, 2025			U-4079	
		>A> 9670163	Dec 28, 2026			DP U-3155	
		>A> 9670163	Dec 28, 2026			DP U-4078	
		>A> 9931334	Dec 28, 2026			DP U-3155	
		>A> 9931334	Dec 28, 2026			DP U-4078	
		>A> 9974781	Apr 09, 2027			DP U-3144	
		>A> 9974781	Apr 09, 2027			DP U-4073	
ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)							
N 217660	001	>A> 10081621	Mar 25, 2031			DP U-3600	
		>A> 10081621	Mar 25, 2031			DP U-4065	
		>A> 10239867	Apr 09, 2027		DS	DP U-3590	
		>A> 10239867	Apr 09, 2027		DS	DP U-4053	
		>A> 10272046	Feb 27, 2033			DP U-3599	
		>A> 10272046	Feb 27, 2033			DP U-4062	
		>A> 10758534	Oct 06, 2035		DS	DP U-3589	
		>A> 10758534	Oct 06, 2035		DS	DP U-4066	
		>A> 10793547	Dec 08, 2037		DS	DP U-3588	
		>A> 10793547	Dec 08, 2037		DS	DP U-4066	
		>A> 11147770	Feb 27, 2033			DP U-3598	
		>A> 11147770	Feb 27, 2033			DP U-4060	
		>A> 11179367	Dec 08, 2037			DP U-3597	
		>A> 11179367	Dec 08, 2037			DP U-4059	
		>A> 11426407	Oct 06, 2035		DS	DP U-3595	
		>A> 11426407	Oct 06, 2035		DS	DP U-4058	
		>A> 11517564	Dec 08, 2037			DP U-3586	
		>A> 11517564	Dec 08, 2037			DP U-4057	
		>A> 11564916	Aug 13, 2029			U-3585	
		>A> 11564916	Aug 13, 2029			U-4055	
		>A> 11578062	Mar 25, 2031			DP U-3584	
		>A> 11578062	Mar 25, 2031			DP U-4054	

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ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)							
N 217660	001	>A> 11639347	Apr 09, 2027		DS	DP U-3583	
		>A> 11639347	Apr 09, 2027		DS	DP U-4053	
		>A> 11752106	Feb 27, 2033			DP U-3696	
		>A> 11752106	Feb 27, 2033			DP U-4052	
		>A> 8324242	Aug 05, 2027			U-3589	
		>A> 8324242	Aug 05, 2027			U-4066	
		>A> 8415387	Nov 12, 2027			U-3589	
		>A> 8415387	Nov 12, 2027			U-4066	
		>A> 8598181	May 01, 2027			U-3589	
		>A> 8598181	May 01, 2027			U-4066	
		>A> 8629162	Jun 24, 2025			U-3592	
		>A> 8629162	Jun 24, 2025			U-4072	
		>A> 9670163	Dec 28, 2026			DP U-3591	
		>A> 9670163	Dec 28, 2026			DP U-4068	
		>A> 9931334	Dec 28, 2026			DP U-3591	
		>A> 9931334	Dec 28, 2026			DP U-4068	
		>A> 9974781	Apr 09, 2027			DP U-3589	
		>A> 9974781	Apr 09, 2027			DP U-4066	
ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)							
N 217660	002	>A> 10081621	Mar 25, 2031			DP U-3600	
		>A> 10081621	Mar 25, 2031			DP U-4065	
		>A> 10239867	Apr 09, 2027		DS	DP U-3590	
		>A> 10239867	Apr 09, 2027		DS	DP U-4053	
		>A> 10272046	Feb 27, 2033			DP U-3599	
		>A> 10272046	Feb 27, 2033			DP U-4062	
		>A> 10758534	Oct 06, 2035		DS	DP U-3589	
		>A> 10758534	Oct 06, 2035		DS	DP U-4066	
		>A> 10793547	Dec 08, 2037		DS	DP U-3588	
		>A> 10793547	Dec 08, 2037		DS	DP U-4066	
		>A> 11147770	Feb 27, 2033			DP U-3598	
		>A> 11147770	Feb 27, 2033			DP U-4060	
		>A> 11179367	Dec 08, 2037			DP U-3597	
		>A> 11179367	Dec 08, 2037			DP U-4059	
		>A> 11426407	Oct 06, 2035		DS	DP U-3595	
		>A> 11426407	Oct 06, 2035		DS	DP U-4058	
		>A> 11517564	Dec 08, 2037			DP U-3586	
		>A> 11517564	Dec 08, 2037			DP U-4057	
		>A> 11564916	Aug 13, 2029			U-3585	
		>A> 11564916	Aug 13, 2029			U-4055	
		>A> 11578062	Mar 25, 2031			DP U-3584	
		>A> 11578062	Mar 25, 2031			DP U-4054	
		>A> 11639347	Apr 09, 2027		DS	DP U-3583	
		>A> 11639347	Apr 09, 2027		DS	DP U-4053	
		>A> 11752106	Feb 27, 2033			DP U-3696	
		>A> 11752106	Feb 27, 2033			DP U-4052	
		>A> 8324242	Aug 05, 2027			U-3589	
		>A> 8324242	Aug 05, 2027			U-4066	
		>A> 8415387	Nov 12, 2027			U-3589	
		>A> 8415387	Nov 12, 2027			U-4066	
		>A> 8598181	May 01, 2027			U-3589	
		>A> 8598181	May 01, 2027			U-4066	
		>A> 8629162	Jun 24, 2025			U-3592	
		>A> 8629162	Jun 24, 2025			U-4072	
		>A> 9670163	Dec 28, 2026			DP U-3591	
		>A> 9670163	Dec 28, 2026			DP U-4068	
		>A> 9931334	Dec 28, 2026			DP U-3591	
		>A> 9931334	Dec 28, 2026			DP U-4068	
		>A> 9974781	Apr 09, 2027			DP U-3589	
		>A> 9974781	Apr 09, 2027			DP U-4066	
EMPAGLIFLOZIN; LINAGLIPTIN - GLYXAMBI							
N 206073	001	>A> 12178819	May 04, 2027			DP	
EMPAGLIFLOZIN; LINAGLIPTIN - GLYXAMBI							
N 206073	002	>A> 12178819	May 04, 2027			DP	

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EMTRICITABINE; RILPIVIRINE HYDROCHLORIDE; TENOFOVIR ALAFENAMIDE FUMARATE - ODEFSEY							
N 208351	001	>A> 7390791	Jan 07, 2025	DS DP			
		>A> 7390791*PED	Jul 07, 2025				
EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - DESCOVY							
N 208215	001	>A> 7390791	Jan 07, 2025	DS DP			
		>A> 7390791*PED	Jul 07, 2025				
EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - DESCOVY							
N 208215	002	>A> 7390791	Jan 07, 2025	DS DP			
		>A> 7390791*PED	Jul 07, 2025				
ENCORAFENIB - BRAFTOVI							
N 210496	002	>A> 10005761	Aug 27, 2030	U-2335			
		>A> 10005761	Aug 27, 2030	U-2802			
		>A> 10005761	Aug 27, 2030	U-2803			
		>A> 10005761	Aug 27, 2030	U-3738			
		>A> 10005761	Aug 27, 2030	U-4051			
		>A> 10258622	Nov 21, 2032	U-2802			
		>A> 10258622	Nov 21, 2032	U-4051			
		>A> 8541575	Feb 26, 2030	DS DP U-2335			
		>A> 8541575	Feb 26, 2030	DS DP U-2802			
		>A> 8541575	Feb 26, 2030	DS DP U-2803			
		>A> 8541575	Feb 26, 2030	DS DP U-3738			
		>A> 8541575	Feb 26, 2030	DS DP U-4051			
		>A> 9314464	Jul 04, 2031	U-2336			
		>A> 9314464	Jul 04, 2031	U-2802			
		>A> 9314464	Jul 04, 2031	U-2803			
		>A> 9314464	Jul 04, 2031	U-3738			
		>A> 9314464	Jul 04, 2031	U-4051			
		>A> 9474754	Aug 05, 2033	U-2802			
		>A> 9474754	Aug 05, 2033	U-4051			
		>A> 9850230	Aug 27, 2030	U-2334			
		>A> 9850230	Aug 27, 2030	U-2802			
		>A> 9850230	Aug 27, 2030	U-2803			
		>A> 9850230	Aug 27, 2030	U-3738			
		>A> 9850230	Aug 27, 2030	U-4051			
ENSARTINIB HYDROCHLORIDE - ENSACOVE							
N 218171	001	>A> 10899744	Jun 01, 2037	DS U-4099		>A> NCE	Dec 18, 2029
		>A> 8551995	Feb 09, 2029	DS			
		>A> 9126947	Nov 29, 2031	DS			
		>A> 9296724	Jun 18, 2029	DS U-4099			
ENSARTINIB HYDROCHLORIDE - ENSACOVE							
N 218171	002	>A> 10899744	Jun 01, 2037	DS U-4099		>A> NCE	Dec 18, 2029
		>A> 8551995	Feb 09, 2029	DS			
		>A> 9126947	Nov 29, 2031	DS			
		>A> 9296724	Jun 18, 2029	DS U-4099			
ENZALUTAMIDE - XTANDI							
N 203415	001	>A> 12161628	Feb 23, 2037	U-4101			
		>A> 12161628	Feb 23, 2037	U-4102			
		>A> 12161628	Feb 23, 2037	U-4103			
		>A> 12161628	Feb 23, 2037	U-4104			
ENZALUTAMIDE - XTANDI							
N 213674	001	>A> 12161628	Feb 23, 2037	U-4101			
		>A> 12161628	Feb 23, 2037	U-4102			
		>A> 12161628	Feb 23, 2037	U-4103			
		>A> 12161628	Feb 23, 2037	U-4104			
ENZALUTAMIDE - XTANDI							
N 213674	002	>A> 12161628	Feb 23, 2037	U-4101			
		>A> 12161628	Feb 23, 2037	U-4102			
		>A> 12161628	Feb 23, 2037	U-4103			

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ENZALUTAMIDE - XTANDI							
N 213674	002	>A> 12161628	Feb 23, 2037	U-4104			
ESKETAMINE HYDROCHLORIDE - SPRAVATO							
N 211243	001	>A> 10869844	Sep 10, 2035	U-3034			
		>A> 10869844	Sep 10, 2035	U-3035			
		>A> 10869844	Sep 10, 2035	U-3036			
		>A> 10869844	Sep 10, 2035	U-4113			
		>A> 10869844	Sep 10, 2035	U-4114			
		>A> 11173134	Sep 10, 2035	U-3257			
		>A> 11173134	Sep 10, 2035	U-3536			
		>A> 11173134	Sep 10, 2035	U-4115			
		>A> 11311500	Sep 10, 2035	U-3034			
		>A> 11311500	Sep 10, 2035	U-3035			
		>A> 11311500	Sep 10, 2035	U-3036			
		>A> 11311500	Sep 10, 2035	U-4116			
		>A> 11311500	Sep 10, 2035	U-4117			
		>A> 11446260	Mar 14, 2034	U-3444			
		>A> 11446260	Mar 14, 2034	U-3445			
		>A> 11446260	Mar 14, 2034	U-3446			
		>A> 11446260	Mar 14, 2034	U-4118			
		>A> 11446260	Mar 14, 2034	U-4119			
		>A> 11883526	Feb 18, 2040	U-3812			
		>A> 11883526	Feb 18, 2040	U-3813			
		>A> 11883526	Feb 18, 2040	U-4120			
		>A> 8785500	Mar 05, 2033	U-2502			
		>A> 8785500	Mar 05, 2033	U-4112			
		>A> 9592207	Mar 20, 2027	U-2502			
		>A> 9592207	Mar 20, 2027	U-4112			
ETHINYL ESTRADIOL; NORETHINDRONE ACETATE - FEMLYV							
N 218718	001	>A> 12178824	Jun 24, 2041	DP			
FOSCARBIDOPA; FOSLEVODOPA - VYALEV							
N 216962	001					>A> NP	Oct 16, 2027
IBRUTINIB - IMBRUVICA							
N 205552	001	>A> 8476284	Dec 28, 2026	U-1650			
		>A> 8476284	Dec 28, 2026	U-1946			
		>A> 8476284*PED	Jun 28, 2027				
		>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-2241			
		>A> 8497277	Dec 28, 2026	U-2242			
		>A> 8497277	Dec 28, 2026	U-3422			
		>A> 8497277*PED	Jun 28, 2027				
		>A> 9540382	Aug 18, 2033	U-1650			
		>A> 9540382	Aug 18, 2033	U-1684			
		>A> 9540382	Aug 18, 2033	U-1946			
		>A> 9540382*PED	Feb 18, 2034				
IBRUTINIB - IMBRUVICA							
N 205552	002	>A> 8476284	Dec 28, 2026	U-1650			
		>A> 8476284	Dec 28, 2026	U-1946			
		>A> 8476284*PED	Jun 28, 2027				
		>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-2241			
		>A> 8497277	Dec 28, 2026	U-2242			
		>A> 8497277	Dec 28, 2026	U-3422			
		>A> 8497277*PED	Jun 28, 2027				
		>A> 9540382	Aug 18, 2033	U-1491			
		>A> 9540382	Aug 18, 2033	U-1650			
		>A> 9540382	Aug 18, 2033	U-1946			
		>A> 9540382*PED	Feb 18, 2034				

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IBRUTINIB - IMBRUVICA							
N 205552	002	>A> 8476284	Dec 28, 2026	U-1650			
		>A> 8476284	Dec 28, 2026	U-1946			
		>A> 8476284*PED	Jun 28, 2027				
		>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-2241			
		>A> 8497277	Dec 28, 2026	U-2242			
		>A> 8497277	Dec 28, 2026	U-3422			
		>A> 8497277*PED	Jun 28, 2027				
		>A> 9540382	Aug 18, 2033	U-1491			
		>A> 9540382	Aug 18, 2033	U-1650			
		>A> 9540382	Aug 18, 2033	U-1946			
		>A> 9540382*PED	Feb 18, 2034				
ICOSAPENT ETHYL - VASCEPA							
N 202057	001	>A> 12171738	Feb 09, 2030	U-4105			
ICOSAPENT ETHYL - VASCEPA							
N 202057	002	>A> 12171738	Feb 09, 2030	U-4105			
IMETELSTAT SODIUM - RYTELO							
N 217779	001	>A> 12171778	Jun 16, 2039	U-3956			
IMETELSTAT SODIUM - RYTELO							
N 217779	002	>A> 12171778	Jun 16, 2039	U-3956			
IOMEPROL - IOMERVU							
N 216016	001					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU							
N 216016	002					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU							
N 216016	003					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU							
N 216016	004					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU							
N 216016	005					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU							
N 216016	006					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU							
N 216016	007					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU							
N 216016	008					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU							
N 216016	009					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU							
N 216016	010					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU							
N 216016	011					>A> NCE	Nov 27, 2029

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
IOMEPROL - IOMERVU						
N 216016 012					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216016 013					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 001					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 002					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 003					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 004					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 005					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 006					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 007					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 008					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 009					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 010					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 011					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 012					>A> NCE	Nov 27, 2029
IOMEPROL - IOMERVU						
N 216017 013					>A> NCE	Nov 27, 2029
IVABRADINE HYDROCHLORIDE - IVABRADINE HYDROCHLORIDE						
A 214051 001					>A> PC	Jan 11, 2025
IVABRADINE HYDROCHLORIDE - IVABRADINE HYDROCHLORIDE						
A 214051 002					>A> PC	Jan 11, 2025
IVACAFTOR; LUMACAFTOR - ORKAMBI						
N 211358 001					>A> M-14	Dec 13, 2027
					>A> PED	Jun 13, 2028
IVACAFTOR; LUMACAFTOR - ORKAMBI						
N 211358 002					>A> M-14	Dec 13, 2027
					>A> PED	Jun 13, 2028

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APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
IVACAFTOR; LUMACAFTOR - ORKAMBI							
N 211358	003					>A> M-14	Dec 13, 2027
						>A> PED	Jun 13, 2028
LEVOKETOCONAZOLE - RECORLEV							
N 214133	001					>A> NCE*	Dec 30, 2026
LINAGLIPTIN - TRADJENTA							
N 201280	001	>A> 12178819	May 04, 2027	DP			
LISINOPRIL - QBRELIS							
N 208401	001	>A> 12186360	Nov 06, 2035	DP			
LOTILANER - XDEMVY							
N 217603	001	>A> 12171750	Dec 14, 2038	U-3674			
MESNA - MESNA							
A 218871	001					>A> CGT	Jul 13, 2025
METOCLOPRAMIDE HYDROCHLORIDE - GIMOTI							
N 209388	001	>A> 12194008	Dec 22, 2029	U-2843			
		>A> 12194009	Dec 22, 2029	U-2843			
MYCOPHENOLATE MOFETIL - MYHIBBIN							
N 216482	001	>A> 12194143	Aug 16, 2039	DP U-1752			
NIMODIPINE - NYMALIZE							
N 203340	002	>A> 12186308	Apr 16, 2038	DP U-2804			
NIRAPARIB TOSYLATE - ZEJULA							
N 214876	001	>A> 11730725	Jan 25, 2039	DP			
NIRAPARIB TOSYLATE - ZEJULA							
N 214876	002	>A> 11730725	Jan 25, 2039	DP			
NIRAPARIB TOSYLATE - ZEJULA							
N 214876	003	>A> 11730725	Jan 25, 2039	DP			
ODEVIXIBAT - BYLVAY							
N 215498	001	>A> 12187812	Nov 08, 2031	U-3186			
		>A> 12187812	Nov 08, 2031	U-3648			
ODEVIXIBAT - BYLVAY							
N 215498	002	>A> 12187812	Nov 08, 2031	U-3186			
		>A> 12187812	Nov 08, 2031	U-3648			
ODEVIXIBAT - BYLVAY							
N 215498	003	>A> 12187812	Nov 08, 2031	U-3186			
		>A> 12187812	Nov 08, 2031	U-3648			
ODEVIXIBAT - BYLVAY							
N 215498	004	>A> 12187812	Nov 08, 2031	U-3186			
		>A> 12187812	Nov 08, 2031	U-3648			
OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI							
N 213378	001	>A> 12194035	Aug 23, 2031	U-3141			
OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI							
N 213378	002	>A> 12194035	Aug 23, 2031	U-3141			

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APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI							
N 213378	003	>A> 12194035	Aug 23, 2031	U-3141			
OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI							
N 213378	004	>A> 12194035	Aug 23, 2031	U-3141			
OLAPARIB - LYNPARZA							
N 208558	001	>A> 12178816	Oct 07, 2029	DP			
OLAPARIB - LYNPARZA							
N 208558	002	>A> 12178816	Oct 07, 2029	DP			
OLEZARSEN SODIUM - TRYNGOLZA (AUTOINJECTOR)							
N 218614	001	>A> 9127276	May 01, 2034	DS			
		>A> 9157082	Apr 27, 2032	U-4050			
		>A> 9163239	May 01, 2034	DS			
		>A> 9181549	May 01, 2034	DS			
		>A> 9593333	Feb 14, 2034	U-4050			
PALIPERIDONE PALMITATE - INVEGA HAFYERA							
N 207946	005	>A> 12208100	May 07, 2041	U-3359			
		>A> 12208100	May 07, 2041	U-4110			
PALIPERIDONE PALMITATE - INVEGA HAFYERA							
N 207946	006	>A> 12208100	May 07, 2041	U-3359			
		>A> 12208100	May 07, 2041	U-4110			
PALOPEGTERIPARATIDE - YORVIPATH							
N 216490	001					>A> NCE	Aug 09, 2029
PALOPEGTERIPARATIDE - YORVIPATH							
N 216490	002					>A> NCE	Aug 09, 2029
PALOPEGTERIPARATIDE - YORVIPATH							
N 216490	003					>A> NCE	Aug 09, 2029
PATISIRAN SODIUM - ONPATTRO							
N 210922	001	>A> 8168775	Aug 10, 2032	DS DP U-2378			
PEGULICIANINE ACETATE - LUMISIGHT							
N 214511	001	>A> 11592396	Sep 01, 2030	DS			
PHENTOLAMINE MESYLATE - RYZUMVI							
N 217064	001	>A> 12201615	Dec 25, 2039	U-3804			
		>A> 12201616	Oct 25, 2039	U-3804			
REVUMENIB CITRATE - REVUFORJ							
N 218944	001					>A> ODE-504	Nov 15, 2031
						>A> ODE-505	Nov 15, 2031
REVUMENIB CITRATE - REVUFORJ							
N 218944	002					>A> ODE-504	Nov 15, 2031
						>A> ODE-505	Nov 15, 2031
REVUMENIB CITRATE - REVUFORJ							
N 218944	003					>A> ODE-504	Nov 15, 2031
						>A> ODE-505	Nov 15, 2031
RIFAXIMIN - XIFAXAN							
N 021361	002	>A> 8309569	Jul 18, 2029	U-1707	Y		
		>A> 8309569	Jul 18, 2029	U-1708	Y		

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RIPRETINIB - QINLOCK							
N 213973 001	>A>	12213967	Dec 30, 2040	DP			
	>A>	12213968	Dec 30, 2040	DP			
SELPERCATINIB - RETEVMO							
N 213246 001						>A> M-311	Sep 27, 2027
						>A> M-312	Sep 27, 2027
SELPERCATINIB - RETEVMO							
N 213246 002						>A> M-311	Sep 27, 2027
						>A> M-312	Sep 27, 2027
SELPERCATINIB - RETEVMO							
N 218160 001						>A> M-311	Sep 27, 2027
						>A> M-312	Sep 27, 2027
SELPERCATINIB - RETEVMO							
N 218160 002						>A> M-311	Sep 27, 2027
						>A> M-312	Sep 27, 2027
SELPERCATINIB - RETEVMO							
N 218160 003						>A> M-311	Sep 27, 2027
						>A> M-312	Sep 27, 2027
SELPERCATINIB - RETEVMO							
N 218160 004						>A> M-311	Sep 27, 2027
						>A> M-312	Sep 27, 2027
SELUMETINIB SULFATE - KOSELUGO							
N 213756 001	>A>	7425637	Mar 13, 2026	DS			
SELUMETINIB SULFATE - KOSELUGO							
N 213756 002	>A>	7425637	Mar 13, 2026	DS			
SETMELANOTIDE ACETATE - IMCIVREE							
N 213793 001						>A> NPP	Dec 20, 2027
SILDENAFIL CITRATE - LIQREV							
N 214952 001	>A>	12186321	Dec 24, 2038	DP U-3582			
SOLRIAMFETOL HYDROCHLORIDE - SUNOSI							
N 211230 001	>A>	12194016	Mar 19, 2040	U-4106			
SOLRIAMFETOL HYDROCHLORIDE - SUNOSI							
N 211230 002	>A>	12194016	Mar 19, 2040	U-4106			
SOTORASIB - LUMAKRAS							
N 214665 001	>A>	11236091	May 20, 2040	DS DP U-3306			
	>A>	11236091	May 20, 2040	DS DP U-4107			
	>A>	11426404	Sep 15, 2040	U-3306			
	>A>	11426404	Sep 15, 2040	U-4107			
	>A>	11827635	May 20, 2040	DS DP U-3306			
	>A>	11827635	May 20, 2040	DS DP U-4107			
SOTORASIB - LUMAKRAS							
N 214665 002	>A>	11236091	May 20, 2040	DS DP U-3306			
	>A>	11236091	May 20, 2040	DS DP U-4107			
	>A>	11426404	Sep 15, 2040	U-3306			
	>A>	11426404	Sep 15, 2040	U-4107			
	>A>	11827635	May 20, 2040	DS DP U-3306			
	>A>	11827635	May 20, 2040	DS DP U-4107			

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SOTORASIB - LUMAKRAS							
N 214665	003	>A> 11236091	May 20, 2040	DS DP U-3306			
		>A> 11236091	May 20, 2040	DS DP U-4107			
		>A> 11426404	Sep 15, 2040	U-3306			
		>A> 11426404	Sep 15, 2040	U-4107			
		>A> 11827635	May 20, 2040	DS DP U-3306			
		>A> 11827635	May 20, 2040	DS DP U-4107			
SUGAMMADEX SODIUM - BRIDION							
N 022225	001					>A> NPP	Dec 12, 2027
						>A> PED	Jun 12, 2028
SUGAMMADEX SODIUM - BRIDION							
N 022225	002					>A> NPP	Dec 12, 2027
						>A> PED	Jun 12, 2028
TADALAFIL - TADLIQ							
N 214522	001	>A> 12186322	Dec 24, 2038	DP U-3397			
TAPINAROF - VTAMA							
N 215272	001	>A> 10426743	May 19, 2036	U-2625		>A> I-956	Dec 12, 2027
		>A> 10426743	May 19, 2036	U-4048			
		>A> 11497718	Nov 13, 2039	U-4048			
		>A> 11612573	May 19, 2036	U-2625			
		>A> 11612573	May 19, 2036	U-4048			
		>A> 11938099	Nov 13, 2039	U-4048			
TAZEMETOSTAT HYDROBROMIDE - TAZVERIK							
N 211723	001	>A> 12161645	Sep 12, 2031	U-2853			
		>A> 12162865	May 21, 2034	U-2736			
		>A> 12168014	May 03, 2038	U-2736			
		>A> 12168014	May 03, 2038	U-2852			
		>A> 12168014	May 03, 2038	U-2853			
		>A> 12168015	Sep 12, 2031	DS DP			
		>A> 12168016	Sep 12, 2031	U-2736			
		>A> 12168016	Sep 12, 2031	U-2853			
TENOFOVIR ALAFENAMIDE FUMARATE - VEMLIDY							
N 208464	001	>A> 7390791	Jan 07, 2025	DS DP			
		>A> 7390791*PED	Jul 07, 2025				
TETRACAINE HYDROCHLORIDE - TETRACAINE HYDROCHLORIDE							
A 217227	001					>A> CGT	Jun 25, 2025
TRILACICLIB DIHYDROCHLORIDE - COSELA							
N 214200	001	>A> 12168666	Nov 13, 2040	DS DP			
UBROGEPANT - UBRELVY							
N 211765	001	>A> 12168004	Jan 30, 2035	DP			
		>A> 12194030	Dec 22, 2041	U-4121			
		>A> 12194030	Dec 22, 2041	U-4122			
UBROGEPANT - UBRELVY							
N 211765	002	>A> 12168004	Jan 30, 2035	DP			
VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE							
N 211962	001	>A> 12161690	Nov 06, 2035	DP			
VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE							
N 211962	002	>A> 12161690	Nov 06, 2035	DP			
VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE							
N 211962	003	>A> 12161690	Nov 06, 2035	DP			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE						
N 211962 004	>A> 12161690	Nov 06, 2035	DP			
VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE						
N 211962 005	>A> 12161690	Nov 06, 2035	DP			
VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE						
N 211962 006	>A> 12161690	Nov 06, 2035	DP			
VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE						
N 211962 007	>A> 12161690	Nov 06, 2035	DP			
VASOPRESSIN - VASOSTRICT						
N 204485 005	>A> 12186362	Jan 30, 2035	DP			
VIBEGRON - GEMTESA						
N 213006 001	>A> 12180219	Mar 12, 2034	DS DP		>A> I-955	Dec 18, 2027
ZURANOLONE - ZURZUVAE						
N 217369 001	>A> 11884696	Aug 23, 2037	U-2552			
ZURANOLONE - ZURZUVAE						
N 217369 002	>A> 11884696	Aug 23, 2037	U-2552			
ZURANOLONE - ZURZUVAE						
N 217369 003	>A> 11884696	Aug 23, 2037	U-2552			

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, 45TH 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