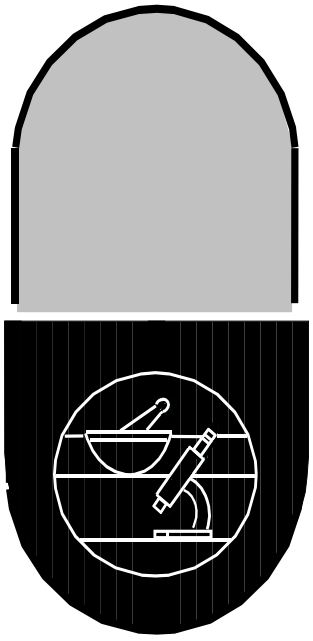
CUMULATIVE SUPPLEMENT 1
JANUARY 2022



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

42nd 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

2022

Prepared By
Food and Drug Administration
Office of Medical Products and Tobacco
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January 2022

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1.0 INTRODUCTION

This Cumulative Supplement is one of a series of monthly updates to the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the List, commonly known as the Orange Book). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; approved over-the-counter (OTC) drug products for those drugs that may not be marketed without NDAs or ANDAs because they are not covered under existing OTC monographs; drug products with approval under Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) administered by the Center for Biologics Evaluation and Research; and approved products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, Discontinued Drug Product, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to mark to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement. Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case, the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a

"@" symbol in the 12th Cumulative Supplement of this Edition List will then be added to the "Discontinued Drug Product List" appearing in the next Edition. The current Annual Edition Section 2., How To Use The Drug Product Lists, describes the layout and usage of the List.

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.

- All product changes received and processed as of the date of publication.
  - Refer to CS Section 1.7 Cumulative Supplement Legend for types of changes

- New Drug Application (NDA) approvals appear in the CS month they were approved.

- Patent information, also updated daily in the EOB, is current to the date of publication.

- Exclusivity information is updated monthly and is current as of the date of publication.

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

1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each, and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. The Electronic Orange Book Query, updated monthly, will contain the most current applicant holder name.

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
HERITAGE PHARMACEUTICALS INC (HERITAGE PHARMS INC)	HERITAGE PHARMACEUTICALS INC DBA AVET PHARMACEUTICALS INC (HERITAGE PHARMS)

1.4 LEVOTHYROXINE SODIUM[1]

Because there are multiple reference listed drugs for levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character therapeutic equivalence codes may be potentially confusing and inadequate for these drug products. Looking at the Orange Book listing alone for a product identified as a reference listed drug or reference standard, it may be difficult to determine to which therapeutic equivalence code the reference listed drugs and/or reference standard designation corresponds. For example, Unithroid 0.3 mg strength has been assigned the therapeutic equivalence codes AB1, AB2, and AB3 and it is identified as the reference listed drug and reference standard, but it is unclear that the reference listed drug and reference standard designations are associated with the AB1 therapeutic equivalence code.

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

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

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

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

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

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

1.5 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm, has been available on the internet and has become the updated-every-month Orange Book. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder, applicant number or patent number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product.

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Publications. The PDF annual and cumulative supplements duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The downloaded Annual Edition and Cumulative Supplements are also available in a paper version (Approved Drug Products with Therapeutic Equivalence Evaluations, ADP) from the U.S. Government Printing Office: http://bookstore.gpo.gov; toll free 866-512-1800.

There are historical lists of Orange Book cumulative supplement product monthly changes at http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm. There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at http://www.fda.gov/Drugs/InformationOnDrugs/ucm129689.htm. The drug product text files are provided in eobzip.zip format. The files are updated concurrently with the monthly cumulative supplements. The annual Orange Book Edition Appendices A, B, and C in PDF format are updated quarterly.

Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List,
Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List,
https://www.fda.gov/about-fda/reports-manuals-forms/forms.

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

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

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (December of the previous Annual Edition) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST
COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 2021	MAR 2022	JUN 2022	SEP 2022	DEC 2022
DRUG PRODUCTS	21133				
LISTED SINGLE SOURCE	2701 (12.8%)				
MULTISOURCE	18432 (87.2%)				

THERAPEUTICALLY EQUIVALENT	18298 (86.6%)
NOT THERAPEUTICALLY EQUIVALENT	134 (0.6%)
EXCEPTIONS[4]	54 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	13
NUMBER OF APPLICANTS	1190

1.7 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route of Administration and then by trade name (or established name of the active ingredient, if no trade name exists).

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, Reference Standard symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The application number preceded by "N" is a New Drug Application (NDA or innovator). The application number preceded by an "A" is an Abbreviated New Drug Application (ANDA or generic). The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form, new route(s) of administration, new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be proceeded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

NEWA	New drug product approval
NFTG	New first-time generic approval
CAHN[5]	Applicant holder firm name has changed
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration

[4] Amino acid containing products of varying composition (see Introduction, page xx of the List).
[5] The Cumulative Supplement (CS) currently displays a condensed 20 character collapsed applicant holder firm name and the Electronic Orange Book (EOB) query may display up to a 250-character full applicant holder firm name. An applicant holder firm name change usually changes both the collapsed name and long name. On occasion, only the long name is changed resulting in the CS displaying only the collapsed name for the >D> and >A> action. The new firm long name will display in the EOB query.

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.

>A>		ABROCITINIB						
>A>		TABLET;ORAL						
>A>		CIBINQO						
>A>	+	PFIZER	50MG	N213871	001	Jan 14, 2022	Jan NEWA	
>A>	+		100MG	N213871	002	Jan 14, 2022	Jan NEWA	
>A>	+!		200MG	N213871	003	Jan 14, 2022	Jan NEWA	
		ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE						
		CAPSULE;ORAL						
		BUTALBITAL, ACETAMINOPHEN, CAFFEINE AND CODEINE PHOSPHATE						
>A>	AB	HIKMA	300MG;50MG;40MG;30MG	A215138	002	Jan 26, 2022	Jan NEWA	
>A>	AB		325MG;50MG;40MG;30MG	A215138	001	Jan 26, 2022	Jan NEWA	
>D>		LGM PHARMA	300MG;50MG;40MG;30MG	A076560	002	Jul 19, 2012	Jan CTEC	
>A>	AB		300MG;50MG;40MG;30MG	A076560	002	Jul 19, 2012	Jan CTEC	
		ACETYLCYSTEINE						
		INJECTABLE;INTRAVENOUS						
		ACETYLCYSTEINE						
>A>	AP	ASPEN	6GM/30ML (200MG/ML)	A213693	001	Feb 03, 2022	Jan NEWA	
		ALLOPURINOL						
		INJECTABLE;INJECTION						
		ALLOPURINOL						
>A>	AP	GLAND PHARMA LTD	EQ 500MG BASE/VIAL	A212363	001	Jan 26, 2022	Jan NEWA	
		AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE						
		TABLET;ORAL						
		CHLORDIAZEPOXIDE AND AMITRIPTYLINE HYDROCHLORIDE						
>A>	AB	MICRO LABS	EQ 12.5MG BASE;5MG	A211925	001	Feb 02, 2022	Jan NEWA	
>A>	AB		EQ 25MG BASE;10MG	A211925	002	Feb 02, 2022	Jan NEWA	
>D>		MYLAN PHARMS INC	EQ 12.5MG BASE;5MG	A071297	002	Dec 10, 1986	Jan CTEC	
>A>	AB		EQ 12.5MG BASE;5MG	A071297	002	Dec 10, 1986	Jan CTEC	
>D>		!	EQ 25MG BASE;10MG	A071297	001	Dec 10, 1986	Jan CTEC	
>A>	AB	!	EQ 25MG BASE;10MG	A071297	001	Dec 10, 1986	Jan CTEC	
		AMLODIPINE BESYLATE						
		TABLET;ORAL						
		AMLODIPINE BESYLATE						
>A>		@ CHARTWELL RX	EQ 2.5MG BASE	A076859	001	Sep 10, 2007	Jan CAHN	
>A>		@	EQ 5MG BASE	A076859	002	Sep 10, 2007	Jan CAHN	
>A>		@	EQ 10MG BASE	A076859	003	Sep 10, 2007	Jan CAHN	
>D>		@ YAOPHARMA CO LTD	EQ 2.5MG BASE	A076859	001	Sep 10, 2007	Jan CAHN	
>D>		@	EQ 5MG BASE	A076859	002	Sep 10, 2007	Jan CAHN	
>D>		@	EQ 10MG BASE	A076859	003	Sep 10, 2007	Jan CAHN	
		NORVASC						
>D>	AB	+ UPJOHN	EQ 2.5MG BASE	N019787	001	Jul 31, 1992	Jan CAHN	
>D>	AB	+	EQ 5MG BASE	N019787	002	Jul 31, 1992	Jan CAHN	
>D>	AB	+!	EQ 10MG BASE	N019787	003	Jul 31, 1992	Jan CAHN	
>A>	AB	+ VIATRIS	EQ 2.5MG BASE	N019787	001	Jul 31, 1992	Jan CAHN	
>A>	AB	+	EQ 5MG BASE	N019787	002	Jul 31, 1992	Jan CAHN	
>A>	AB	+!	EQ 10MG BASE	N019787	003	Jul 31, 1992	Jan CAHN	
		AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE						
		CAPSULE, EXTENDED RELEASE;ORAL						
		DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE						
>A>	AB	TEVA PHARMS USA	3.125MG;3.125MG;3.125MG;3.125MG	A210876	001	Jan 31, 2022	Jan NEWA	
>A>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A210876	002	Jan 31, 2022	Jan NEWA	
>A>	AB		9.375MG;9.375MG;9.375MG;9.375MG	A210876	003	Jan 31, 2022	Jan NEWA	
>A>	AB		12.5MG;12.5MG;12.5MG;12.5MG	A210876	004	Jan 31, 2022	Jan NEWA	
		APREMILAST						
		TABLET;ORAL						
		APREMILAST						
>D>	AB	AMNEAL	10MG	A211782	001	Jun 30, 2021	Jan DISC	
>A>		@	10MG	A211782	001	Jun 30, 2021	Jan DISC	
>D>	AB		20MG	A211782	002	Jun 30, 2021	Jan DISC	
>A>		@	20MG	A211782	002	Jun 30, 2021	Jan DISC	
>D>	AB		30MG	A211782	003	Jun 30, 2021	Jan DISC	
>A>		@	30MG	A211782	003	Jun 30, 2021	Jan DISC	

ARFORMOTEROL TARTRATE

SOLUTION;INHALATION

ARFORMOTEROL TARTRATE

>A> AN		LUPIN	EQ 0.015MG BASE/2ML	A213068	001	Feb 07, 2022	Jan NEWA	

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

FOR SOLUTION;INTRAVENOUS

>D> M.V.I. PEDIATRIC

>D>	+!	HOSPIRA	80MG/VIAL;0.02MG/VIAL;0.001MG/VIAL;5MG/VIAL;0.01MG/VIAL;0.14MG/VIAL;17MG/VIAL;0.2MG/VIAL;1MG/VIAL;1.4MG/VIAL;EQ 1.2MG BASE/VIAL;0.7MG/VIAL;7MG/VIAL	N018920	001	Sep 21, 2000	Jan DISC	
>A>	+ @		80MG/VIAL;0.02MG/VIAL;0.001MG/VIAL;5MG/VIAL;0.01MG/VIAL;0.14MG/VIAL;17MG/VIAL;0.2MG/VIAL;1MG/VIAL;1.4MG/VIAL;EQ 1.2MG BASE/VIAL;0.7MG/VIAL;7MG/VIAL	N018920	001	Sep 21, 2000	Jan DISC	

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E; VITAMIN K

INJECTABLE;INTRAVENOUS

>D> M.V.I. ADULT

>D>	+!	HOSPIRA	200MG/VIAL;0.06MG/VIAL;0.005MG/VIAL;15MG/VIAL;0.005MG/VIAL;0.6MG/VIAL;40MG/VIAL;6MG/VIAL;3.6MG/VIAL;6MG/VIAL;1MG/VIAL;10MG/VIAL;0.15MG/VIAL	N021625	001	Jan 30, 2004	Jan DISC	
>A>	+ @		200MG/VIAL;0.06MG/VIAL;0.005MG/VIAL;15MG/VIAL;0.005MG/VIAL;0.6MG/VIAL;40MG/VIAL;6MG/VIAL;3.6MG/VIAL;6MG/VIAL;1MG/VIAL;10MG/VIAL;0.15MG/VIAL	N021625	001	Jan 30, 2004	Jan DISC	

>D> M.V.I. ADULT (PHARMACY BULK PACKAGE)

>D>	+!	HOSPIRA	200MG/5ML;0.06MG/5ML;0.005MG/5ML;15MG/5ML;0.005MG/5ML;0.6MG/5ML;40MG/5ML;6MG/5ML;3.6MG/5ML;6MG/5ML;1MG/5ML;10MG/5ML;0.15MG/5ML	N021643	001	Feb 18, 2004	Jan DISC	
>A>	+ @		200MG/5ML;0.06MG/5ML;0.005MG/5ML;15MG/5ML;0.005MG/5ML;0.6MG/5ML;40MG/5ML;6MG/5ML;3.6MG/5ML;6MG/5ML;1MG/5ML;10MG/5ML;0.15MG/5ML	N021643	001	Feb 18, 2004	Jan DISC	

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE;ORAL

BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE

>D> AB		MAYNE PHARMA INC	325MG;50MG;40MG;30MG	A203335	001	Oct 30, 2015	Jan DISC	
>A>	@		325MG;50MG;40MG;30MG	A203335	001	Oct 30, 2015	Jan DISC	

ATAZANAVIR SULFATE

CAPSULE;ORAL

ATAZANAVIR SULFATE

>A> AB		HETERO LABS LTD III	EQ 150MG BASE	A212278	001	Feb 02, 2022	Jan NEWA	
>A> AB			EQ 200MG BASE	A212278	002	Feb 02, 2022	Jan NEWA	
>A> AB			EQ 300MG BASE	A212278	003	Feb 02, 2022	Jan NEWA	

ATROPINE SULFATE

SOLUTION;INTRAVENOUS

ATROPINE SULFATE

>A> AP		AMNEAL	0.5MG/5ML (0.1MG/ML)	A215342	001	Jan 26, 2022	Jan NEWA	
>D>	+ @	HOSPIRA	0.5MG/5ML (0.1MG/ML)	N021146	001	Jul 09, 2001	Jan CMFD	
>A> AP	+!		0.5MG/5ML (0.1MG/ML)	N021146	001	Jul 09, 2001	Jan CMFD	

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET;ORAL

DIPHENOXYLATE HYDROCHLORIDE AND ATROPINE SULFATE

>D> AA		MAYNE PHARMA INC	0.025MG;2.5MG	A210789	001	Jun 03, 2020	Jan DISC	
>A>	@		0.025MG;2.5MG	A210789	001	Jun 03, 2020	Jan DISC	

ATROPINE; PRALIDOXIME CHLORIDE

INJECTABLE;INTRAMUSCULAR

DUODOTE

>D>		+!	MERIDIAN MEDCL	2.1MG/0.7ML;600MG/2ML	N021983	001	Sep 28, 2006	Jan CAHN
>A>		+!	MMT	2.1MG/0.7ML;600MG/2ML	N021983	001	Sep 28, 2006	Jan CAHN

AZACITIDINE

POWDER;INTRAVENOUS, SUBCUTANEOUS

AZACITIDINE

>A>	AP		AMNEAL	100MG/VIAL	A211549	001	Feb 03, 2022	Jan NEWA

AZELASTINE HYDROCHLORIDE

SPRAY, METERED;NASAL

AZELASTINE HYDROCHLORIDE

>D>	AB		AMNEAL	0.2055MG/SPRAY	A208199	001	Dec 15, 2017	Jan DISC
>A>		@		0.2055MG/SPRAY	A208199	001	Dec 15, 2017	Jan DISC

BACLOFEN

TABLET;ORAL

BACLOFEN

>A>	AB		MANKIND PHARMA	5MG	A215885	001	Jan 25, 2022	Jan NEWA
>A>	AB			10MG	A215885	002	Jan 25, 2022	Jan NEWA
>A>	AB			20MG	A215885	003	Jan 25, 2022	Jan NEWA

BENZONATATE

CAPSULE;ORAL

BENZONATATE

>A>	AA		ACELLA	100MG	A091310	001	Jan 16, 2015	Jan CAHN
>A>	AA			200MG	A091310	002	Jan 16, 2015	Jan CAHN
>D>	AA		APOTEX INC	100MG	A091310	001	Jan 16, 2015	Jan CAHN
>D>	AA			200MG	A091310	002	Jan 16, 2015	Jan CAHN
>A>	AA	!	THEPHARMANETWORK LLC	100MG	A040627	002	Mar 30, 2007	Jan CMS1
>A>	AA	!		150MG	A040627	003	Sep 24, 2014	Jan CMS1

>D> BENZOYL PEROXIDE; TRETINOIN

>D> CREAM;TOPICAL

>D> TWYNEO

>D>		+!	SOL-GEL TECHNOLOGIES	3%;0.1%	N214902	001	Jul 26, 2021	Jan DISC
>A>		+ @		3%;0.1%	N214902	001	Jul 26, 2021	Jan DISC

BETAINE

FOR SOLUTION;ORAL

BETAINE

>A>	AB		LUKARE MEDICAL LLC	1GM/SCOOPFUL	A210508	001	Jan 28, 2022	Jan NEWA

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET;ORAL

BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE

>A>	AB		GLENMARK PHARMS LTD	2.5MG;6.25MG	A215995	001	Jan 26, 2022	Jan NEWA
>A>	AB			5MG;6.25MG	A215995	002	Jan 26, 2022	Jan NEWA
>A>	AB			10MG;6.25MG	A215995	003	Jan 26, 2022	Jan NEWA

BRIMONIDINE TARTRATE

SOLUTION/DROPS;OPHTHALMIC

BRIMONIDINE TARTRATE

>A>	AT		APOTEX	0.15%	A078479	001	Jan 31, 2022	Jan NEWA

BUDESONIDE

CAPSULE, DELAYED RELEASE;ORAL

BUDESONIDE

>D>		@	ALVOGEN	3MG	A206724	001	Nov 23, 2016	Jan CAHN
>A>		@	NATCO	3MG	A206724	001	Nov 23, 2016	Jan CAHN

BUPRENORPHINE HYDROCHLORIDE

FILM;BUCCAL

BELBUCA

>D>	AB	+	BDSI	EQ 0.075MG BASE	N207932	001	Oct 23, 2015	Jan CTEC
>A>		+		EQ 0.075MG BASE	N207932	001	Oct 23, 2015	Jan CTEC
>D>	AB	+		EQ 0.15MG BASE	N207932	002	Oct 23, 2015	Jan CTEC
>A>		+		EQ 0.15MG BASE	N207932	002	Oct 23, 2015	Jan CTEC
>D>	AB	+		EQ 0.3MG BASE	N207932	003	Oct 23, 2015	Jan CTEC

FILM;BUCCAL
BELBUCA

>A>	+		EQ 0.3MG BASE	N207932	003	Oct 23, 2015	Jan CTEC
>D> AB	+		EQ 0.45MG BASE	N207932	004	Oct 23, 2015	Jan CTEC
>A>	+		EQ 0.45MG BASE	N207932	004	Oct 23, 2015	Jan CTEC
>D> AB	+		EQ 0.6MG BASE	N207932	005	Oct 23, 2015	Jan CTEC
>A>	+		EQ 0.6MG BASE	N207932	005	Oct 23, 2015	Jan CTEC
>D> AB	+		EQ 0.75MG BASE	N207932	006	Oct 23, 2015	Jan CTEC
>A>	+		EQ 0.75MG BASE	N207932	006	Oct 23, 2015	Jan CTEC
>D> AB	+!		EQ 0.9MG BASE	N207932	007	Oct 23, 2015	Jan CTEC
>A>	+!		EQ 0.9MG BASE	N207932	007	Oct 23, 2015	Jan CTEC
		BUPRENORPHINE HYDROCHLORIDE					
>D> AB		ALVOGEN	EQ 0.075MG BASE	A211594	001	Aug 03, 2021	Jan DISC
>A>		@	EQ 0.075MG BASE	A211594	001	Aug 03, 2021	Jan DISC
>D> AB			EQ 0.15MG BASE	A211594	002	Aug 03, 2021	Jan DISC
>A>		@	EQ 0.15MG BASE	A211594	002	Aug 03, 2021	Jan DISC
>D> AB			EQ 0.3MG BASE	A211594	003	Aug 03, 2021	Jan DISC
>A>		@	EQ 0.3MG BASE	A211594	003	Aug 03, 2021	Jan DISC
>D> AB			EQ 0.45MG BASE	A211594	004	Aug 03, 2021	Jan DISC
>A>		@	EQ 0.45MG BASE	A211594	004	Aug 03, 2021	Jan DISC
>D> AB			EQ 0.6MG BASE	A211594	005	Aug 03, 2021	Jan DISC
>A>		@	EQ 0.6MG BASE	A211594	005	Aug 03, 2021	Jan DISC
>D> AB			EQ 0.75MG BASE	A211594	006	Aug 03, 2021	Jan DISC
>A>		@	EQ 0.75MG BASE	A211594	006	Aug 03, 2021	Jan DISC
>D> AB			EQ 0.9MG BASE	A211594	007	Aug 03, 2021	Jan DISC
>A>		@	EQ 0.9MG BASE	A211594	007	Aug 03, 2021	Jan DISC

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
BUPROPION HYDROCHLORIDE

>A> AB3	GRANULES	150MG	A215568	001	Feb 02, 2022	Jan NEWA
>A> AB3		300MG	A215568	002	Feb 02, 2022	Jan NEWA

CAFFEINE CITRATE

SOLUTION;ORAL
CAFCIT

>D> AA	+! HIKMA	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	N020793	002	Apr 12, 2000	Jan DISC
>A>	+ @	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	N020793	002	Apr 12, 2000	Jan DISC
	CAFFEINE CITRATE					
>D> AA	EXELA PHARMA	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	A077304	001	Sep 21, 2006	Jan CHRS
>A> AA	!	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	A077304	001	Sep 21, 2006	Jan CHRS

CARBIDOPA; ENTACAPONE; LEVODOPA

TABLET;ORAL
CARBIDOPA, LEVODOPA AND ENTACAPONE

>A> AB	RISING	12.5MG;200MG;50MG	A213212	001	Jan 25, 2022	Jan NEWA
>A> AB		18.75MG;200MG;75MG	A213212	002	Jan 25, 2022	Jan NEWA
>A> AB		25MG;200MG;100MG	A213212	003	Jan 25, 2022	Jan NEWA
>A> AB		31.25MG;200MG;125MG	A213212	004	Jan 25, 2022	Jan NEWA
>A> AB		37.5MG;200MG;150MG	A213212	005	Jan 25, 2022	Jan NEWA
>A> AB		50MG;200MG;200MG	A213212	006	Jan 25, 2022	Jan NEWA
	STALEVO 125					
>D>	+ ORION PHARMA	31.25MG;200MG;125MG	N021485	006	Aug 29, 2008	Jan CTEC
>A> AB	+	31.25MG;200MG;125MG	N021485	006	Aug 29, 2008	Jan CTEC
	STALEVO 200					
>D>	+! ORION PHARMA	50MG;200MG;200MG	N021485	004	Aug 02, 2007	Jan CTEC
>A> AB	+!	50MG;200MG;200MG	N021485	004	Aug 02, 2007	Jan CTEC
	STALEVO 50					
>D>	+! ORION PHARMA	12.5MG;200MG;50MG	N021485	001	Jun 11, 2003	Jan CTEC
>A> AB	+!	12.5MG;200MG;50MG	N021485	001	Jun 11, 2003	Jan CTEC
	STALEVO 75					
>D>	+ ORION PHARMA	18.75MG;200MG;75MG	N021485	005	Aug 29, 2008	Jan CTEC
>A> AB	+	18.75MG;200MG;75MG	N021485	005	Aug 29, 2008	Jan CTEC

CARBOPROST TROMETHAMINE

INJECTABLE;INJECTION
CARBOPROST TROMETHAMINE

>A> AP	AMNEAL	EQ 0.25MG BASE/ML	A215337	001	Jan 27, 2022	Jan NEWA

CEFEPIME HYDROCHLORIDE

INJECTABLE;INJECTION

CEFEPIME HYDROCHLORIDE

>D>	@ ASTRAL	EQ 1GM BASE/VIAL	A212721	001	Jul 21, 2020	Jan CMFD
>A> AP		EQ 1GM BASE/VIAL	A212721	001	Jul 21, 2020	Jan CMFD
>D>	@	EQ 2GM BASE/VIAL	A212721	002	Jul 21, 2020	Jan CMFD
>A> AP		EQ 2GM BASE/VIAL	A212721	002	Jul 21, 2020	Jan CMFD

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE;ORAL

LIBRIUM

>D> AB	VALEANT PHARM INTL	5MG	A085461	001		Jan CRLD
>A> AB	+	5MG	A085461	001		Jan CRLD
>D> AB		10MG	A085472	001		Jan CRLD
>A> AB	+	10MG	A085472	001		Jan CRLD

CHLORPROMAZINE HYDROCHLORIDE

TABLET;ORAL

CHLORPROMAZINE HYDROCHLORIDE

>A> AB	MSN	25MG	A214827	001	Jan 27, 2022	Jan NEWA
>A> AB		50MG	A214827	002	Jan 27, 2022	Jan NEWA
>A> AB		100MG	A214827	003	Jan 27, 2022	Jan NEWA
>A> AB		200MG	A214827	004	Jan 27, 2022	Jan NEWA

CHLORTHALIDONE

TABLET;ORAL

CHLORTHALIDONE

>A> AB	CHARTWELL RX	25MG	A211063	001	Feb 26, 2019	Jan CAHN
>A> AB		50MG	A211063	002	Feb 26, 2019	Jan CAHN
>A> AB	INVENTIA	25MG	A211320	001	Feb 09, 2022	Jan NEWA
>A> AB		50MG	A211320	002	Feb 09, 2022	Jan NEWA
>A> AB	SUNNY	25MG	A209068	001	Jan 25, 2022	Jan NEWA
>A> AB		50MG	A209068	002	Jan 25, 2022	Jan NEWA
>D> AB	VISTAPHARM	25MG	A211063	001	Feb 26, 2019	Jan CAHN
>D> AB		50MG	A211063	002	Feb 26, 2019	Jan CAHN

CHOLESTYRAMINE

POWDER;ORAL

CHOLESTYRAMINE

>A> AB	UPSHER SMITH LABS	EQ 4GM RESIN/PACKET	A214877	001	Jan 21, 2022	Jan NEWA
>A> AB		EQ 4GM RESIN/SCOOPFUL	A214877	002	Jan 21, 2022	Jan NEWA

CIMETIDINE

TABLET;ORAL

CIMETIDINE

>A>	@ CHARTWELL RX	200MG	A074100	001	Jan 31, 1995	Jan CAHN
>A>	@	300MG	A074100	002	Jan 31, 1995	Jan CAHN
>A>	@	400MG	A074100	003	Jan 31, 1995	Jan CAHN
>A>	@	800MG	A074100	004	Jan 31, 1995	Jan CAHN
>D>	@ YAOPHARMA CO LTD	200MG	A074100	001	Jan 31, 1995	Jan CAHN
>D>	@	300MG	A074100	002	Jan 31, 1995	Jan CAHN
>D>	@	400MG	A074100	003	Jan 31, 1995	Jan CAHN
>D>	@	800MG	A074100	004	Jan 31, 1995	Jan CAHN

CIPROFLOXACIN HYDROCHLORIDE

TABLET;ORAL

CIPROFLOXACIN HYDROCHLORIDE

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

CITALOPRAM HYDROBROMIDE

CAPSULE;ORAL

CITALOPRAM HYDROBROMIDE

>A>	+! ALMATICA	EQ 30MG BASE	N215428	001	Jan 31, 2022	Jan NEWA

CLARITHROMYCIN

TABLET;ORAL

CLARITHROMYCIN

>A>	AB		ALEMBIC PHARMS LTD	250MG	A210459	001	Jan 31, 2022	Jan NEWA
>A>	AB			500MG	A210459	002	Jan 31, 2022	Jan NEWA

CLINDAMYCIN PHOSPHATE

LOTION;TOPICAL

CLINDAMYCIN PHOSPHATE

>A>	AB		ENCUBE	EQ 1% BASE	A215607	001	Jan 18, 2022	Jan NEWA

CLONIDINE

TABLET, EXTENDED RELEASE;ORAL

NEXICLON XR

>A>			@ ATHENA	EQ 0.17MG BASE	N022500	001	Dec 03, 2009	Jan CAHN
>A>			@	EQ 0.26MG BASE	N022500	002	Dec 03, 2009	Jan CAHN
>D>			@ TRIS PHARMA INC	EQ 0.17MG BASE	N022500	001	Dec 03, 2009	Jan CAHN
>D>			@	EQ 0.26MG BASE	N022500	002	Dec 03, 2009	Jan CAHN

COLESEVELAM HYDROCHLORIDE

TABLET;ORAL

COLESEVELAM HYDROCHLORIDE

>A>	AB		SPH	625MG	A213456	001	Jan 21, 2022	Jan NEWA

CYCLOSPORINE

EMULSION;OPHTHALMIC

>A>			CYCLOSPORINE					
>A>	AB		MYLAN	0.05%	A205894	001	Feb 02, 2022	Jan NFTG
			RESTASIS					
>D>		+!	ALLERGAN	0.05%	N050790	001	Dec 23, 2002	Jan CFTG
>A>	AB	+!		0.05%	N050790	001	Dec 23, 2002	Jan CFTG

DAPSONE

GEL;TOPICAL

DAPSONE

>A>	AB		MYLAN	7.5%	A213847	001	Feb 04, 2022	Jan NEWA

TABLET;ORAL

DAPSONE

>D>	AB		VIRTUS PHARMS	25MG	A204074	001	May 10, 2016	Jan DISC
>A>			@	25MG	A204074	001	May 10, 2016	Jan DISC
>D>	AB			100MG	A204074	002	May 10, 2016	Jan DISC
>A>			@	100MG	A204074	002	May 10, 2016	Jan DISC

DAPTOMYCIN

POWDER;INTRAVENOUS

>A>			DAPZURA RT					
>A>		+!	BAXTER HLTHCARE CORP	500MG/VIAL	N213645	001	Jan 25, 2022	Jan NEWA

DEFERIPRONE

TABLET;ORAL

DEFERIPRONE

>A>	AB		HIKMA	1GM	A213239	002	Feb 08, 2022	Jan NFTG
			FERRIPROX					
>D>		+	CHIESI	1GM	N021825	002	Jul 25, 2019	Jan CFTG
>A>	AB	+		1GM	N021825	002	Jul 25, 2019	Jan CFTG

DESOGESTREL; ETHINYL ESTRADIOL

TABLET;ORAL-28

DESOGESTREL AND ETHINYL ESTRADIOL

>D>	AB		MAYNE PHARMA	0.15MG,N/A;0.02MG,0.01MG	A076916	001	Dec 29, 2008	Jan DISC
>A>			@	0.15MG,N/A;0.02MG,0.01MG	A076916	001	Dec 29, 2008	Jan DISC
>D>	AB			0.1MG,0.125MG,0.15MG;0.025MG,0.025MG,0.025MG	A077182	001	Jan 24, 2006	Jan DISC
>A>			@	0.1MG,0.125MG,0.15MG;0.025MG,0.025MG,0.025MG	A077182	001	Jan 24, 2006	Jan DISC

DEXAMETHASONE

TABLET;ORAL

DEXAMETHASONE

>D>	BP		HIKMA	0.5MG	A084611	001		Jan CRLD
>A>	BP	+		0.5MG	A084611	001		Jan CRLD

DEXTROAMPHETAMINE SULFATE

TABLET;ORAL

DEXTROAMPHETAMINE SULFATE

>D>	AA		ARBOR PHARMS LLC	2.5MG	A090533	001	Oct 25, 2011	Jan CTEC
>A>				2.5MG	A090533	001	Oct 25, 2011	Jan CTEC
>D>	AA			7.5MG	A090533	003	Oct 25, 2011	Jan CTEC
>A>				7.5MG	A090533	003	Oct 25, 2011	Jan CTEC
>D>	AA			15MG	A090533	005	Oct 25, 2011	Jan CTEC
>A>				15MG	A090533	005	Oct 25, 2011	Jan CTEC
>D>	AA			20MG	A090533	006	Oct 25, 2011	Jan CTEC
>A>				20MG	A090533	006	Oct 25, 2011	Jan CTEC
>D>	AA			30MG	A090533	007	Oct 25, 2011	Jan CTEC
>A>				30MG	A090533	007	Oct 25, 2011	Jan CTEC
>D>	AA		WINDER LABS LLC	2.5MG	A212160	001	Jun 07, 2021	Jan DISC
>A>		@		2.5MG	A212160	001	Jun 07, 2021	Jan DISC
>D>	AA			5MG	A212160	002	Jun 07, 2021	Jan DISC
>A>		@		5MG	A212160	002	Jun 07, 2021	Jan DISC
>D>	AA			7.5MG	A212160	003	Jun 07, 2021	Jan DISC
>A>		@		7.5MG	A212160	003	Jun 07, 2021	Jan DISC
>D>	AA			10MG	A212160	004	Jun 07, 2021	Jan DISC
>A>		@		10MG	A212160	004	Jun 07, 2021	Jan DISC
>D>	AA			15MG	A212160	005	Jun 07, 2021	Jan DISC
>A>		@		15MG	A212160	005	Jun 07, 2021	Jan DISC
>D>	AA			20MG	A212160	006	Jun 07, 2021	Jan DISC
>A>		@		20MG	A212160	006	Jun 07, 2021	Jan DISC
>D>	AA			30MG	A212160	007	Jun 07, 2021	Jan DISC
>A>		@		30MG	A212160	007	Jun 07, 2021	Jan DISC

DIGOXIN

TABLET;ORAL

DIGOXIN

>A>	AB		AUROBINDO PHARMA LTD	0.0625MG	A214982	001	Feb 08, 2022	Jan NFTG
>A>	AB			0.125MG	A214982	002	Feb 08, 2022	Jan NEWA
>A>	AB			0.25MG	A214982	003	Feb 08, 2022	Jan NEWA

LANOXIN

>D>		+	CONCORDIA	0.0625MG	N020405	001	Sep 30, 1997	Jan CFTG
>A>	AB	+		0.0625MG	N020405	001	Sep 30, 1997	Jan CFTG

DORZOLAMIDE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

DORZOLAMIDE HYDROCHLORIDE

>A>	AT		GLAND PHARMA LTD	EQ 2% BASE	A215660	001	Jan 27, 2022	Jan NEWA

DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC

DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE

>A>	AT		MICRO LABS	EQ 2% BASE;EQ 0.5% BASE	A215936	001	Jan 25, 2022	Jan NEWA

DOXAZOSIN MESYLATE

TABLET;ORAL

CARDURA

>D>	AB	+!	UPJOHN	EQ 1MG BASE	N019668	001	Nov 02, 1990	Jan CAHN
>D>	AB	+		EQ 2MG BASE	N019668	002	Nov 02, 1990	Jan CAHN
>D>	AB	+		EQ 4MG BASE	N019668	003	Nov 02, 1990	Jan CAHN
>D>	AB	+		EQ 8MG BASE	N019668	004	Nov 02, 1990	Jan CAHN
>A>	AB	+!	VIATRIS	EQ 1MG BASE	N019668	001	Nov 02, 1990	Jan CAHN
>A>	AB	+		EQ 2MG BASE	N019668	002	Nov 02, 1990	Jan CAHN
>A>	AB	+		EQ 4MG BASE	N019668	003	Nov 02, 1990	Jan CAHN
>A>	AB	+		EQ 8MG BASE	N019668	004	Nov 02, 1990	Jan CAHN

DOXAZOSIN MESYLATE

>A>		@	CHARTWELL RX	EQ 1MG BASE	A075646	001	Oct 18, 2000	Jan CAHN
>A>		@		EQ 2MG BASE	A075646	002	Oct 18, 2000	Jan CAHN
>A>		@		EQ 4MG BASE	A075646	003	Oct 18, 2000	Jan CAHN
>A>		@		EQ 8MG BASE	A075646	004	Oct 18, 2000	Jan CAHN
>D>		@	YAOPHARMA CO LTD	EQ 1MG BASE	A075646	001	Oct 18, 2000	Jan CAHN
>D>		@		EQ 2MG BASE	A075646	002	Oct 18, 2000	Jan CAHN

TABLET;ORAL
DOXAZOSIN MESYLATE

>D>		@		EQ 4MG BASE	A075646	003	Oct 18, 2000	Jan CAHN
>D>		@		EQ 8MG BASE	A075646	004	Oct 18, 2000	Jan CAHN

TABLET, EXTENDED RELEASE;ORAL
CARDURA XL

>D>		+	UPJOHN	EQ 4MG BASE	N021269	001	Feb 22, 2005	Jan CAHN
>D>		+!		EQ 8MG BASE	N021269	002	Feb 22, 2005	Jan CAHN
>A>		+	VIATRIS	EQ 4MG BASE	N021269	001	Feb 22, 2005	Jan CAHN
>A>		+!		EQ 8MG BASE	N021269	002	Feb 22, 2005	Jan CAHN

DOXEPIN HYDROCHLORIDE

CAPSULE;ORAL
DOXEPIN HYDROCHLORIDE

>A>	AB		MANKIND PHARMA	EQ 10MG BASE	A215710	001	Feb 09, 2022	Jan NEWA
>A>	AB			EQ 25MG BASE	A215710	002	Feb 09, 2022	Jan NEWA
>A>	AB			EQ 50MG BASE	A215710	003	Feb 09, 2022	Jan NEWA
>A>	AB			EQ 75MG BASE	A215710	004	Feb 09, 2022	Jan NEWA
>A>	AB			EQ 100MG BASE	A215710	005	Feb 09, 2022	Jan NEWA

TABLET;ORAL
DOXEPIN HYDROCHLORIDE

>D>		@	STRIDES ARCOLAB LTD	EQ 3MG BASE	A202510	001	Jul 24, 2020	Jan CAHN
>D>		@		EQ 6MG BASE	A202510	002	Jul 24, 2020	Jan CAHN
>A>		@	STRIDES PHARMA	EQ 3MG BASE	A202510	001	Jul 24, 2020	Jan CAHN
>A>		@		EQ 6MG BASE	A202510	002	Jul 24, 2020	Jan CAHN

DOXERCALCIFEROL

INJECTABLE;INJECTION
DOXERCALCIFEROL

>A>	AP		EUGIA PHARMA	2MCG/ML (2MCG/ML)	A213717	001	Jan 24, 2022	Jan NEWA
>A>	AP			4MCG/2ML (2MCG/ML)	A213717	002	Jan 24, 2022	Jan NEWA

DOXYCYCLINE HYCLATE

TABLET;ORAL
DOXYCYCLINE HYCLATE

>D>	AB		EMCURE PHARMS LTD	EQ 100MG BASE	A209969	001	Nov 09, 2018	Jan DISC
>A>		@		EQ 100MG BASE	A209969	001	Nov 09, 2018	Jan DISC

EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL
EFAVIRENZ, EMTRICITABINE, AND TENOFOVIR DISOPROXIL FUMARATE

>A>	AB		HETERO LABS LTD V	600MG;200MG;300MG	A203053	001	Jan 24, 2022	Jan NEWA

EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE

TABLET;ORAL
DESCOVY

>A>		+	GILEAD SCIENCES INC	120MG;EQ 15MG BASE	N208215	002	Jan 07, 2022	Jan NEWA

ENALAPRILAT

INJECTABLE;INJECTION
ENALAPRILAT

>D>	AP	!	ATHENEX INC	1.25MG/ML	A075634	001	Aug 22, 2000	Jan CHRS
>A>	AP			1.25MG/ML	A075634	001	Aug 22, 2000	Jan CHRS
>D>	AP		HIKMA FARMACEUTICA	1.25MG/ML	A078687	001	Dec 23, 2008	Jan CHRS
>A>	AP	!		1.25MG/ML	A078687	001	Dec 23, 2008	Jan CHRS
>D>	AP	!	HOSPIRA	1.25MG/ML	A075458	001	Aug 22, 2000	Jan CHRS
>A>	AP			1.25MG/ML	A075458	001	Aug 22, 2000	Jan CHRS

EPINEPHRINE BITARTRATE; LIDOCAINE HYDROCHLORIDE

INJECTABLE;INJECTION
LIGNOSPAN STANDARD

>D>		!	DEPROCO	EQ 0.01MG BASE/ML;2%	A088390	001	Jan 22, 1985	Jan CRLD
>A>		+!		EQ 0.01MG BASE/ML;2%	A088390	001	Jan 22, 1985	Jan CRLD

ESZOPICLONE

TABLET;ORAL
ESZOPICLONE

>A>		@	CHARTWELL RX	1MG	A091165	001	Jul 14, 2011	Jan CAHN
>A>		@		2MG	A091165	002	Jul 14, 2011	Jan CAHN
>A>		@		3MG	A091165	003	Jul 14, 2011	Jan CAHN
>D>		@	WOCKHARDT LTD	1MG	A091165	001	Jul 14, 2011	Jan CAHN
>D>		@		2MG	A091165	002	Jul 14, 2011	Jan CAHN

TABLET;ORAL
ESZOPICLONE

>D>		@	3MG	A091165	003	Jul 14, 2011	Jan	CAHN

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE

TABLET;ORAL-28
ZOVIA 1/35E-28

>D>	AB	MAYNE PHARMA	0.035MG;1MG	A072721	001	Dec 30, 1991	Jan	DISC
>A>		@	0.035MG;1MG	A072721	001	Dec 30, 1991	Jan	DISC

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET;ORAL-28
NORETHINDRONE AND ETHINYL ESTRADIOL

>D>	AB	MAYNE PHARMA	0.035MG;0.5MG	A070686	001	Jan 29, 1987	Jan	DISC
>A>		@	0.035MG;0.5MG	A070686	001	Jan 29, 1987	Jan	DISC

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET;ORAL-21
MICROGESTIN 1.5/30

>D>	AB	MAYNE PHARMA	0.03MG;1.5MG	A075548	002	Jul 30, 2003	Jan	DISC
>A>		@	0.03MG;1.5MG	A075548	002	Jul 30, 2003	Jan	DISC

>D> MICROGESTIN 1/20

>D>	AB	MAYNE PHARMA	0.02MG;1MG	A075647	002	Jul 30, 2003	Jan	DISC
>A>		@	0.02MG;1MG	A075647	002	Jul 30, 2003	Jan	DISC

TABLET;ORAL-28
MICROGESTIN FE 1.5/30

>D>	AB	MAYNE PHARMA	0.03MG;1.5MG	A075548	001	Feb 05, 2001	Jan	DISC
>A>		@	0.03MG;1.5MG	A075548	001	Feb 05, 2001	Jan	DISC

>D> MICROGESTIN FE 1/20

>D>	AB	MAYNE PHARMA	0.02MG;1MG	A075647	001	Feb 05, 2001	Jan	DISC
>A>		@	0.02MG;1MG	A075647	001	Feb 05, 2001	Jan	DISC

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL

>D>	AB	MAYNE PHARMA	0.02MG,0.03MG,0.035MG;1MG,1MG,1MG	A076629	001	Mar 18, 2010	Jan	DISC
>A>		@	0.02MG,0.03MG,0.035MG;1MG,1MG,1MG	A076629	001	Mar 18, 2010	Jan	DISC

TABLET, CHEWABLE;ORAL
FINZALA

>D>		@ TEVA PHARMS USA INC	0.02MG;1MG	A210087	001	Apr 07, 2020	Jan	CMFD
>A>	AB		0.02MG;1MG	A210087	001	Apr 07, 2020	Jan	CMFD

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

>D>	AB	AMNEAL PHARMS	0.02MG;1MG	A207514	001	Sep 11, 2017	Jan	DISC
>A>		@	0.02MG;1MG	A207514	001	Sep 11, 2017	Jan	DISC

ETONOGESTREL

IMPLANT;IMPLANTATION
IMPLANON

>A>		@ ORGANON	68MG/IMPLANT	N021529	001	Jul 17, 2006	Jan	CAHN
>D>		@ ORGANON USA INC	68MG/IMPLANT	N021529	001	Jul 17, 2006	Jan	CAHN

NEXPLANON

>A>		+! ORGANON	68MG/IMPLANT	N021529	002	May 31, 2011	Jan	CAHN
>D>		+! ORGANON USA INC	68MG/IMPLANT	N021529	002	May 31, 2011	Jan	CAHN

FEXOFENADINE HYDROCHLORIDE

CAPSULE;ORAL
ALLEGRA

>A>		@ CHATTEM SANOFI	60MG	N020625	001	Jul 25, 1996	Jan	CAHN
>A>		@	60MG	N020625	001	Jul 25, 1996	Jan	CAHN
>D>		@ SANOFI AVENTIS US	60MG	N020625	001	Jul 25, 1996	Jan	CAHN

FLUTAMIDE

CAPSULE;ORAL
FLUTAMIDE

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

FOSFOMYCIN TROMETHAMINE

FOR SOLUTION;ORAL
FOSFOMYCIN TROMETHAMINE

>A>	AA	CIPLA	EQ 3GM BASE/PACKET	A211881	001	Jan 26, 2022	Jan	NEWA

FULVESTRANT
INJECTABLE;INTRAMUSCULAR
FULVESTRANT

>D>	AO		APOTEX	50MG/ML	A211730	001	Jun 11, 2021	Jan DISC
>A>		@		50MG/ML	A211730	001	Jun 11, 2021	Jan DISC

FUROSEMIDE
INJECTABLE;INJECTION
FUROSEMIDE

>A>	AP		HONG KONG	10MG/ML	A212803	001	Jan 27, 2022	Jan NEWA

GEMIFLOXACIN MESYLATE
TABLET;ORAL
>D> FACTIVE

>D>	AB	+!	LG CHEM LTD	EQ 320MG BASE	N021158	001	Apr 04, 2003	Jan DISC
>A>		+ @		EQ 320MG BASE	N021158	001	Apr 04, 2003	Jan DISC

>D> GEMIFLOXACIN MESYLATE

>D>	AB		ORBION PHARMS	EQ 320MG BASE	A090466	001	Jun 15, 2015	Jan DISC
>A>		@		EQ 320MG BASE	A090466	001	Jun 15, 2015	Jan DISC

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE
TABLET;ORAL
PROPRANOLOL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>A>		@	CHARTWELL RX	25MG;80MG	A071061	001	Aug 26, 1987	Jan CAHN
>D>		@	YAOPHARMA CO LTD	25MG;80MG	A071061	001	Aug 26, 1987	Jan CAHN

HYDROXYCHLOROQUINE SULFATE
TABLET;ORAL
HYDROXYCHLOROQUINE SULFATE

>D>			ACCORD HLTHCARE	400MG	A213342	004	Aug 18, 2021	Jan CHRS
>A>		!		400MG	A213342	004	Aug 18, 2021	Jan CHRS
>A>		+	NOVITIUM PHARMA	200MG	N214581	001	Jan 14, 2022	Jan NEWA
>A>		+!		300MG	N214581	002	Jan 14, 2022	Jan NEWA

HYDROXYZINE HYDROCHLORIDE
SYRUP;ORAL
HYDROXYZINE HYDROCHLORIDE

>A>		@	PAI HOLDINGS PHARM	10MG/5ML	A040391	001	Apr 10, 2002	Jan CAHN
>D>		@	VINTAGE PHARMS	10MG/5ML	A040391	001	Apr 10, 2002	Jan CAHN

IVABRADINE HYDROCHLORIDE
TABLET;ORAL
CORLANOR

>D>	AB	+	AMGEN INC	EQ 5MG BASE	N206143	001	Apr 15, 2015	Jan CTEC
>A>		+		EQ 5MG BASE	N206143	001	Apr 15, 2015	Jan CTEC
>D>	AB	+!		EQ 7.5MG BASE	N206143	002	Apr 15, 2015	Jan CTEC
>A>		+!		EQ 7.5MG BASE	N206143	002	Apr 15, 2015	Jan CTEC

>D> IVABRADINE HYDROCHLORIDE

>D>	AB		CENTAUR PHARMS PVT	EQ 5MG BASE	A214051	001	Dec 30, 2021	Jan DISC
>A>		@		EQ 5MG BASE	A214051	001	Dec 30, 2021	Jan DISC
>D>	AB			EQ 7.5MG BASE	A214051	002	Dec 30, 2021	Jan DISC
>A>		@		EQ 7.5MG BASE	A214051	002	Dec 30, 2021	Jan DISC

LAMOTRIGINE
>D> TABLET, CHEWABLE;ORAL
>D> LAMICTAL CD

>D>	AB	+	GLAXOSMITHKLINE LLC	2MG	N020764	004	Sep 08, 2000	Jan CDFR
>D>	AB	+		5MG	N020764	001	Aug 24, 1998	Jan CDFR
>D>	AB	+!		25MG	N020764	002	Aug 24, 1998	Jan CDFR
>D>		@		100MG	N020764	003	Aug 24, 1998	Jan CDFR

>D> LAMOTRIGINE

>D>	AB		ALEMBIC PHARMS LTD	5MG	A201168	001	Jun 12, 2014	Jan CDFR
>D>	AB			25MG	A201168	002	Jun 12, 2014	Jan CDFR
>D>	AB		AUROBINDO PHARMA	5MG	A090401	002	Nov 04, 2009	Jan CDFR
>D>	AB			25MG	A090401	003	Nov 04, 2009	Jan CDFR
>D>	AB		DR REDDYS LABS LTD	5MG	A076701	001	Jan 22, 2009	Jan CDFR
>D>	AB			25MG	A076701	002	Jan 22, 2009	Jan CDFR
>D>	AB		GLENMARK PHARMS LTD	5MG	A079099	001	Feb 19, 2009	Jan CDFR
>D>	AB			25MG	A079099	002	Feb 19, 2009	Jan CDFR
>D>		@	JUBILANT GENERICS	5MG	A200220	001	Feb 28, 2011	Jan CDFR
>D>		@		25MG	A200220	002	Feb 28, 2011	Jan CDFR

>D>		TABLET, CHEWABLE;ORAL						
>D>		LAMOTRIGINE						
>D>		@ MYLAN	5MG	A076630	001	Jan 22, 2009	Jan CDFR	
>D>		@	25MG	A076630	002	Jan 22, 2009	Jan CDFR	
>D>		@ SANDOZ	5MG	A078409	002	Jan 22, 2009	Jan CDFR	
>D>		@	25MG	A078409	003	Jan 22, 2009	Jan CDFR	
>D>	AB	TARO	5MG	A079204	001	Feb 04, 2009	Jan CDFR	
>D>	AB		25MG	A079204	002	Feb 04, 2009	Jan CDFR	
>D>		@ TEVA	5MG	A076420	001	Jun 21, 2006	Jan CDFR	
>D>		@	25MG	A076420	002	Jun 21, 2006	Jan CDFR	
>D>	AB	WATSON LABS	2MG	A076928	001	Jan 22, 2009	Jan CDFR	
>D>	AB		5MG	A076928	002	Jan 22, 2009	Jan CDFR	
>D>	AB		25MG	A076928	003	Jan 22, 2009	Jan CDFR	
>D>	AB	ZYDUS PHARMS USA INC	5MG	A078009	002	Jan 22, 2009	Jan CDFR	
>D>	AB		25MG	A078009	003	Jan 22, 2009	Jan CDFR	
>A>		TABLET, FOR SUSPENSION;ORAL						
>A>		LAMICTAL CD						
>A>	AB +	GLAXOSMITHKLINE LLC	2MG	N020764	004	Sep 08, 2000	Jan CDFR	
>A>	AB +		5MG	N020764	001	Aug 24, 1998	Jan CDFR	
>A>	AB +!		25MG	N020764	002	Aug 24, 1998	Jan CDFR	
>A>		@	100MG	N020764	003	Aug 24, 1998	Jan CDFR	
>A>		LAMOTRIGINE						
>A>	AB	ALEMBIC PHARMS LTD	5MG	A201168	001	Jun 12, 2014	Jan CDFR	
>A>	AB		25MG	A201168	002	Jun 12, 2014	Jan CDFR	
>A>	AB	AUROBINDO PHARMA	5MG	A090401	002	Nov 04, 2009	Jan CDFR	
>A>	AB		25MG	A090401	003	Nov 04, 2009	Jan CDFR	
>A>	AB	DR REDDYS LABS LTD	5MG	A076701	001	Jan 22, 2009	Jan CDFR	
>A>	AB		25MG	A076701	002	Jan 22, 2009	Jan CDFR	
>A>	AB	GLENMARK PHARMS LTD	5MG	A079099	001	Feb 19, 2009	Jan CDFR	
>A>	AB		25MG	A079099	002	Feb 19, 2009	Jan CDFR	
>A>		@ JUBILANT GENERICS	5MG	A200220	001	Feb 28, 2011	Jan CDFR	
>A>		@	25MG	A200220	002	Feb 28, 2011	Jan CDFR	
>A>		@ MYLAN	5MG	A076630	001	Jan 22, 2009	Jan CDFR	
>A>		@	25MG	A076630	002	Jan 22, 2009	Jan CDFR	
>A>		@ SANDOZ	5MG	A078409	002	Jan 22, 2009	Jan CDFR	
>A>		@	25MG	A078409	003	Jan 22, 2009	Jan CDFR	
>A>	AB	TARO	5MG	A079204	001	Feb 04, 2009	Jan CDFR	
>A>	AB		25MG	A079204	002	Feb 04, 2009	Jan CDFR	
>A>		@ TEVA	5MG	A076420	001	Jun 21, 2006	Jan CDFR	
>A>		@	25MG	A076420	002	Jun 21, 2006	Jan CDFR	
>A>	AB	WATSON LABS	2MG	A076928	001	Jan 22, 2009	Jan CDFR	
>A>	AB		5MG	A076928	002	Jan 22, 2009	Jan CDFR	
>A>	AB		25MG	A076928	003	Jan 22, 2009	Jan CDFR	
>A>	AB	ZYDUS PHARMS USA INC	5MG	A078009	002	Jan 22, 2009	Jan CDFR	
>A>	AB		25MG	A078009	003	Jan 22, 2009	Jan CDFR	
		TABLET, ORALLY DISINTEGRATING;ORAL						
		LAMOTRIGINE						
>A>	AB	AMRING PHARMS	25MG	A214124	001	Feb 03, 2022	Jan NEWA	
>A>	AB		50MG	A214124	002	Feb 03, 2022	Jan NEWA	
>A>	AB		100MG	A214124	003	Feb 03, 2022	Jan NEWA	
>A>	AB		200MG	A214124	004	Feb 03, 2022	Jan NEWA	

LANTHANUM CARBONATE

		TABLET, CHEWABLE;ORAL						
		LANTHANUM CARBONATE						
>A>	AB	BARR	EQ 500MG BASE	A090977	001	Jan 27, 2022	Jan NEWA	
>A>	AB		EQ 750MG BASE	A090977	002	Jan 27, 2022	Jan NEWA	
>A>	AB		EQ 1GM BASE	A090977	003	Jan 27, 2022	Jan NEWA	
>A>	AB	INVAGEN PHARMS	EQ 500MG BASE	A206868	001	Jan 24, 2022	Jan NEWA	
>A>	AB		EQ 750MG BASE	A206868	002	Jan 24, 2022	Jan NEWA	
>A>	AB		EQ 1GM BASE	A206868	003	Jan 24, 2022	Jan NEWA	

LEFLUNOMIDE

		TABLET;ORAL						
		LEFLUNOMIDE						
>D>		@ AET PHARMA	10MG	A213497	001	May 10, 2021	Jan CMFD	
>A>	AB		10MG	A213497	001	May 10, 2021	Jan CMFD	
>D>		@	20MG	A213497	002	May 10, 2021	Jan CMFD	
>A>	AB		20MG	A213497	002	May 10, 2021	Jan CMFD	

LEUPROLIDE MESYLATE

EMULSION;SUBCUTANEOUS

CAMCEVI KIT

>A>		+!	ACCORD	EQ 42MG BASE	N211488	001	May 25, 2021	Jan CAHN
>D>		+!	FORESEE PHARMS	EQ 42MG BASE	N211488	001	May 25, 2021	Jan CAHN

LEVETIRACETAM

TABLET;ORAL

LEVETIRACETAM

>D>	AB		SECAN PHARMS	500MG	A205102	004	Dec 16, 2015	Jan DISC
>A>		@		500MG	A205102	004	Dec 16, 2015	Jan DISC
>D>	AB			1GM	A205102	003	Dec 16, 2015	Jan DISC
>A>		@		1GM	A205102	003	Dec 16, 2015	Jan DISC

LEVOCETIRIZINE DIHYDROCHLORIDE

SOLUTION;ORAL

XYZAL

>A>		+ @	CHATTEM SANOFI	2.5MG/5ML	N022157	001	Jan 28, 2008	Jan CAHN
>D>		+ @	SANOFI	2.5MG/5ML	N022157	001	Jan 28, 2008	Jan CAHN

TABLET;ORAL

XYZAL

>A>		+ @	CHATTEM SANOFI	5MG	N022064	001	May 25, 2007	Jan CAHN
>D>		+ @	SANOFI	5MG	N022064	001	May 25, 2007	Jan CAHN

LEVOTHYROXINE SODIUM

CAPSULE;ORAL

>D> LEVOTHYROXINE SODIUM

>D>	AB		TEVA PHARMS USA INC	0.112MG	A211369	003	Apr 16, 2021	Jan DISC
>A>		@		0.112MG	A211369	003	Apr 16, 2021	Jan DISC

TIROSINT

>D>	AB	+	INSTITUT BIOCHIMIQUE	0.112MG	N021924	008	Oct 02, 2009	Jan CTEC
>A>		+		0.112MG	N021924	008	Oct 02, 2009	Jan CTEC

LEVOTHYROXINE SODIUM **

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

TABLET;ORAL

LEVOLET

>D>		@	GENUS LIFESCIENCES	0.025MG	N021137	001	Jun 06, 2003	Jan CMFD
>A>	AB1, AB3, AB4			0.025MG	N021137	001	Jun 06, 2003	Jan CMFD
>D>		@		0.05MG	N021137	002	Jun 06, 2003	Jan CMFD
>A>	AB1, AB3, AB4			0.05MG	N021137	002	Jun 06, 2003	Jan CMFD
>D>		@		0.075MG	N021137	003	Jun 06, 2003	Jan CMFD
>A>	AB1, AB3, AB4			0.075MG	N021137	003	Jun 06, 2003	Jan CMFD
>D>		@		0.088MG	N021137	004	Jun 06, 2003	Jan CMFD
>A>	AB1, AB3, AB4			0.088MG	N021137	004	Jun 06, 2003	Jan CMFD
>D>		@		0.1MG	N021137	005	Jun 06, 2003	Jan CMFD
>A>	AB1, AB3, AB4			0.1MG	N021137	005	Jun 06, 2003	Jan CMFD
>D>		@		0.112MG	N021137	006	Jun 06, 2003	Jan CMFD
>A>	AB1, AB3, AB4			0.112MG	N021137	006	Jun 06, 2003	Jan CMFD
>D>		@		0.125MG	N021137	007	Jun 06, 2003	Jan CMFD
>A>	AB1, AB3, AB4			0.125MG	N021137	007	Jun 06, 2003	Jan CMFD
>D>		@		0.137MG	N021137	008	Jun 06, 2003	Jan CMFD
>A>	AB1, AB3, AB4			0.137MG	N021137	008	Jun 06, 2003	Jan CMFD
>D>		@		0.15MG	N021137	009	Jun 06, 2003	Jan CMFD
>A>	AB1, AB3, AB4			0.15MG	N021137	009	Jun 06, 2003	Jan CMFD
>D>		@		0.175MG	N021137	010	Jun 06, 2003	Jan CMFD

TABLET;ORAL
LEVOLET

>A>	AB1, AB3, AB4		0.175MG	N021137	010	Jun 06, 2003	Jan	CMFD
>D>		@	0.2MG	N021137	011	Jun 06, 2003	Jan	CMFD
>A>	AB1, AB3, AB4		0.2MG	N021137	011	Jun 06, 2003	Jan	CMFD
>D>		@	0.3MG	N021137	012	Jun 06, 2003	Jan	CMFD
>A>	AB1, AB3, AB4		0.3MG	N021137	012	Jun 06, 2003	Jan	CMFD

LIDOCAINE; PRILOCAINE
CREAM;TOPICAL
LIDOCAINE AND PRILOCAINE

>D>	AB	ACRUX DDS PTY	2.5%;2.5%	A212482	001	Jul 27, 2021	Jan	DISC
>A>		@	2.5%;2.5%	A212482	001	Jul 27, 2021	Jan	DISC

LISINOPRIL
TABLET;ORAL
LISINOPRIL

>D>		@ MYLAN	2.5MG	A076071	001	Jul 01, 2002	Jan	CAHN
>D>		@	5MG	A076071	002	Jul 01, 2002	Jan	CAHN
>D>		@	10MG	A076071	003	Jul 01, 2002	Jan	CAHN
>D>		@	20MG	A076071	004	Jul 01, 2002	Jan	CAHN
>D>		@	30MG	A076071	005	Jul 01, 2002	Jan	CAHN
>D>		@	40MG	A076071	006	Jul 01, 2002	Jan	CAHN
>A>		@ STRIDES PHARMA	2.5MG	A076071	001	Jul 01, 2002	Jan	CAHN
>A>		@	5MG	A076071	002	Jul 01, 2002	Jan	CAHN
>A>		@	10MG	A076071	003	Jul 01, 2002	Jan	CAHN
>A>		@	20MG	A076071	004	Jul 01, 2002	Jan	CAHN
>A>		@	30MG	A076071	005	Jul 01, 2002	Jan	CAHN
>A>		@	40MG	A076071	006	Jul 01, 2002	Jan	CAHN

LUBIPROSTONE
CAPSULE;ORAL
LUBIPROSTONE

>A>	AB	DR REDDYS LABS LTD	8MCG	A206994	001	Feb 08, 2022	Jan	NEWA
>A>	AB		24MCG	A206994	002	Feb 08, 2022	Jan	NEWA
>A>	AB	TEVA PHARMS USA INC	8MCG	A209920	001	Jan 18, 2022	Jan	NEWA
>A>	AB		24MCG	A209920	002	Jan 18, 2022	Jan	NEWA

MARAVIROC
TABLET;ORAL
>A> MARAVIROC

>A>	AB	HETERO LABS LTD III	150MG	A203347	001	Feb 07, 2022	Jan	NFTG
>A>	AB		300MG	A203347	002	Feb 07, 2022	Jan	NFTG

SELZENTRY

>D>	+	VIIV HLTHCARE	150MG	N022128	001	Aug 06, 2007	Jan	CFTG
>A>	AB +		150MG	N022128	001	Aug 06, 2007	Jan	CFTG
>D>	+!		300MG	N022128	002	Aug 06, 2007	Jan	CFTG
>A>	AB +!		300MG	N022128	002	Aug 06, 2007	Jan	CFTG

MEMANTINE HYDROCHLORIDE
TABLET;ORAL
MEMANTINE HYDROCHLORIDE

>D>		@ MYLAN	5MG	A079225	001	Jan 30, 2015	Jan	CAHN
>D>		@	10MG	A079225	002	Jan 30, 2015	Jan	CAHN
>A>		@ RISING	5MG	A079225	001	Jan 30, 2015	Jan	CAHN
>A>		@	10MG	A079225	002	Jan 30, 2015	Jan	CAHN

METFORMIN HYDROCHLORIDE
TABLET, EXTENDED RELEASE;ORAL
METFORMIN HYDROCHLORIDE

>D>	AB2	AMTA	500MG	A213394	001	Aug 03, 2021	Jan	DISC
>A>		@	500MG	A213394	001	Aug 03, 2021	Jan	DISC
>D>	AB2		1GM	A213394	002	Aug 03, 2021	Jan	DISC
>A>		@	1GM	A213394	002	Aug 03, 2021	Jan	DISC

METHOTREXATE SODIUM

INJECTABLE;INJECTION

METHOTREXATE LPF

>D>		@ HOSPIRA	EQ 25MG BASE/ML	N011719	007	Mar 31, 1982	Jan CRLD
>A>	+ @		EQ 25MG BASE/ML	N011719	007	Mar 31, 1982	Jan CRLD

METHOTREXATE PRESERVATIVE FREE

>D>		@ HOSPIRA	EQ 20MG BASE/2ML (EQ 10MG BASE/ML)	N011719	014	Apr 13, 2005	Jan CRLD
>A>	+ @		EQ 20MG BASE/2ML (EQ 10MG BASE/ML)	N011719	014	Apr 13, 2005	Jan CRLD
>D>		@	EQ 2.5GM BASE/100ML (EQ 25MG BASE/ML)	N011719	011	Apr 13, 2005	Jan CRLD
>A>	+ @		EQ 2.5GM BASE/100ML (EQ 25MG BASE/ML)	N011719	011	Apr 13, 2005	Jan CRLD

METHOTREXATE SODIUM

>D>		@ HOSPIRA	EQ 2.5MG BASE/ML	N011719	004		Jan CRLD
>A>	+ @		EQ 2.5MG BASE/ML	N011719	004		Jan CRLD
>D>		@	EQ 20MG BASE/VIAL	N011719	001		Jan CRLD
>A>	+ @		EQ 20MG BASE/VIAL	N011719	001		Jan CRLD
>D>		@	EQ 25MG BASE/ML	N011719	005		Jan CRLD
>A>	+ @		EQ 25MG BASE/ML	N011719	005		Jan CRLD
>D>		@	EQ 50MG BASE/VIAL	N011719	003		Jan CRLD
>A>	+ @		EQ 50MG BASE/VIAL	N011719	003		Jan CRLD
>D>		@	EQ 100MG BASE/VIAL	N011719	006		Jan CRLD
>A>	+ @		EQ 100MG BASE/VIAL	N011719	006		Jan CRLD

METHOTREXATE SODIUM PRESERVATIVE FREE

>D> AP	!	HIKMA	EQ 250MG BASE/10ML (EQ 25MG BASE/ML)	A089343	001	Sep 16, 1986	Jan CHRS
>A> AP			EQ 250MG BASE/10ML (EQ 25MG BASE/ML)	A089343	001	Sep 16, 1986	Jan CHRS
>D>		@ HOSPIRA	EQ 1GM BASE/VIAL	N011719	009	Apr 07, 1988	Jan CRLD
>A>	+ @		EQ 1GM BASE/VIAL	N011719	009	Apr 07, 1988	Jan CRLD

MEXATE-AQ

>D>		@ BRISTOL MYERS	EQ 25MG BASE/ML	A088760	001	Feb 14, 1985	Jan CRLD
>A>	+ @		EQ 25MG BASE/ML	A088760	001	Feb 14, 1985	Jan CRLD

METHYLPREDNISOLONE ACETATE

INJECTABLE;INJECTION

METHYLPREDNISOLONE ACETATE

>A> AB		PAR STERILE PRODUCTS	40MG/ML	A214297	001	Jan 21, 2022	Jan NEWA
>A> AB			80MG/ML	A214297	002	Jan 21, 2022	Jan NEWA

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE;INJECTION

METHYLPREDNISOLONE SODIUM SUCCINATE

>D>		@ TIANJIN KINGYORK	EQ 40MG BASE/VIAL	A212396	001	Apr 20, 2021	Jan CMFD
>A> AP			EQ 40MG BASE/VIAL	A212396	001	Apr 20, 2021	Jan CMFD
>D>		@	EQ 125MG BASE/VIAL	A212396	002	Apr 20, 2021	Jan CMFD
>A> AP			EQ 125MG BASE/VIAL	A212396	002	Apr 20, 2021	Jan CMFD
>D>		@	EQ 500MG BASE/VIAL	A212396	003	Apr 20, 2021	Jan CMFD
>A> AP			EQ 500MG BASE/VIAL	A212396	003	Apr 20, 2021	Jan CMFD
>D>		@	EQ 1GM BASE/VIAL	A212396	004	Apr 20, 2021	Jan CMFD
>A> AP			EQ 1GM BASE/VIAL	A212396	004	Apr 20, 2021	Jan CMFD
>D>		@	EQ 2GM BASE/VIAL	A212396	005	Apr 20, 2021	Jan CMFD
>A> AP			EQ 2GM BASE/VIAL	A212396	005	Apr 20, 2021	Jan CMFD

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE;INJECTION

REGLAN

>D>		@ HIKMA	EQ 5MG BASE/ML	N017862	001		Jan CRLD
>A>	+ @		EQ 5MG BASE/ML	N017862	001		Jan CRLD

METRONIDAZOLE

GEL;VAGINAL

METRONIDAZOLE

>A> AB		GLENMARK PHARMS LTD	0.75%	A215794	001	Jan 27, 2022	Jan NEWA

INJECTABLE;INJECTION

METRONIDAZOLE IN PLASTIC CONTAINER

>D>		@ MYLAN LABS LTD	500MG/100ML	A205531	001	May 09, 2017	Jan CAHN
>A>		@ RISING	500MG/100ML	A205531	001	May 09, 2017	Jan CAHN

MIDAZOLAM HYDROCHLORIDE

INJECTABLE;INJECTION

MIDAZOLAM HYDROCHLORIDE PRESERVATIVE FREE

>D>		@ MYLAN ASI	EQ 1MG BASE/ML	A	090315	001	Nov 29, 2010	Jan CAHN
>D>		@	EQ 5MG BASE/ML	A	090315	002	Nov 29, 2010	Jan CAHN
>A>		@ STERISCIENCE	EQ 1MG BASE/ML	A	090315	001	Nov 29, 2010	Jan CAHN
>A>		@	EQ 5MG BASE/ML	A	090315	002	Nov 29, 2010	Jan CAHN

MIGLUSTAT

CAPSULE;ORAL

MIGLUSTAT

>A>	AB	BRECKENRIDGE	100MG	A	209325	001	Feb 03, 2022	Jan NEWA

MINOCYCLINE HYDROCHLORIDE

AEROSOL, FOAM;TOPICAL

AMZEEQ

>A>		+! JOURNEY	EQ 4% BASE	N	212379	001	Oct 18, 2019	Jan CAHN
>D>		+! VYNE	EQ 4% BASE	N	212379	001	Oct 18, 2019	Jan CAHN

ZILXI

>A>		+! JOURNEY	EQ 1.5% BASE	N	213690	001	May 28, 2020	Jan CAHN
>D>		+! VYNE	EQ 1.5% BASE	N	213690	001	May 28, 2020	Jan CAHN

MIRTAZAPINE

TABLET, ORALLY DISINTEGRATING;ORAL

MIRTAZAPINE

>A>	AB	SQUARE PHARMS	15MG	A	205798	001	Jun 01, 2017	Jan CAHN
>A>	AB		30MG	A	205798	002	Jun 01, 2017	Jan CAHN
>A>	AB		45MG	A	205798	003	Jun 01, 2017	Jan CAHN
>D>	AB	ZYDUS PHARMS	15MG	A	205798	001	Jun 01, 2017	Jan CAHN
>D>	AB		30MG	A	205798	002	Jun 01, 2017	Jan CAHN
>D>	AB		45MG	A	205798	003	Jun 01, 2017	Jan CAHN

MOMETASONE FUROATE; OLOPATADINE HYDROCHLORIDE

SPRAY, METERED;NASAL

RYALTRIS

>A>		+! GLENMARK SPECIALTY	0.025MG/SPRAY;0.665MG/SPRAY	N	211746	001	Jan 13, 2022	Jan NEWA

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE;ORAL

MORPHINE SULFATE

>D>	AB	NORTEC DEV ASSOC	20MG	A	203158	001	Aug 04, 2021	Jan DISC
>A>		@	20MG	A	203158	001	Aug 04, 2021	Jan DISC
>D>	AB		30MG	A	203158	002	Aug 04, 2021	Jan DISC
>A>		@	30MG	A	203158	002	Aug 04, 2021	Jan DISC
>D>	AB		50MG	A	203158	003	Aug 04, 2021	Jan DISC
>A>		@	50MG	A	203158	003	Aug 04, 2021	Jan DISC
>D>	AB		60MG	A	203158	004	Aug 04, 2021	Jan DISC
>A>		@	60MG	A	203158	004	Aug 04, 2021	Jan DISC
>D>	AB		80MG	A	203158	005	Aug 04, 2021	Jan DISC
>A>		@	80MG	A	203158	005	Aug 04, 2021	Jan DISC
>D>	AB		100MG	A	203158	006	Aug 04, 2021	Jan DISC
>A>		@	100MG	A	203158	006	Aug 04, 2021	Jan DISC

INJECTABLE;INJECTION

MORPHINE SULFATE

>D>		+! HOSPIRA INC	50MG/ML	N	202515	006	Apr 29, 2021	Jan DISC
>A>		+ @	50MG/ML	N	202515	006	Apr 29, 2021	Jan DISC
>D>		@ INTL MEDICATION SYS	1MG/ML	A	202861	001	Apr 29, 2021	Jan CMFD
>A>			1MG/ML	A	202861	001	Apr 29, 2021	Jan CMFD

TABLET;ORAL

MORPHINE SULFATE

>A>	AB	RICONPHARMA LLC	15MG	A	215584	001	Feb 07, 2022	Jan NEWA
>A>	AB		30MG	A	215584	002	Feb 07, 2022	Jan NEWA

MYCOPHENOLATE MOFETIL

FOR SUSPENSION;ORAL

MYCOPHENOLATE MOFETIL

>A>	AB	TEVA PHARMS USA	200MG/ML	A	211272	001	Jan 25, 2022	Jan NEWA

NALMEFENE HYDROCHLORIDE

>D>			INJECTABLE;INJECTION					
>D>			REVEX					
>D>		+ @	EUROHLTH INTL SARL	EQ 0.1MG BASE/ML	N020459	001	Apr 17, 1995	Jan CDFR
>D>		+ @		EQ 1MG BASE/ML	N020459	002	Apr 17, 1995	Jan CDFR
			SOLUTION;INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS					
>A>			NALMEFENE HYDROCHLORIDE					
>A>		!	PURDUE PHARMA LP	EQ 2MG BASE/2ML (EQ 1MG BASE/ML)	A212955	001	Feb 08, 2022	Jan NEWA
>A>			REVEX					
>A>		+ @	EUROHLTH INTL SARL	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	N020459	001	Apr 17, 1995	Jan CDFR
>A>		+ @		EQ 2MG BASE/2ML (EQ 1MG BASE/ML)	N020459	002	Apr 17, 1995	Jan CDFR

NITROGLYCERIN

			TABLET;SUBLINGUAL					
			NITROSTAT					
>D>	AB	+	UPJOHN	0.3MG	N021134	001	May 01, 2000	Jan CAHN
>D>	AB	+		0.4MG	N021134	002	May 01, 2000	Jan CAHN
>D>	AB	+!		0.6MG	N021134	003	May 01, 2000	Jan CAHN
>A>	AB	+	VIATRIS	0.3MG	N021134	001	May 01, 2000	Jan CAHN
>A>	AB	+		0.4MG	N021134	002	May 01, 2000	Jan CAHN
>A>	AB	+!		0.6MG	N021134	003	May 01, 2000	Jan CAHN

OCTREOTIDE ACETATE

			CAPSULE, DELAYED RELEASE;ORAL					
			MYCAPSSA					
>A>		+!	AMRYT	EQ 20MG BASE	N208232	001	Jun 26, 2020	Jan CAHN
>D>		+!	CHIASMA	EQ 20MG BASE	N208232	001	Jun 26, 2020	Jan CAHN

OFLOXACIN

			SOLUTION/DROPS;OTIC					
			OFLOXACIN					
>A>	AT		FDC LTD	0.3%	A215038	001	Jan 19, 2022	Jan NEWA

OMEPRAZOLE

			CAPSULE, DELAYED REL PELLETS;ORAL					
			OMEPRAZOLE					
>D>			@ MYLAN	10MG	A075876	001	May 29, 2003	Jan CAHN
>D>			@	20MG	A075876	002	May 29, 2003	Jan CAHN
>D>			@	40MG	A075876	003	Jan 21, 2009	Jan CAHN
>A>			@ STRIDES PHARMA	10MG	A075876	001	May 29, 2003	Jan CAHN
>A>			@	20MG	A075876	002	May 29, 2003	Jan CAHN
>A>			@	40MG	A075876	003	Jan 21, 2009	Jan CAHN

OSELTAMIVIR PHOSPHATE

			FOR SUSPENSION;ORAL					
			OSELTAMIVIR PHOSPHATE					
>A>	AB		STRIDES PHARMA	EQ 6MG BASE/ML	A211894	001	Jan 13, 2022	Jan NEWA

OXAZEPAM

			CAPSULE;ORAL					
			SERAX					
>D>			@ ALPHARMA US PHARMS	10MG	N015539	002		Jan CRLD
>A>		+ @		10MG	N015539	002		Jan CRLD
>D>			@	15MG	N015539	004		Jan CRLD
>A>		+ @		15MG	N015539	004		Jan CRLD
>D>			@	30MG	N015539	006		Jan CRLD
>A>		+ @		30MG	N015539	006		Jan CRLD

PALONOSETRON HYDROCHLORIDE

			INJECTABLE;INTRAVENOUS					
			PALONOSETRON HYDROCHLORIDE					
>D>			EMCURE PHARMS LTD	EQ 0.075MG BASE/1.5ML (EQ 0.05MG BASE/ML)	A202951	001	Jun 29, 2021	Jan DISC
>A>			@	EQ 0.075MG BASE/1.5ML (EQ 0.05MG BASE/ML)	A202951	001	Jun 29, 2021	Jan DISC
>D>	AP			EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A202951	002	Jun 29, 2021	Jan DISC
>A>			@	EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A202951	002	Jun 29, 2021	Jan DISC

PAROXETINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

PAROXETINE HYDROCHLORIDE

>D>	AB		SINOTHERAPEUTICS INC	EQ 12.5MG BASE	A213612	001	Aug 11, 2021	Jan DISC
>A>		@		EQ 12.5MG BASE	A213612	001	Aug 11, 2021	Jan DISC
>D>	AB			EQ 25MG BASE	A213612	002	Aug 11, 2021	Jan DISC
>A>		@		EQ 25MG BASE	A213612	002	Aug 11, 2021	Jan DISC

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION;INTRAVENOUS

PHENYLEPHRINE HYDROCHLORIDE

>D>	AP1		PAR STERILE PRODUCTS	10MG/ML (10MG/ML)	A210025	001	Dec 21, 2018	Jan DISC
>A>		@		10MG/ML (10MG/ML)	A210025	001	Dec 21, 2018	Jan DISC

PIRFENIDONE

CAPSULE;ORAL

PIRFENIDONE

>A>	AB		ACCORD HLTHCARE	267MG	A212731	001	Jan 20, 2022	Jan NEWA
>D>	AB		AMNEAL	267MG	A212569	001	Jan 03, 2022	Jan DISC
>A>		@		267MG	A212569	001	Jan 03, 2022	Jan DISC

TABLET;ORAL

ESBRIET

>D>		+	GENENTECH INC	267MG	N208780	001	Jan 11, 2017	Jan CFTG
>A>	AB	+		267MG	N208780	001	Jan 11, 2017	Jan CFTG
>D>		+!		801MG	N208780	003	Jan 11, 2017	Jan CFTG
>A>	AB	+!		801MG	N208780	003	Jan 11, 2017	Jan CFTG

PIRFENIDONE

>A>	AB		ACCORD HLTHCARE	267MG	A212730	001	Jan 25, 2022	Jan NFTG
>A>	AB			801MG	A212730	002	Jan 25, 2022	Jan NFTG
>A>	AB		TEVA PHARMS USA	267MG	A212759	001	Jan 25, 2022	Jan NFTG
>A>	AB			801MG	A212759	002	Jan 25, 2022	Jan NFTG

POMALIDOMIDE

CAPSULE;ORAL

POMALIDOMIDE

>A>	AB		MYLAN	1MG	A210275	001	Jan 26, 2022	Jan NEWA
>A>	AB			2MG	A210275	002	Jan 26, 2022	Jan NEWA
>A>	AB			3MG	A210275	003	Jan 26, 2022	Jan NEWA
>A>	AB			4MG	A210275	004	Jan 26, 2022	Jan NEWA

POMALYST

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

POSACONAZOLE

>D> FOR SUSPENSION, DELAYED RELEASE;ORAL

>D> NOXAFIL POWDERMIX KIT

>D>		+!	MSD MERCK CO	300MG	N214770	001	May 31, 2021	Jan DISC
>A>		+	@	300MG	N214770	001	May 31, 2021	Jan DISC

TABLET, DELAYED RELEASE;ORAL

POSACONAZOLE

>A>	AB		BIOCON PHARMA	100MG	A214476	001	Feb 04, 2022	Jan NEWA

POTASSIUM CHLORIDE

FOR SOLUTION;ORAL

POTASSIUM CHLORIDE

>A>	AA		GRANULES	20MEQ	A213467	001	Jan 27, 2022	Jan NEWA

SOLUTION;ORAL

POTASSIUM CHLORIDE

>A>	AA		RUBICON	20MEQ/15ML	A214656	001	Jan 13, 2022	Jan NEWA
>A>	AA			40MEQ/15ML	A214656	002	Jan 13, 2022	Jan NEWA
>A>	AA		TRIS PHARMA INC	20MEQ/15ML	A214076	001	Jan 26, 2022	Jan NEWA
>A>	AA			40MEQ/15ML	A214076	002	Jan 26, 2022	Jan NEWA

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
PRAMIPEXOLE DIHYDROCHLORIDE

>A> AB	NOVAST LABS	0.375MG	A213444	001	Feb 03, 2022	Jan	NEWA
>A> AB		0.75MG	A213444	002	Feb 03, 2022	Jan	NEWA
>A> AB		1.5MG	A213444	003	Feb 03, 2022	Jan	NEWA
>A> AB		2.25MG	A213444	004	Feb 03, 2022	Jan	NEWA
>A> AB		3MG	A213444	005	Feb 03, 2022	Jan	NEWA
>A> AB		3.75MG	A213444	006	Feb 03, 2022	Jan	NEWA
>A> AB		4.5MG	A213444	007	Feb 03, 2022	Jan	NEWA

RANOLAZINE

TABLET, EXTENDED RELEASE;ORAL
RANOLAZINE

>A> AB	VKT PHARMA	500MG	A214035	001	Jan 19, 2022	Jan	NEWA
>A> AB		1GM	A214035	002	Jan 19, 2022	Jan	NEWA

RASAGILINE MESYLATE

TABLET;ORAL
RASAGILINE MESYLATE

>D> AB	DR REDDYS	EQ 0.5MG BASE	A201942	001	Nov 18, 2021	Jan	DISC
>A>	@	EQ 0.5MG BASE	A201942	001	Nov 18, 2021	Jan	DISC
>D> AB		EQ 1MG BASE	A201942	002	Nov 18, 2021	Jan	DISC
>A>	@	EQ 1MG BASE	A201942	002	Nov 18, 2021	Jan	DISC

RILUZOLE

SUSPENSION;ORAL
TIGLUTIK KIT

>D>	+! ITALFARMACO SPA	50MG/10ML	N209080	001	Sep 05, 2018	Jan	CAHN
>A>	+!	50MG/10ML	N209080	001	Sep 05, 2018	Jan	CAHN

ROSUVASTATIN CALCIUM

TABLET;ORAL
ROSUVASTATIN CALCIUM

>D>	@ MYLAN	EQ 5MG BASE	A079161	001	Jul 19, 2016	Jan	CAHN
>D>	@	EQ 10MG BASE	A079161	002	Jul 19, 2016	Jan	CAHN
>D>	@	EQ 20MG BASE	A079161	003	Jul 19, 2016	Jan	CAHN
>D>	@	EQ 40MG BASE	A079161	004	Jul 19, 2016	Jan	CAHN
>A>	@ STRIDES PHARMA	EQ 5MG BASE	A079161	001	Jul 19, 2016	Jan	CAHN
>A>	@	EQ 10MG BASE	A079161	002	Jul 19, 2016	Jan	CAHN
>A>	@	EQ 20MG BASE	A079161	003	Jul 19, 2016	Jan	CAHN
>A>	@	EQ 40MG BASE	A079161	004	Jul 19, 2016	Jan	CAHN

SAMARIUM SM-153 LEXIDRONAM PENTASODIUM

INJECTABLE;INJECTION
QUADRAMET

>D>	+! LANTHEUS MEDICAL	50mCi/ML	N020570	001	Mar 28, 1997	Jan	DISC
>A>	+ @	50mCi/ML	N020570	001	Mar 28, 1997	Jan	DISC

SERTRALINE HYDROCHLORIDE

CONCENTRATE;ORAL
ZOLOFT

>D> AA	+! UPJOHN	EQ 20MG BASE/ML	N020990	001	Dec 07, 1999	Jan	CAHN
>A> AA	+! VIATRIS	EQ 20MG BASE/ML	N020990	001	Dec 07, 1999	Jan	CAHN

TABLET;ORAL
ZOLOFT

>D> AB	+ UPJOHN	EQ 25MG BASE	N019839	005	Mar 06, 1996	Jan	CAHN
>D> AB	+	EQ 50MG BASE	N019839	001	Dec 30, 1991	Jan	CAHN
>D> AB	+!	EQ 100MG BASE	N019839	002	Dec 30, 1991	Jan	CAHN
>D>	+ @	EQ 150MG BASE	N019839	003	Dec 30, 1991	Jan	CAHN
>D>	+ @	EQ 200MG BASE	N019839	004	Dec 30, 1991	Jan	CAHN
>A> AB	+ VIATRIS	EQ 25MG BASE	N019839	005	Mar 06, 1996	Jan	CAHN
>A> AB	+	EQ 50MG BASE	N019839	001	Dec 30, 1991	Jan	CAHN
>A> AB	+!	EQ 100MG BASE	N019839	002	Dec 30, 1991	Jan	CAHN
>A>	+ @	EQ 150MG BASE	N019839	003	Dec 30, 1991	Jan	CAHN
>A>	+ @	EQ 200MG BASE	N019839	004	Dec 30, 1991	Jan	CAHN

SEVELAMER CARBONATE

TABLET;ORAL

SEVELAMER CARBONATE

>A>	AB		MICRO LABS	800MG	A215537	001	Feb 07, 2022	Jan NEWA
>D>		@	MYLAN	800MG	A201069	001	Aug 05, 2020	Jan CAHN
>A>		@	STRIDES PHARMA	800MG	A201069	001	Aug 05, 2020	Jan CAHN

SILDENAFIL CITRATE

FOR SUSPENSION;ORAL

SILDENAFIL CITRATE

>A>	AB		MSN	EQ 10MG BASE/ML	A214641	001	Feb 08, 2022	Jan NEWA

SODIUM NITROPRUSSIDE

INJECTABLE;INJECTION

SODIUM NITROPRUSSIDE

>D>	AP		BE PHARMS	25MG/ML	A214971	001	Jul 12, 2021	Jan DISC
>A>		@		25MG/ML	A214971	001	Jul 12, 2021	Jan DISC

SOFOSBUVIR

TABLET;ORAL

>A> SOFOSBUVIR

>A>	AB		TEVA PHARMS USA INC	400MG	A211353	001	Jan 27, 2022	Jan NFTG

SOVALDI

>D>		+!	GILEAD SCIENCES INC	400MG	N204671	001	Dec 06, 2013	Jan CFTG
>A>	AB	+!		400MG	N204671	001	Dec 06, 2013	Jan CFTG

SOLIFENACIN SUCCINATE

TABLET;ORAL

SOLIFENACIN SUCCINATE

>D>	AB		AMNEAL PHARMS CO	5MG	A209719	001	May 20, 2019	Jan DISC
>A>		@		5MG	A209719	001	May 20, 2019	Jan DISC
>D>	AB			10MG	A209719	002	May 20, 2019	Jan DISC
>A>		@		10MG	A209719	002	May 20, 2019	Jan DISC

SUCCINYLCHOLINE CHLORIDE

INJECTABLE;INJECTION

SUCCINYLCHOLINE CHLORIDE

>A>	AP		BE PHARMS	20MG/ML	A216003	001	Feb 07, 2022	Jan NEWA

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION;ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

>A>	AB		NOVITIUM PHARMA	200MG/5ML;40MG/5ML	A214330	001	Feb 08, 2022	Jan NEWA

TAFLUPROST

SOLUTION/DROPS;OPHTHALMIC

TAFLUPROST

>A>	AT		SANDOZ INC	0.0015%	A209040	001	Jan 28, 2022	Jan NEWA

TEMOZOLOMIDE

CAPSULE;ORAL

TEMOZOLOMIDE

>D>		@	HERITAGE	5MG	A078879	001	Mar 01, 2010	Jan CMFD
>A>	AB			5MG	A078879	001	Mar 01, 2010	Jan CMFD
>D>		@		20MG	A078879	002	Mar 01, 2010	Jan CMFD
>A>	AB			20MG	A078879	002	Mar 01, 2010	Jan CMFD
>D>		@		100MG	A078879	003	Mar 01, 2010	Jan CMFD
>A>	AB			100MG	A078879	003	Mar 01, 2010	Jan CMFD
>D>		@		140MG	A078879	005	Mar 01, 2010	Jan CMFD
>A>	AB			140MG	A078879	005	Mar 01, 2010	Jan CMFD
>D>		@		180MG	A078879	006	Mar 01, 2010	Jan CMFD
>A>	AB			180MG	A078879	006	Mar 01, 2010	Jan CMFD
>D>		@		250MG	A078879	004	Mar 01, 2010	Jan CMFD
>A>	AB			250MG	A078879	004	Mar 01, 2010	Jan CMFD

TESTOSTERONE

GEL;TRANSDERMAL

ANDROGEL

>D>	AB2	+	ABBVIE	1.62% (20.25MG/1.25GM PACKET)	N022309	002	Sep 07, 2012	Jan DISC
>A>		+ @		1.62% (20.25MG/1.25GM PACKET)	N022309	002	Sep 07, 2012	Jan DISC
>D>	AB2	+!		1.62% (40.5MG/2.5GM PACKET)	N022309	003	Sep 07, 2012	Jan DISC

GEL;TRANSDERMAL
ANDROGEL

>A>		+ @		1.62% (40.5MG/2.5GM PACKET)	N022309	003	Sep 07, 2012	Jan DISC
>D>	AB1	+		25MG/2.5GM PACKET	N021015	001	Feb 28, 2000	Jan DISC
>A>		+ @		25MG/2.5GM PACKET	N021015	001	Feb 28, 2000	Jan DISC
>D>	AB1	+!		50MG/5GM PACKET	N021015	002	Feb 28, 2000	Jan DISC
>A>		+ @		50MG/5GM PACKET	N021015	002	Feb 28, 2000	Jan DISC

TESTOSTERONE

>D>	AB1		ACTAVIS LABS UT INC	50MG/5GM PACKET	A076737	002	Jan 27, 2006	Jan CHRS
>A>	AB1	!		50MG/5GM PACKET	A076737	002	Jan 27, 2006	Jan CHRS
>D>	AB2		PADAGIS ISRAEL	1.62% (40.5MG/2.5GM PACKET)	A205781	002	Jul 12, 2017	Jan CHRS
>A>	AB2	!		1.62% (40.5MG/2.5GM PACKET)	A205781	002	Jul 12, 2017	Jan CHRS

TOFACITINIB CITRATE

TABLET, EXTENDED RELEASE;ORAL
TOFACITINIB

>D>	AB		ZYDUS PHARMS	EQ 11MG BASE	A214264	001	Aug 19, 2021	Jan DISC
>A>		@		EQ 11MG BASE	A214264	001	Aug 19, 2021	Jan DISC
>D>	AB			EQ 22MG BASE	A214264	002	Aug 19, 2021	Jan DISC
>A>		@		EQ 22MG BASE	A214264	002	Aug 19, 2021	Jan DISC

XELJANZ XR

>D>	AB	+	PFIZER	EQ 11MG BASE	N208246	001	Feb 23, 2016	Jan CTEC
>A>		+		EQ 11MG BASE	N208246	001	Feb 23, 2016	Jan CTEC
>D>	AB	+!		EQ 22MG BASE	N208246	002	Dec 12, 2019	Jan CTEC
>A>		+!		EQ 22MG BASE	N208246	002	Dec 12, 2019	Jan CTEC

TRIAMCINOLONE ACETONIDE

AEROSOL, METERED;NASAL
NASACORT

>A>		@	CHATTEM SANOFI	0.055MG/INH	N019798	001	Jul 11, 1991	Jan CAHN
>A>		@		0.055MG/INH	N019798	001	Jul 11, 1991	Jan CAHN
>D>		@	SANOFI AVENTIS US	0.055MG/INH	N019798	001	Jul 11, 1991	Jan CAHN

INJECTABLE;INJECTION
TRIAMCINOLONE ACETONIDE

>A>	AB		LONG GROVE PHARMS	40MG/ML	A213543	001	Jan 19, 2022	Jan CAHN

SPRAY, METERED;NASAL
TRIAMCINOLONE ACETONIDE

>D>		@	PERRIGO	0.055MG/SPRAY	A078104	001	Jul 30, 2009	Jan CAHN
>A>		@	PERRIGO PHARMA INTL	0.055MG/SPRAY	A078104	001	Jul 30, 2009	Jan CAHN

UPADACITINIB

TABLET, EXTENDED RELEASE;ORAL
RINVOQ

>D>		+!	ABBVIE INC	15MG	N211675	001	Aug 16, 2019	Jan CHRS
>A>		+		15MG	N211675	001	Aug 16, 2019	Jan CHRS
>A>		+!		30MG	N211675	002	Jan 14, 2022	Jan NEWA

VANCOMYCIN HYDROCHLORIDE

INJECTABLE;INJECTION
VANCOCIN HYDROCHLORIDE

>D>		@	ANI PHARMS	EQ 500MG BASE/VIAL	A060180	001		Jan CAHN
>D>		@		EQ 500MG BASE/VIAL	A062476	001	Mar 15, 1984	Jan CAHN
>D>		@		EQ 500MG BASE/VIAL	A062716	001	Mar 13, 1987	Jan CAHN
>D>		@		EQ 500MG BASE/VIAL	A062812	001	Nov 17, 1987	Jan CAHN
>D>		@		EQ 1GM BASE/VIAL	A060180	002	Mar 21, 1986	Jan CAHN
>D>		@		EQ 1GM BASE/VIAL	A062476	002	Mar 21, 1986	Jan CAHN
>D>		@		EQ 1GM BASE/VIAL	A062716	002	Mar 13, 1987	Jan CAHN
>D>		@		EQ 1GM BASE/VIAL	A062812	002	Nov 17, 1987	Jan CAHN
>D>		@		EQ 10GM BASE/VIAL	A062812	003	Nov 17, 1987	Jan CAHN
>A>		@	STERISCIENCE	EQ 500MG BASE/VIAL	A060180	001		Jan CAHN
>A>		@		EQ 500MG BASE/VIAL	A062476	001	Mar 15, 1984	Jan CAHN
>A>		@		EQ 500MG BASE/VIAL	A062716	001	Mar 13, 1987	Jan CAHN
>A>		@		EQ 500MG BASE/VIAL	A062812	001	Nov 17, 1987	Jan CAHN
>A>		@		EQ 1GM BASE/VIAL	A060180	002	Mar 21, 1986	Jan CAHN
>A>		@		EQ 1GM BASE/VIAL	A062476	002	Mar 21, 1986	Jan CAHN
>A>		@		EQ 1GM BASE/VIAL	A062716	002	Mar 13, 1987	Jan CAHN
>A>		@		EQ 1GM BASE/VIAL	A062812	002	Nov 17, 1987	Jan CAHN
>A>		@		EQ 10GM BASE/VIAL	A062812	003	Nov 17, 1987	Jan CAHN

VENLAFAXINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

VENLAFAXINE HYDROCHLORIDE

>D>	AB		YICHANG HUMANWELL	EQ 37.5MG BASE	A214654	001	Aug 06, 2021	Jan DISC
>A>		@		EQ 37.5MG BASE	A214654	001	Aug 06, 2021	Jan DISC
>D>	AB			EQ 75MG BASE	A214654	002	Aug 06, 2021	Jan DISC
>A>		@		EQ 75MG BASE	A214654	002	Aug 06, 2021	Jan DISC
>D>	AB			EQ 150MG BASE	A214654	003	Aug 06, 2021	Jan DISC
>A>		@		EQ 150MG BASE	A214654	003	Aug 06, 2021	Jan DISC

VIGABATRIN

TABLET;ORAL

VIGABATRIN

>A>	AB		ZYDUS	500MG	A215707	001	Jan 19, 2022	Jan NEWA

ZIPRASIDONE HYDROCHLORIDE

CAPSULE;ORAL

GEODON

>D>	AB	+!	UPJOHN	EQ 20MG BASE	N020825	001	Feb 05, 2001	Jan CAHN
>D>	AB	+		EQ 40MG BASE	N020825	002	Feb 05, 2001	Jan CAHN
>D>	AB	+		EQ 60MG BASE	N020825	003	Feb 05, 2001	Jan CAHN
>D>	AB	+		EQ 80MG BASE	N020825	004	Feb 05, 2001	Jan CAHN
>A>	AB	+!	VIATRIS	EQ 20MG BASE	N020825	001	Feb 05, 2001	Jan CAHN
>A>	AB	+		EQ 40MG BASE	N020825	002	Feb 05, 2001	Jan CAHN
>A>	AB	+		EQ 60MG BASE	N020825	003	Feb 05, 2001	Jan CAHN
>A>	AB	+		EQ 80MG BASE	N020825	004	Feb 05, 2001	Jan CAHN

ZIPRASIDONE MESYLATE

INJECTABLE;INTRAMUSCULAR

GEODON

>D>	AP	+!	UPJOHN	EQ 20MG BASE/ML	N020919	001	Jun 21, 2002	Jan CAHN
>A>	AP	+!	VIATRIS	EQ 20MG BASE/ML	N020919	001	Jun 21, 2002	Jan CAHN

ACETAMINOPHEN; ASPIRIN; CAFFEINE

TABLET;ORAL
ACETAMINOPHEN, ASPIRIN AND CAFFEINE

>A>		AUROBINDO PHARMA LTD	250MG;250MG;65MG	A211695	001	Feb 02, 2022	Jan NEWA

ADAPALENE

GEL;TOPICAL
ADAPALENE

>A>		TARO PHARMS	0.1%	A215940	001	Jan 14, 2022	Jan NEWA

ESOMEPRAZOLE MAGNESIUM

TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL
ESOMEPRAZOLE MAGNESIUM

>D>	+!	DEXCEL PHARMA	EQ 20MG BASE	N214278	001	Oct 20, 2020	Jan DISC
>A>	+ @		EQ 20MG BASE	N214278	001	Oct 20, 2020	Jan DISC

FAMOTIDINE

TABLET;ORAL
FAMOTIDINE

>A>		VKT PHARMA	10MG	A215822	001	Jan 28, 2022	Jan NEWA
>A>			20MG	A215822	002	Jan 28, 2022	Jan NEWA

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
ALLEGRA-D 12 HOUR ALLERGY AND CONGESTION

>A>	+!	CHATTEM SANOFI	60MG;120MG	N020786	002	Jan 24, 2011	Jan CAHN
>A>	+!		60MG;120MG	N020786	002	Jan 24, 2011	Jan CAHN
>D>	+!	SANOFI AVENTIS US	60MG;120MG	N020786	002	Jan 24, 2011	Jan CAHN

ALLEGRA-D 24 HOUR ALLERGY AND CONGESTION

>A>	+!	CHATTEM SANOFI	180MG;240MG	N021704	002	Jan 24, 2011	Jan CAHN
>A>	+!		180MG;240MG	N021704	002	Jan 24, 2011	Jan CAHN
>D>	+!	SANOFI AVENTIS US	180MG;240MG	N021704	002	Jan 24, 2011	Jan CAHN

GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
GUAIFENESIN AND PSEUDOEPHEDRINE HYDROCHLORIDE

>A>		L PERRIGO CO	600MG;60MG	A214407	001	Feb 01, 2022	Jan NEWA
>A>			1.2GM;120MG	A214407	002	Feb 01, 2022	Jan NEWA

LEVOCETIRIZINE DIHYDROCHLORIDE

SOLUTION;ORAL
XYZAL ALLERGY 24HR

>A>	+!	CHATTEM SANOFI	2.5MG/5ML	N209090	001	Jan 31, 2017	Jan CAHN
>D>	+!	SANOFI	2.5MG/5ML	N209090	001	Jan 31, 2017	Jan CAHN

TABLET;ORAL
XYZAL ALLERGY 24HR

>A>	+!	CHATTEM SANOFI	5MG	N209089	001	Jan 31, 2017	Jan CAHN
>D>	+!	SANOFI	5MG	N209089	001	Jan 31, 2017	Jan CAHN

MINOXIDIL

AEROSOL, FOAM;TOPICAL
MINOXIDIL

>D>		PERRIGO	5%	A091344	001	Apr 28, 2011	Jan CAHN
>A>		PERRIGO PHARMA INTL	5%	A091344	001	Apr 28, 2011	Jan CAHN

NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
>D> ALEVE-D SINUS & COLD

>D>	+!	BAYER	220MG;120MG	N021076	001	Nov 29, 1999	Jan DISC
>A>	+ @		220MG;120MG	N021076	001	Nov 29, 1999	Jan DISC

NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE

>D>		PERRIGO	220MG;120MG	A076518	001	Mar 17, 2004	Jan CHRS
>A>	!		220MG;120MG	A076518	001	Mar 17, 2004	Jan CHRS

POTASSIUM IODIDE

SOLUTION;ORAL

POTASSIUM IODIDE

>D>	@ ROXANE	1GM/ML	N018551	001	Feb 19, 1982	Jan	CRLD
>A>	+ @	1GM/ML	N018551	001	Feb 19, 1982	Jan	CRLD

RANITIDINE HYDROCHLORIDE

TABLET;ORAL

ZANTAC 150

>A>	+ @ CHATTEM SANOFI	EQ 150MG BASE	N021698	001	Aug 31, 2004	Jan	CAHN
>A>	+ @	EQ 150MG BASE	N021698	002	Mar 13, 2007	Jan	CAHN
>D>	+ @ SANOFI US	EQ 150MG BASE	N021698	001	Aug 31, 2004	Jan	CAHN
>D>	+ @	EQ 150MG BASE	N021698	002	Mar 13, 2007	Jan	CAHN

ZANTAC 75

>A>	+ @ CHATTEM SANOFI	EQ 75MG BASE	N020520	001	Dec 19, 1995	Jan	CAHN
>D>	+ @ SANOFI US	EQ 75MG BASE	N020520	001	Dec 19, 1995	Jan	CAHN

TABLET, EFFERVESCENT;ORAL

ZANTAC 75

>A>	+ @ CHATTEM SANOFI	EQ 75MG BASE	N020745	001	Feb 26, 1998	Jan	CAHN
>D>	+ @ SANOFI US	EQ 75MG BASE	N020745	001	Feb 26, 1998	Jan	CAHN

TRIAMCINOLONE ACETONIDE

SPRAY, METERED;NASAL

NASACORT ALLERGY 24 HOUR

>A>	+! CHATTEM SANOFI	0.055MG/SPRAY	N020468	002	Oct 11, 2013	Jan	CAHN
>A>	+!	0.055MG/SPRAY	N020468	002	Oct 11, 2013	Jan	CAHN
>D>	+! SANOFI AVENTIS US	0.055MG/SPRAY	N020468	002	Oct 11, 2013	Jan	CAHN

TRIAMCINOLONE ACETONIDE

>D>	PERRIGO	0.055MG/SPRAY	A078104	002	Nov 14, 2014	Jan	CAHN
>A>	PERRIGO PHARMA INTL	0.055MG/SPRAY	A078104	002	Nov 14, 2014	Jan	CAHN

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

CUMULATIVE SUPPLEMENT NUMBER 1 JANUARY 2022

NO JANUARY 2022 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 2022 ADDITIONS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2022

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
AMANTADINE HYDROCHLORIDE - GOCOVRI						
N 208944 001	>A> 11197835	Dec 02, 2030	U-2106			
AMANTADINE HYDROCHLORIDE - GOCOVRI						
N 208944 002	>A> 11197835	Dec 02, 2030	U-2106			
AMISULPRIDE - BARHEMSYS						
N 209510 002	>A> 10525033	Mar 10, 2031	DP			
	>A> 9084765	Mar 10, 2031	U-1744			
	>A> 9084765	Mar 10, 2031	U-2754			
	>A> 9545426	Mar 10, 2031	U-1744			
	>A> 9545426	Mar 10, 2031	U-2754			
	>A> 9889118	Mar 10, 2031	U-1744			
	>A> 9889118	Mar 10, 2031	U-2754			
ANGIOTENSIN II ACETATE - GIAPREZA						
N 209360 003	>A> 10028995	Dec 18, 2034	U-2338			
	>A> 10335451	Dec 16, 2029	U-2581			
	>A> 10493124	Dec 18, 2034	U-2679			
	>A> 10500247	Dec 16, 2029	U-2680			
	>A> 10500247	Dec 16, 2029	U-2681			
	>A> 10548943	Dec 16, 2029	U-2739			
	>A> 10548943	Dec 16, 2029	U-2740			
	>A> 11096983	Dec 18, 2034	U-3211			
	>A> 11096983	Dec 18, 2034	U-3212			
	>A> 9220745	Dec 18, 2034	U-2217			
	>A> 9220745	Dec 18, 2034	U-2218			
	>A> 9572856	Jul 18, 2031	U-2221			
	>A> 9867863	Dec 16, 2029	U-2231			
APREMILAST - OTEZLA						
N 205437 001	>A> 6962940	Mar 19, 2023	U-1504			
	>A> 6962940	Mar 19, 2023	U-2656			
	>A> 6962940	Mar 19, 2023	U-2658			
	>A> 6962940	Mar 19, 2023	U-3276			
	>A> 7659302	Mar 19, 2023	U-1505			
	>A> 7659302	Mar 19, 2023	U-1595			
	>A> 7659302	Mar 19, 2023	U-2658			
	>A> 7659302	Mar 19, 2023	U-3276			
	>A> 8455536	Mar 19, 2023	U-1505			
	>A> 8455536	Mar 19, 2023	U-1595			
	>A> 8455536	Mar 19, 2023	U-2658			
	>A> 8455536	Mar 19, 2023	U-3276			
	>A> 9018243	Mar 19, 2023	U-1505			
	>A> 9018243	Mar 19, 2023	U-1595			
	>A> 9018243	Mar 19, 2023	U-2656			
	>A> 9018243	Mar 19, 2023	U-2658			
	>A> 9018243	Mar 19, 2023	U-3276			
	>A> 9724330	Mar 19, 2023	U-1561			
	>A> 9724330	Mar 19, 2023	U-1595			
	>A> 9724330	Mar 19, 2023	U-2656			
	>A> 9724330	Mar 19, 2023	U-2658			
	>A> 9724330	Mar 19, 2023	U-3276			
APREMILAST - OTEZLA						
N 205437 002	>A> 6962940	Mar 19, 2023	U-1504			
	>A> 6962940	Mar 19, 2023	U-2656			
	>A> 6962940	Mar 19, 2023	U-2658			
	>A> 6962940	Mar 19, 2023	U-3276			
	>A> 7659302	Mar 19, 2023	U-1505			
	>A> 7659302	Mar 19, 2023	U-1595			
	>A> 7659302	Mar 19, 2023	U-2658			
	>A> 7659302	Mar 19, 2023	U-3276			
	>A> 8455536	Mar 19, 2023	U-1505			
	>A> 8455536	Mar 19, 2023	U-1595			
	>A> 8455536	Mar 19, 2023	U-2658			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2022

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
APREMILAST - OTEZLA						
N 205437 002	>A> 8455536	Mar 19, 2023	U-3276			
	>A> 9018243	Mar 19, 2023	U-1505			
	>A> 9018243	Mar 19, 2023	U-1595			
	>A> 9018243	Mar 19, 2023	U-2656			
	>A> 9018243	Mar 19, 2023	U-2658			
	>A> 9018243	Mar 19, 2023	U-3276			
	>A> 9724330	Mar 19, 2023	U-1561			
	>A> 9724330	Mar 19, 2023	U-1595			
	>A> 9724330	Mar 19, 2023	U-2656			
	>A> 9724330	Mar 19, 2023	U-2658			
	>A> 9724330	Mar 19, 2023	U-3276			
APREMILAST - OTEZLA						
N 205437 003	>A> 6962940	Mar 19, 2023	U-1504			
	>A> 6962940	Mar 19, 2023	U-2656			
	>A> 6962940	Mar 19, 2023	U-2658			
	>A> 6962940	Mar 19, 2023	U-3276			
	>A> 7659302	Mar 19, 2023	U-1505			
	>A> 7659302	Mar 19, 2023	U-1595			
	>A> 7659302	Mar 19, 2023	U-2658			
	>A> 7659302	Mar 19, 2023	U-3276			
	>A> 8455536	Mar 19, 2023	U-1505			
	>A> 8455536	Mar 19, 2023	U-1595			
	>A> 8455536	Mar 19, 2023	U-2658			
	>A> 8455536	Mar 19, 2023	U-3276			
	>A> 9018243	Mar 19, 2023	U-1505			
	>A> 9018243	Mar 19, 2023	U-1595			
	>A> 9018243	Mar 19, 2023	U-2656			
	>A> 9018243	Mar 19, 2023	U-2658			
	>A> 9018243	Mar 19, 2023	U-3276			
	>A> 9724330	Mar 19, 2023	U-1561			
	>A> 9724330	Mar 19, 2023	U-1595			
	>A> 9724330	Mar 19, 2023	U-2656			
	>A> 9724330	Mar 19, 2023	U-2658			
	>A> 9724330	Mar 19, 2023	U-3276			
ASCIMINIB HYDROCHLORIDE - SCEMBLIX						
N 215358 001	>A> 8829195	May 13, 2033	DS U-1374		>A> ODE-381	Oct 29, 2028
					>A> ODE-382	Oct 29, 2028
ASCIMINIB HYDROCHLORIDE - SCEMBLIX						
N 215358 002	>A> 8829195	May 13, 2033	DS U-1374		>A> ODE-381	Oct 29, 2028
					>A> ODE-382	Oct 29, 2028
AVACOPAN - TAVNEOS						
N 214487 001					>A> ODE-377	Oct 07, 2028
BETAINE - BETAINE						
A 214864 001					>A> CGT	Aug 02, 2022
BICTEGRAVIR SODIUM; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - BIKTARVY						
N 210251 002					>A> NCE	Feb 07, 2023
					>A> ODE-378	Oct 07, 2028
BREXPIPRAZOLE - REXULTI						
N 205422 001	>A> 8618109	Apr 12, 2026	U-3281		>A> NPP	Dec 27, 2024
	>A> 8618109	Apr 12, 2026	U-543			
	>A> 9839637	Apr 12, 2026	DP U-1529			
	>A> 9839637	Apr 12, 2026	DP U-3281			
	>A> 9839637	Apr 12, 2026	DP U-543			
BREXPIPRAZOLE - REXULTI						
N 205422 002	>A> 8618109	Apr 12, 2026	U-3281		>A> NPP	Dec 27, 2024
	>A> 8618109	Apr 12, 2026	U-543			
	>A> 9839637	Apr 12, 2026	DP U-1529			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2022

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
BREXPIPRAZOLE - REXULTI						
N 205422 002	>A> 9839637	Apr 12, 2026	DP U-3281			
	>A> 9839637	Apr 12, 2026	DP U-543			
BREXPIPRAZOLE - REXULTI						
N 205422 003	>A> 8618109	Apr 12, 2026	U-3281		>A> NPP	Dec 27, 2024
	>A> 8618109	Apr 12, 2026	U-543			
	>A> 9839637	Apr 12, 2026	DP U-1529			
	>A> 9839637	Apr 12, 2026	DP U-3281			
	>A> 9839637	Apr 12, 2026	DP U-543			
BREXPIPRAZOLE - REXULTI						
N 205422 004	>A> 8618109	Apr 12, 2026	U-3281		>A> NPP	Dec 27, 2024
	>A> 8618109	Apr 12, 2026	U-543			
	>A> 9839637	Apr 12, 2026	DP U-1529			
	>A> 9839637	Apr 12, 2026	DP U-3281			
	>A> 9839637	Apr 12, 2026	DP U-543			
BREXPIPRAZOLE - REXULTI						
N 205422 005	>A> 8618109	Apr 12, 2026	U-3281		>A> NPP	Dec 27, 2024
	>A> 8618109	Apr 12, 2026	U-543			
	>A> 9839637	Apr 12, 2026	DP U-1529			
	>A> 9839637	Apr 12, 2026	DP U-3281			
	>A> 9839637	Apr 12, 2026	DP U-543			
BREXPIPRAZOLE - REXULTI						
N 205422 006	>A> 8618109	Apr 12, 2026	U-3281		>A> NPP	Dec 27, 2024
	>A> 8618109	Apr 12, 2026	U-543			
	>A> 9839637	Apr 12, 2026	DP U-1529			
	>A> 9839637	Apr 12, 2026	DP U-3281			
	>A> 9839637	Apr 12, 2026	DP U-543			
BUDESONIDE - TARPEYO						
N 215935 001					>A> NP	Dec 15, 2024
CABOTEGRAVIR - APRETUDE						
N 215499 001	>A> 10927129	Apr 28, 2026	DS DP			
	>A> 11224597	Sep 15, 2031	DP			
	>A> 8410103	Apr 28, 2026	DS DP			
CANNABIDIOL - EPIDIOLEX						
N 210365 001	>A> 11207292	Apr 26, 2039	DS U-3235			
	>A> 11207292	Apr 26, 2039	DS U-3236			
	>A> 11207292	Apr 26, 2039	DS U-3277			
CITRIC ACID; LACTIC ACID; POTASSIUM BITARTRATE - PHEXXI						
N 208352 001	>A> 6706276	Mar 06, 2023	DP			
CLASCOTERONE - WINLEVI						
N 213433 001	>A> 11207332	Nov 20, 2028	DP U-3280			
CLINDAMYCIN PHOSPHATE - XACIATO						
N 215650 001	>A> 11129896	Sep 22, 2036	U-3293		>A> NP	Dec 07, 2024
					>A> GAIN	Dec 07, 2029
COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - GENVOYA						
N 207561 001	>A> 8633219	Apr 30, 2030	DP U-257			
	>A> 8633219*PED	Oct 30, 2030				
COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - STRIBILD						
N 203100 001	>A> 8633219	Apr 30, 2030	DP U-257			
	>A> 8633219*PED	Oct 30, 2030				

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
DAPTOMYCIN - DAPZURA RT						
N 213645 001	>A> 11173189	Mar 11, 2041	DP U-3294			
DAROLUTAMIDE - NUBEQA						
N 212099 001	>A> 11168058	Feb 27, 2038	DS DP			
DEUTETRABENAZINE - AUSTEDO						
N 208082 001	>A> 11179386	Mar 15, 2038	DP U-1995			
	>A> 11179386	Mar 15, 2038	DP U-3055			
	>A> 11179386*PED	Sep 15, 2038				
DEUTETRABENAZINE - AUSTEDO						
N 208082 002	>A> 11179386	Mar 15, 2038	DP U-1995			
	>A> 11179386	Mar 15, 2038	DP U-3055			
	>A> 11179386*PED	Sep 15, 2038				
DEUTETRABENAZINE - AUSTEDO						
N 208082 003	>A> 11179386	Mar 15, 2038	DP U-1995			
	>A> 11179386	Mar 15, 2038	DP U-3055			
	>A> 11179386*PED	Sep 15, 2038				
DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE						
N 212516 001	>A> 11202772	Apr 13, 2037	DP			
DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE						
N 212516 002	>A> 11202772	Apr 13, 2037	DP			
DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE						
N 212516 003	>A> 11202772	Apr 13, 2037	DP			
DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE						
N 212516 004	>A> 11202772	Apr 13, 2037	DP			
EFINACONAZOLE - JUBLIA						
N 203567 001	>A> 11213519	Jan 03, 2028	U-2720			
ELBASVIR; GRAZOPREVIR - ZEPATIER						
N 208261 001					>A> NPP	Dec 09, 2024
EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - DESCOVY						
N 208215 002	>A> 7390791	Apr 17, 2025	DS DP			
	>A> 8754065	Aug 15, 2032	DS DP U-1663			
	>A> 9296769	Aug 15, 2032	DS DP U-1663			
ENALAPRIL MALEATE - EPANED						
N 208686 001	>A> 11173141	Mar 25, 2036	DP			
ENCORAFENIB - BRAFTOVI						
N 210496 002	>A> 9474754	Aug 05, 2033	U-2802			
ERAVACYCLINE DIHYDROCHLORIDE - XERAVA						
N 211109 001	>A> 10961190	Oct 19, 2037	DS			
ERAVACYCLINE DIHYDROCHLORIDE - XERAVA						
N 211109 002	>A> 10961190	Oct 19, 2037	DS			
ESTRADIOL; PROGESTERONE - BIJUVA						
N 210132 002	>A> 10052386	Nov 21, 2032	DP			
	>A> 10206932	Nov 21, 2032	U-2439			
	>A> 10675288	Nov 21, 2032	U-2439			
	>A> 11033626	Nov 21, 2032	DP U-2439			
	>A> 11166963	Nov 21, 2032	DP			
	>A> 8633178	Nov 21, 2032	DP			

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APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ESTRADIOL; PROGESTERONE - BIJUVA							
N 210132	002	>A> 8846648	Nov 21, 2032	U-2439			
		>A> 8846649	Nov 21, 2032	DP U-2439			
		>A> 8933059	Nov 21, 2032	DP U-2439			
		>A> 8987237	Nov 21, 2032	DP			
		>A> 8993548	Nov 21, 2032	DP			
		>A> 8993549	Nov 21, 2032	DP			
		>A> 9114145	Nov 21, 2032	U-2439			
		>A> 9114146	Nov 21, 2032	DP U-2439			
		>A> 9301920	Nov 21, 2032	DP U-2439			
HALOBETASOL PROPIONATE - LEXETTE							
N 210566	001					>A> NPP	Aug 18, 2024
ICOSAPENT ETHYL - VASCEPA							
N 202057	001	>A> 11213504	Apr 29, 2030	U-3292			
ICOSAPENT ETHYL - VASCEPA							
N 202057	002	>A> 11213504	Apr 29, 2030	U-3292			
IMIQUIMOD - ZYCLARA							
N 022483	001	>A> 11202752	Apr 30, 2030	U-1455			
		>A> 11202752	Apr 30, 2030	U-172			
INCLISIRAN SODIUM - LEQVIO							
N 214012	001	>A> 10125369	Aug 18, 2034	DS DP U-3272		>A> NCE	Dec 22, 2026
		>A> 10131907	Aug 24, 2028	DS DP U-3272			
		>A> 10266825	Nov 04, 2023	U-3272			
		>A> 10273477	Mar 08, 2024	DS			
		>A> 10590418	Jul 19, 2022	U-3272			
		>A> 10669544	Mar 08, 2024	DS			
		>A> 10806791	Dec 04, 2028	DS			
		>A> 10851377	Aug 25, 2036	U-3272			
		>A> 11078485	Nov 04, 2023	DS U-3272			
		>A> 8106022	Dec 12, 2029	DS DP U-3272			
		>A> 8222222	Dec 29, 2027	U-3272			
		>A> 8232383	Feb 20, 2023	DS DP			
		>A> 8546143	Apr 23, 2022	DS U-3272			
		>A> 8809292	May 10, 2027	DS DP U-3272			
		>A> 8828956	Dec 04, 2028	DS DP U-3272			
		>A> 9074213	Mar 09, 2022	DS U-3272			
		>A> 9370582	Dec 04, 2028	DS DP U-3272			
		>A> 9708610	Jan 01, 2024	DS DP U-3272			
		>A> 9708615	Mar 08, 2024	DS			
LACOSAMIDE - VIMPAT							
N 022253	001					>A> NPP	Oct 14, 2024
LACOSAMIDE - VIMPAT							
N 022253	002					>A> NPP	Oct 14, 2024
LACOSAMIDE - VIMPAT							
N 022253	003					>A> NPP	Oct 14, 2024
LACOSAMIDE - VIMPAT							
N 022253	004					>A> NPP	Oct 14, 2024
LACOSAMIDE - VIMPAT							
N 022254	001					>A> NPP	Oct 14, 2024
LACOSAMIDE - VIMPAT							
N 022255	001					>A> NPP	Oct 14, 2024

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APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
LETROZOLE; RIBOCICLIB SUCCINATE - KISQALI FEMARA CO-PACK (COPACKAGED)							
N 209935	001					>A> NPP	Dec 10, 2024
LEVOKETOCONAZOLE - RECORLEV							
N 214133	001	>A> 10098877	Jan 10, 2026	U-3283			
		>A> 10517868	Jan 10, 2026	U-3283			
		>A> 10835530	Jan 10, 2026	U-3283			
		>A> 11020393	Mar 02, 2040	U-3282			
		>A> 9918984	Jan 10, 2026	U-3283			
LOTEPREDNOL ETABONATE - INVELTYS							
N 210565	001	>A> 11219597	May 03, 2033	U-3278			
		>A> 11219597	May 03, 2033	U-3279			
LOTEPREDNOL ETABONATE - EYSUVIS							
N 210933	001	>A> 11219596	May 03, 2033	U-2985			
LUMATEPERONE TOSYLATE - CAPLYTA							
N 209500	001	>A> 10117867	May 27, 2029	U-3271		>A> I-882	Dec 17, 2024
		>A> 11026951	Dec 03, 2034	U-3274			
		>A> RE48839	Dec 28, 2029	U-3271			
		>A> RE48839	Dec 28, 2029	U-814			
MARALIXIBAT CHLORIDE - LIVMARLI							
N 214662	001	>A> 11229647	Feb 12, 2040	U-3290		>A> ODE-379	Sep 29, 2028
MARIBAVIR - LIVTENCITY							
N 215596	001					>A> NCE	Nov 23, 2026
NAPROXEN SODIUM - NAPROXEN SODIUM							
N 021920	001	>A> 11090280	Mar 03, 2026	DP U-1731			
		>A> 11090280	Mar 03, 2026	DP U-1732			
NILOTINIB HYDROCHLORIDE - TASIGNA							
N 022068	001					>A> ODE-380	Sep 23, 2028
						>A> PED	Mar 23, 2029
NILOTINIB HYDROCHLORIDE - TASIGNA							
N 022068	002					>A> ODE-380	Sep 23, 2028
						>A> PED	Mar 23, 2029
NILOTINIB HYDROCHLORIDE - TASIGNA							
N 022068	003					>A> ODE-380	Sep 23, 2028
						>A> PED	Mar 23, 2029
NIMODIPINE - NYMALIZE							
N 203340	002	>A> 11207306	Apr 16, 2038	U-2804			
PAFOLACIANINE SODIUM - CYTALUX							
N 214907	001	>A> 10881747	Aug 26, 2033	DS DP U-3291			
		>A> 9061057	Aug 26, 2033	DS DP U-3291			
		>A> 9254341	Oct 04, 2033	DS DP			
		>A> 9333270	Aug 26, 2033	DS DP U-3291			
		>A> 9341629	Aug 26, 2033	DS DP			
		>A> 9789208	Aug 26, 2033	DS DP U-3291			
POSACONAZOLE - NOXAFIL							
N 205053	001					>A> I-881	Jun 17, 2024
POSACONAZOLE - NOXAFIL							
N 205596	001					>A> I-881	Jun 17, 2024

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RIBOCICLIB SUCCINATE - KISQALI						
N 209092 001					>A> NPP	Dec 10, 2024
RIOCIGUAT - ADEMPAS						
N 204819 001	>A> 11203593	Feb 18, 2034	DS DP U-2834			
	>A> 11203593	Feb 18, 2034	DS DP U-2835			
RIOCIGUAT - ADEMPAS						
N 204819 002	>A> 11203593	Feb 18, 2034	DS DP U-2834			
	>A> 11203593	Feb 18, 2034	DS DP U-2835			
RIOCIGUAT - ADEMPAS						
N 204819 003	>A> 11203593	Feb 18, 2034	DS DP U-2834			
	>A> 11203593	Feb 18, 2034	DS DP U-2835			
RIOCIGUAT - ADEMPAS						
N 204819 004	>A> 11203593	Feb 18, 2034	DS DP U-2834			
	>A> 11203593	Feb 18, 2034	DS DP U-2835			
RIOCIGUAT - ADEMPAS						
N 204819 005	>A> 11203593	Feb 18, 2034	DS DP U-2834			
	>A> 11203593	Feb 18, 2034	DS DP U-2835			
RIVAROXABAN - XARELTO						
N 022406 001	>A> 9415053	Nov 13, 2024	DP U-1167			
	>A> 9415053	Nov 13, 2024	DP U-2142			
	>A> 9415053	Nov 13, 2024	DP U-2640			
	>A> 9415053	Nov 13, 2024	DP U-3284			
	>A> 9415053*PED	May 13, 2025				
	>A> 9539218	Feb 17, 2034	U-1957			
	>A> 9539218	Feb 17, 2034	U-2143			
	>A> 9539218	Feb 17, 2034	U-2641			
	>A> 9539218	Feb 17, 2034	U-3288			
	>A> 9539218*PED	Aug 17, 2034				
RIVAROXABAN - XARELTO						
N 022406 002	>A> 9415053	Nov 13, 2024	DP U-1200			
	>A> 9415053	Nov 13, 2024	DP U-1301			
	>A> 9415053	Nov 13, 2024	DP U-1302			
	>A> 9415053	Nov 13, 2024	DP U-3286			
	>A> 9415053*PED	May 13, 2025				
	>A> 9539218	Feb 17, 2034	U-1953			
	>A> 9539218	Feb 17, 2034	U-3289			
	>A> 9539218*PED	Aug 17, 2034				
RIVAROXABAN - XARELTO						
N 022406 003	>A> 9415053	Nov 13, 2024	DP U-1200			
	>A> 9415053	Nov 13, 2024	DP U-1301			
	>A> 9415053	Nov 13, 2024	DP U-1302			
	>A> 9415053	Nov 13, 2024	DP U-3287			
	>A> 9415053*PED	May 13, 2025				
	>A> 9539218	Feb 17, 2034	U-1953			
	>A> 9539218	Feb 17, 2034	U-1954			
	>A> 9539218	Feb 17, 2034	U-1955			
	>A> 9539218	Feb 17, 2034	U-3285			
	>A> 9539218*PED	Aug 17, 2034				
RIVAROXABAN - XARELTO						
N 215859 001	>A> 7157456	Aug 28, 2024	DS DP		>A> NP	Dec 20, 2024
					>A> PED	Jun 20, 2025
RUXOLITINIB PHOSPHATE - OPZELURA						
N 215309 001	>A> 11219624	May 20, 2031	DP U-3229			

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SOFOSBUVIR - SOVALDI						
N 212480 001					>A> ODE*	Apr 07, 2024
					>A> PED	Oct 07, 2024
SOFOSBUVIR - SOVALDI						
N 212480 002					>A> ODE*	Apr 07, 2024
					>A> PED	Oct 07, 2024
TOFACITINIB CITRATE - XELJANZ						
N 203214 001					>A> I-879	Dec 14, 2024
TOFACITINIB CITRATE - XELJANZ						
N 203214 002					>A> I-879	Dec 14, 2024
TOFACITINIB CITRATE - XELJANZ XR						
N 208246 001					>A> I-879	Dec 14, 2024
UMBRALISIB TOSYLATE - UKONIQ						
N 213176 001	>A> 10981919	Jul 02, 2033	U-3063			
	>A> 10981919	Jul 02, 2033	U-3064			
UPADACITINIB - RINVOQ						
N 211675 001	>A> 8962629	Jan 15, 2031	DS U-3255		>A> I-880	Dec 14, 2024
	>A> 8962629	Jan 15, 2031	DS U-3275			
VARENICLINE TARTRATE - TYRVAYA						
N 213978 001	>A> 11224598	Oct 19, 2035	U-1900			
VASOPRESSIN - VASOSTRICT						
N 204485 005	>A> 10010575	Jan 30, 2035	U-1857			
	>A> 9919026	Jan 30, 2035	DP			
	>A> 9925233	Jan 30, 2035	U-1857			
	>A> 9925234	Jan 30, 2035	U-1857			
	>A> 9962422	Jan 30, 2035	U-1857			
	>A> 9968649	Jan 30, 2035	U-1857			
	>A> 9974827	Jan 30, 2035	U-1857			
	>A> 9981006	Jan 30, 2035	U-1857			
VOXELOTOR - OXBRYTA						
N 216157 001	>A> 10017491	Dec 28, 2032	DP			
	>A> 10034879	Dec 28, 2032	DS DP			
	>A> 10722502	Feb 06, 2035	DP			
	>A> 10806733	Dec 28, 2032	DS			
	>A> 11020382	Dec 02, 2036	U-3133			
	>A> 11020382	Dec 02, 2036	U-3134			
	>A> 9018210	Dec 28, 2032	DS DP			
	>A> 9248199	Jan 29, 2034	U-2676			
	>A> 9248199	Jan 29, 2034	U-2715			
	>A> 9447071	Feb 06, 2035	DS DP			

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, 42ND 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