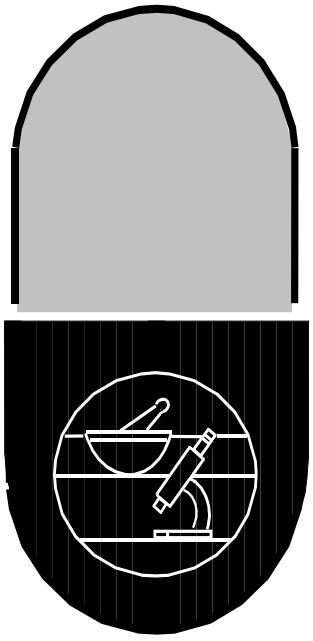
CUMULATIVE SUPPLEMENT 1
JANUARY 2019



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

39th 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

2019

Prepared By
Food and Drug Administration
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January 2019

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 39th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; approved over-the-counter (OTC) drug products for those drugs that may not be marketed without NDAs or ANDAs because they are not covered under existing OTC monographs; drug products with approval under Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) administered by the Center for Biologics Evaluation and Research; and approved products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

Products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the

"@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of this Edition List will then be added to the "Discontinued Drug Product List" appearing in the next Edition. The current Annual Edition Section 2.1, How To Use The Drug Product Lists, describes the layout and usage of the List.

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

- All product changes received and processed as of the date of publication.
  - Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
  - Discontinued products will be processed as of the date of publication. There will be circumstances where a product is discontinued in one month, however, it will be reported in

a different month's CS. For example, the Orange Book Staff received a letter November 7 that the product has been discontinued from manufacturing and marketing. The Orange Book subsequently publishes the October CS on November 14. The product will show in the October CS that it is discontinued even though the date of discontinuance is the day that the Orange Book Staff receives notification (November 7).

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

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

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

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

mail to: FDA/CDER Orange Book Staff
Office of Generic Drugs
7620 Standish Place
Rockville, MD 20855-2773

1.3 APPLICANT NAME CHANGES

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

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

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)

1.4 LEVOTHYROXINE SODIUM

Because there are multiple reference listed drugs of levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character TE codes may be potentially confusing and inadequate for these drug products. Accordingly, FDA provides the following explanation and chart of therapeutic equivalence evaluations for levothyroxine sodium drug products.

Levothyroxine Sodium (Mylan ANDA 076187), Levoxyl (King Pharmas NDA 021301), Synthroid (Abbvie NDA 021402), and Levo-T (Cediprof Inc NDA 021342) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets.

Levo-T (Cediprof Inc NDA 021342), Euthyrox (Provell Pharma LLC NDA 021292), Levothyroxine Sodium (Mylan ANDA 076187), and Unithroid (Jerome Stevens NDA 021210) tablets have been determined to be therapeutically equivalent to corresponding strengths of Synthroid (Abbvie NDA 021402) tablets.

Levo-T (Cediprof Inc NDA 021342), Unithroid (Jerome Stevens NDA 021210), and Levothyroxine Sodium (Mylan ANDA 076187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King Pharms NDA 021301) tablets.

Levothyroxine Sodium (Mylan ANDA 076187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levothroid (Lloyd NDA 021116) tablets.

The chart outlines TE codes for all 0.025mg products in the active section of the Orange Book. Other product strengths may be similar. Therapeutic equivalence has been established between products that have the same AB+number TE code. More than one TE code may apply to some products. One common TE code indicates therapeutic equivalence between products.

Trade Name	Applicant	Strength	TE Code	Appl No	Product No
UNITHROID	STEVENS J	0.025MG	AB1	021210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB1	076187	001
LEVOXYL	KING PHARMS	0.025MG	AB1	021301	001
SYNTHROID	ABBVIE	0.025MG	AB1	021402	001
LEVO-T	CEDIPROF INC	0.025MG	AB1	021342	001
SYNTHROID	ABBVIE	0.025MG	AB2	021402	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB2	076187	001
EUTHYROX	PROVELL PHARMS	0.025MG	AB2	021292	001
LEVO-T	CEDIPROF INC	0.025MG	AB2	021342	001
UNITHROID	STEVENS J	0.025MG	AB2	021210	001
LEVOXYL	KING PHARMS	0.025MG	AB3	021301	001

LEVO-T	CEDIPROF INC	0.025MG	AB3	021342	001
UNITHROID	STEVENS J	0.025MG	AB3	021210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB3	076187	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB4	076187	001

1.5 AVAILABILITY OF THE EDITION

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

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

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

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

Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List, http://www.fda.gov/opacom/morechoices/fdaforms/default.html.

The current listing of the Orphan Product Designations and Approvals is available at http://www.fda.gov/orphan/designat/list.htm.

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

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

DEFINITIONS

Drug Product

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

New Molecular Entity

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

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

CATEGORIES COUNTED	DEC 2018	MAR 2019	JUN 2019	SEP 2019	DEC 2019
DRUG PRODUCTS	20295				
LISTED SINGLE SOURCE	2724 (13.4%)				
MULTISOURCE	17571 (86.6%)				
THERAPEUTICALLY EQUIVALENT	17483 (86.1%)				
NOT THERAPEUTICALLY EQUIVALENT	88 (0.4%)				
EXCEPTIONS[1]	58 (0.3%)				
NEW MOLECULAR ENTITIES APPROVED	25				

NUMBER OF APPLICANTS	1133

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

1.7 CUMULATIVE SUPPLEMENT LEGEND

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

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, Reference Standard symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The application number preceded by "N" is a New Drug Application (NDA or innovator). The application number preceded by an "A" is an Abbreviated New Drug

Application (ANDA or generic). The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

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

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

The change code and description:

NEWA	New drug product approval usually in the supplement month.
NFTG	New first time generic approval.
CAHN**	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CHRS	Change. Reference Standard.
CTEC	Change. Therapeutic Equivalence Code.

CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.

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

ACETAMINOPHEN; BENZHYDROCODONE HYDROCHLORIDE

TABLET;ORAL

APADAZ

>A>	+	KEMPHARM	325MG;EQ 4.08MG BASE	N208653	002	Jan 04, 2019	Jan NEWA
>A>	+		325MG;EQ 8.16MG BASE	N208653	003	Jan 04, 2019	Jan NEWA

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION;ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>D> AA		LANNETT CO INC	120MG/5ML;12MG/5ML	A091238	001	Nov 10, 2011	Jan DISC
>A>	@		120MG/5ML;12MG/5ML	A091238	001	Nov 10, 2011	Jan DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET;ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D> AA		UPSHER SMITH LABS	325MG;5MG	A206484	001	Mar 24, 2017	Jan DISC
>A>	@		325MG;5MG	A206484	001	Mar 24, 2017	Jan DISC
>D> AA			325MG;7.5MG	A206484	002	Mar 24, 2017	Jan DISC
>A>	@		325MG;7.5MG	A206484	002	Mar 24, 2017	Jan DISC
>D> AA			325MG;10MG	A206484	003	Mar 24, 2017	Jan DISC
>A>	@		325MG;10MG	A206484	003	Mar 24, 2017	Jan DISC

ACITRETIN

CAPSULE;ORAL

SORIATANE

>D> AB	+	STIEFEL LABS INC	17.5MG	N019821	003	Aug 06, 2009	Jan DISC
>A>	+ @		17.5MG	N019821	003	Aug 06, 2009	Jan DISC
>D> AB	+		22.5MG	N019821	004	Aug 06, 2009	Jan DISC
>A>	+ @		22.5MG	N019821	004	Aug 06, 2009	Jan DISC

ACYCLOVIR

CREAM;TOPICAL

>A> ACYCLOVIR

>A> AB		PERRIGO UK FINCO	5%	A208702	001	Feb 04, 2019	Jan NFTG

ZOVIRAX

>D>	+!	VIB	5%	N021478	001	Dec 30, 2002	Jan CFTG
>A> AB	+!		5%	N021478	001	Dec 30, 2002	Jan CFTG

OINTMENT;TOPICAL

ACYCLOVIR

>A> AB		CIPLA	5%	A211794	001	Jan 18, 2019	Jan NEWA

ACYCLOVIR SODIUM

INJECTABLE;INJECTION

ACYCLOVIR SODIUM

>D>		ZYDUS PHARMS USA INC	EQ 500MG BASE/VIAL	A206535	001	Aug 31, 2018	Jan CHRS
>A>	!		EQ 500MG BASE/VIAL	A206535	001	Aug 31, 2018	Jan CHRS
>D>			EQ 1GM BASE/VIAL	A206535	002	Aug 31, 2018	Jan CHRS
>A>	!		EQ 1GM BASE/VIAL	A206535	002	Aug 31, 2018	Jan CHRS

ALBUTEROL SULFATE

POWDER, METERED;INHALATION

>A> PROAIR DIGIHALER

>A>	+	TEVA BRANDED PHARM	EQ 0.09MG BASE/INH	N205636	002	Dec 21, 2018	Jan NEWA

PROAIR RESPICLICK

>D>	+!	TEVA BRANDED PHARM	EQ 0.090MG BASE/INH	N205636	001	Mar 31, 2015	Jan CPOT
>A>	+!		EQ 0.09MG BASE/INH	N205636	001	Mar 31, 2015	Jan CPOT

ALOSETRON HYDROCHLORIDE

TABLET;ORAL

ALOSETRON HYDROCHLORIDE

>D> AB		CIPLA	EQ 0.5MG BASE	A209180	001	Jan 14, 2019	Jan CAHN
>D> AB			EQ 1MG BASE	A209180	002	Jan 14, 2019	Jan CAHN
>A> AB		RISING PHARMS	EQ 0.5MG BASE	A209180	001	Jan 14, 2019	Jan CAHN
>A> AB			EQ 1MG BASE	A209180	002	Jan 14, 2019	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		AMERIGEN PHARMS LTD	1.25MG;1.25MG;1.25MG;1.25MG	A205401	001	Jan 22, 2019	Jan NEWA
>A>	AB			2.5MG;2.5MG;2.5MG;2.5MG	A205401	002	Jan 22, 2019	Jan NEWA
>A>	AB			3.75MG;3.75MG;3.75MG;3.75MG	A205401	003	Jan 22, 2019	Jan NEWA
>A>	AB			5MG;5MG;5MG;5MG	A205401	004	Jan 22, 2019	Jan NEWA
>A>	AB			6.25MG;6.25MG;6.25MG;6.25MG	A205401	005	Jan 22, 2019	Jan NEWA
>A>	AB			7.5MG;7.5MG;7.5MG;7.5MG	A205401	006	Jan 22, 2019	Jan NEWA

AMPHETAMINE SULFATE

>A> TABLET, ORALLY DISINTEGRATING;ORAL

>A> EVEKEO ODT

>A>		+	ARBOR PHARMS LLC	5MG	N209905	001	Jan 30, 2019	Jan NEWA
>A>		+		10MG	N209905	002	Jan 30, 2019	Jan NEWA
>A>		+		15MG	N209905	003	Jan 30, 2019	Jan NEWA
>A>		+		20MG	N209905	004	Jan 30, 2019	Jan NEWA

ARIPIPRAZOLE

SOLUTION;ORAL

ARIPIPRAZOLE

>A>	AA		AUROBINDO PHARMA LTD	1MG/ML	A210479	001	Jan 29, 2019	Jan NEWA

BACLOFEN

TABLET;ORAL

BACLOFEN

>A>	AB		EYWA PHARMA	10MG	A211555	001	Feb 01, 2019	Jan NEWA
>A>	AB			20MG	A211555	002	Feb 01, 2019	Jan NEWA

BISOPROLOL FUMARATE

TABLET;ORAL

BISOPROLOL FUMARATE

>D>		@	ANDA REPOSITORY	5MG	A075474	001	Oct 25, 2002	Jan CAHN
>D>		@		10MG	A075474	002	Oct 25, 2002	Jan CAHN
>A>		@	FRONTIDA BIOPHARM	5MG	A075474	001	Oct 25, 2002	Jan CAHN
>A>		@		10MG	A075474	002	Oct 25, 2002	Jan CAHN

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE

FILM;BUCCAL, SUBLINGUAL

BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE

>A>	AB		ALVOGEN PINE BROOK	EQ 2MG BASE;EQ 0.5MG BASE	A205954	001	Jan 24, 2019	Jan NEWA
>A>	AB			EQ 4MG BASE;EQ 1MG BASE	A205954	002	Jan 24, 2019	Jan NEWA
>A>	AB			EQ 8MG BASE;EQ 2MG BASE	A205954	003	Jan 24, 2019	Jan NEWA
>A>	AB			EQ 12MG BASE;EQ 3MG BASE	A205954	004	Jan 24, 2019	Jan NEWA

TABLET;SUBLINGUAL

BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE

>D>	AB		TEVA PHARMS USA	EQ 2MG BASE;EQ 0.5MG BASE	A091149	001	Sep 08, 2014	Jan DISC
>A>		@		EQ 2MG BASE;EQ 0.5MG BASE	A091149	001	Sep 08, 2014	Jan DISC
>D>	AB			EQ 8MG BASE;EQ 2MG BASE	A091149	002	Sep 08, 2014	Jan DISC
>A>		@		EQ 8MG BASE;EQ 2MG BASE	A091149	002	Sep 08, 2014	Jan DISC

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

BUPROPION HYDROCHLORIDE

>A>	AB3		GRAVITI PHARMS	150MG	A211020	001	Jan 28, 2019	Jan NEWA
>A>	AB3			300MG	A211020	002	Jan 28, 2019	Jan NEWA

BUSULFAN

INJECTABLE;INJECTION

BUSULFAN

>A>	AP		ATHENEX INC	6MG/ML	A205106	001	Sep 21, 2018	Jan CAHN
>D>	AP		SANDOZ INC	6MG/ML	A205106	001	Sep 21, 2018	Jan CAHN

CALCIUM ACETATE

TABLET;ORAL

CALCIUM ACETATE

>A>	AB		CHARTWELL MOLECULAR	667MG	A202420	001	Feb 05, 2013	Jan CAHN
>D>	AB		INVAGEN PHARMS	667MG	A202420	001	Feb 05, 2013	Jan CAHN

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE;INJECTION

LACTATED RINGER'S IN PLASTIC CONTAINER

>A>	AP		FRESENIUS KABI USA	20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML	A209338	001	Jan 28, 2019	Jan NEWA

CARBAMAZEPINE

CAPSULE, EXTENDED RELEASE;ORAL

CARBATROL

>D>	AB	+	SHIRE	100MG	N020712	003	Sep 30, 1997	Jan CAHN
>D>	AB	+		200MG	N020712	001	Sep 30, 1997	Jan CAHN
>D>	AB	+!		300MG	N020712	002	Sep 30, 1997	Jan CAHN
>A>	AB	+	SHIRE DEV LLC	100MG	N020712	003	Sep 30, 1997	Jan CAHN
>A>	AB	+		200MG	N020712	001	Sep 30, 1997	Jan CAHN
>A>	AB	+!		300MG	N020712	002	Sep 30, 1997	Jan CAHN

TABLET, EXTENDED RELEASE;ORAL

CARBAMAZEPINE

>A>	AB		ZYDUS PHARMS USA INC	100MG	A205571	001	Feb 07, 2019	Jan NEWA
>A>	AB			200MG	A205571	002	Feb 07, 2019	Jan NEWA
>A>	AB			400MG	A205571	003	Feb 07, 2019	Jan NEWA

CASPOFUNGIN ACETATE

POWDER;INTRAVENOUS

CASPOFUNGIN ACETATE

>D>	AP		CIPLA	50MG/VIAL	A209489	001	Jul 12, 2018	Jan DISC
>A>		@		50MG/VIAL	A209489	001	Jul 12, 2018	Jan DISC
>D>	AP			70MG/VIAL	A209489	002	Jul 12, 2018	Jan DISC
>A>		@		70MG/VIAL	A209489	002	Jul 12, 2018	Jan DISC

CEFPODOXIME PROXETIL

FOR SUSPENSION;ORAL

CEFPODOXIME PROXETIL

>D>	AB		AUROBINDO PHARMA LTD	EQ 50MG BASE/5ML	A065409	001	Jun 08, 2007	Jan CTEC
>A>				EQ 50MG BASE/5ML	A065409	001	Jun 08, 2007	Jan CTEC
>D>	AB			EQ 100MG BASE/5ML	A065409	002	Jun 08, 2007	Jan CTEC
>D>	AB			EQ 100MG BASE/5ML	A065409	002	Jun 08, 2007	Jan CHRS
>A>		!		EQ 100MG BASE/5ML	A065409	002	Jun 08, 2007	Jan CHRS
>A>				EQ 100MG BASE/5ML	A065409	002	Jun 08, 2007	Jan CTEC
>D>	AB		SANDOZ	EQ 50MG BASE/5ML	A090031	001	Jan 14, 2009	Jan DISC
>A>		@		EQ 50MG BASE/5ML	A090031	001	Jan 14, 2009	Jan DISC
>D>	AB	!		EQ 100MG BASE/5ML	A090031	002	Jan 14, 2009	Jan DISC
>A>		@		EQ 100MG BASE/5ML	A090031	002	Jan 14, 2009	Jan DISC

CETIRIZINE HYDROCHLORIDE

SYRUP;ORAL

CETIRIZINE HYDROCHLORIDE

>D>	AA		BIO PHARM INC	5MG/5ML	A078870	001	Apr 27, 2009	Jan CAHN
>A>	AA		TORRENT	5MG/5ML	A078870	001	Apr 27, 2009	Jan CAHN

CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE

SOLUTION;ORAL

HYDROCODONE BITARTRATE, CHLORPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE HYDROCHLORIDE

>D>		@	BIO-PHARM INC	4MG/5ML;5MG/5ML;60MG/5ML	A206660	001	May 15, 2017	Jan CAHN
>A>		@	TORRENT	4MG/5ML;5MG/5ML;60MG/5ML	A206660	001	May 15, 2017	Jan CAHN

CHROMIC PHOSPHATE P-32

INJECTABLE;INJECTION

PHOSPHOCOL P32

>A>		@	CURIUM	5mCi/ML	N017084	001		Jan CAHN
>D>		@	MALLINKRODT NUCLEAR	5mCi/ML	N017084	001		Jan CAHN

CLINDAMYCIN PHOSPHATE

SOLUTION;TOPICAL

CLINDAMYCIN PHOSPHATE

>A>	AT		ENCUBE ETHICALS	EQ 1% BASE	A209914	001	Jan 28, 2019	Jan NEWA

CLOBAZAM

TABLET;ORAL

CLOBAZAM

>A> AB	MICRO LABS	10MG	A211711	001	Jan 30, 2019	Jan NEWA
>A> AB		20MG	A211711	002	Jan 30, 2019	Jan NEWA

CLOBETASOL PROPIONATE

OINTMENT;TOPICAL

CLOBETASOL PROPIONATE

>A> AB	TELIGENT PHARMA INC	0.05%	A208589	001	Jan 23, 2019	Jan NEWA

CLORAZEPATE DIPOTASSIUM

TABLET;ORAL

CLORAZEPATE DIPOTASSIUM

>A>	@ AUROLIFE PHARMA LLC	3.75MG	A072514	002	May 11, 1990	Jan CMS1
>A>	@	7.5MG	A072514	003	May 11, 1990	Jan CMS1

COLCHICINE

>A> SOLUTION;ORAL

>A> GLOPERBA

>A>	+! ROMEG THERAPS LLC	0.6MG/5ML	N210942	001	Jan 30, 2019	Jan NEWA

TABLET;ORAL

COLCHICINE

>A> AB	AMNEAL PHARMS	0.6MG	A204711	001	Sep 28, 2016	Jan NEWA

COLCRYS

>D>	+! TAKEDA PHARMS USA	0.6MG	N022352	001	Jul 29, 2009	Jan CTEC
>A> AB	+!	0.6MG	N022352	001	Jul 29, 2009	Jan CTEC

CYCLOBENZAPRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

AMRIX

>D> AB	+ TEVA PHARMS INTL	15MG	N021777	001	Feb 01, 2007	Jan CTEC
>A>	+	15MG	N021777	001	Feb 01, 2007	Jan CTEC
>D> AB	+!	30MG	N021777	002	Feb 01, 2007	Jan CTEC
>A>	+!	30MG	N021777	002	Feb 01, 2007	Jan CTEC

>D> CYCLOBENZAPRINE HYDROCHLORIDE

>D> AB	APOTEX INC	15MG	A206703	001	Jul 24, 2018	Jan DISC
>A>	@	15MG	A206703	001	Jul 24, 2018	Jan DISC
>D> AB		30MG	A206703	002	Jul 24, 2018	Jan DISC
>A>	@	30MG	A206703	002	Jul 24, 2018	Jan DISC

CYCLOPHOSPHAMIDE

CAPSULE;ORAL

CYCLOPHOSPHAMIDE

>A> AB	CIPLA	25MG	A211608	001	Jan 18, 2019	Jan NEWA
>A> AB		50MG	A211608	002	Jan 18, 2019	Jan NEWA

CYPROHEPTADINE HYDROCHLORIDE

SYRUP;ORAL

CYPROHEPTADINE HYDROCHLORIDE

>D> AA	BIO-PHARM INC	2MG/5ML	A204823	001	Dec 27, 2016	Jan CAHN
>A> AA	TORRENT	2MG/5ML	A204823	001	Dec 27, 2016	Jan CAHN

DESMOPRESSIN ACETATE

TABLET;ORAL

DESMOPRESSIN ACETATE

>A> AB	ABHAI LLC	0.1MG	A210371	001	Jan 28, 2019	Jan NEWA
>A> AB		0.2MG	A210371	002	Jan 28, 2019	Jan NEWA

DESONIDE

OINTMENT;TOPICAL

DESONIDE

>A> AB	ENCUBE ETHICALS	0.05%	A210998	001	Jan 30, 2019	Jan NEWA

DESOXIMETASONE

CREAM;TOPICAL

DESOXIMETASONE

>D> AB	RICONPHARMA LLC	0.05%	A210980	001	Dec 21, 2018	Jan CAHN
>A> AB	RISING PHARMS	0.05%	A210980	001	Dec 21, 2018	Jan CAHN

DEXMEDETOMIDINE HYDROCHLORIDE

INJECTABLE;INJECTION

DEXMEDETOMIDINE HYDROCHLORIDE

>A>	AP		CIPLA	EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML)	A204843	001	Jan 18, 2019	Jan NEWA

DICYCLOMINE HYDROCHLORIDE

INJECTABLE;INJECTION

DICYCLOMINE HYDROCHLORIDE

>A>	AP		CUSTOPHARM INC	10MG/ML	A210788	001	Feb 11, 2019	Jan NEWA
>A>	AP		FRESENIUS KABI USA	10MG/ML	A210257	001	Jan 25, 2019	Jan NEWA
>A>	AP		NEXUS PHARMS	10MG/ML	A206468	001	Feb 01, 2019	Jan NEWA

DIHYDROERGOTAMINE MESYLATE

SPRAY, METERED;NASAL

MIGRANAL

>D>		+!	VALEANT	0.5MG/INH	N020148	001	Dec 08, 1997	Jan CPOT
>A>		+!		0.5MG/SPRAY	N020148	001	Dec 08, 1997	Jan CPOT

DOCETAXEL

SOLUTION;INTRAVENOUS

DOCETAXEL

>A>	AP		SUN PHARMA GLOBAL	20MG/ML (20MG/ML)	N022534	003	Jan 08, 2019	Jan NEWA
>A>	AP			80MG/4ML (20MG/ML)	N022534	004	Jan 08, 2019	Jan NEWA
>A>	AP			160MG/8ML (20MG/ML)	N022534	005	Jan 08, 2019	Jan NEWA

DOFETILIDE

CAPSULE;ORAL

DOFETILDE

>A>	AB		AUROBINDO PHARMA LTD	0.125MG	A210740	001	Jan 22, 2019	Jan NEWA
>A>	AB			0.25MG	A210740	002	Jan 22, 2019	Jan NEWA
>A>	AB			0.5MG	A210740	003	Jan 22, 2019	Jan NEWA

DORZOLAMIDE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

DORZOLAMIDE HYDROCHLORIDE

>A>	AT		FDC LTD	EQ 2% BASE	A205294	001	Jan 24, 2019	Jan NEWA

DOXEPIN HYDROCHLORIDE

CAPSULE;ORAL

DOXEPIN HYDROCHLORIDE

>D>			@ PAR PHARM	EQ 10MG BASE	A071697	001	Nov 09, 1987	Jan CMFD
>A>	AB			EQ 10MG BASE	A071697	001	Nov 09, 1987	Jan CMFD
>D>			@	EQ 25MG BASE	A071437	001	Nov 09, 1987	Jan CMFD
>A>	AB			EQ 25MG BASE	A071437	001	Nov 09, 1987	Jan CMFD
>D>			@	EQ 75MG BASE	A071608	001	Nov 09, 1987	Jan CMFD
>A>	AB			EQ 75MG BASE	A071608	001	Nov 09, 1987	Jan CMFD

EPINEPHRINE

>A> SOLUTION;INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS

>A> ADRENALIN

>A>	AP	+!	PAR STERILE PRODUCTS	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	N204200	001	Dec 07, 2012	Jan CDFR
>A>		+!		EQ 30MG BASE/30ML (EQ 1MG BASE/ML)	N204640	001	Dec 18, 2013	Jan CDFR

>D> SOLUTION;INTRAMUSCULAR, SUBCUTANEOUS

>D> ADRENALIN

>D>	AP	+!	PAR STERILE PRODUCTS	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	N204200	001	Dec 07, 2012	Jan CDFR
>D>		+!		EQ 30MG BASE/30ML (EQ 1MG BASE/ML)	N204640	001	Dec 18, 2013	Jan CDFR

EPTIFIBATIDE

INJECTABLE;INJECTION

EPTIFIBATIDE

>A>	AP		BAXTER HLTHCARE CORP	2MG/ML	A208554	001	Nov 23, 2018	Jan CAHN
>A>	AP			75MG/100ML	A208554	002	Nov 23, 2018	Jan CAHN
>D>	AP		CELERITY PHARMS	2MG/ML	A208554	001	Nov 23, 2018	Jan CAHN
>D>	AP			75MG/100ML	A208554	002	Nov 23, 2018	Jan CAHN
>A>	AP		HAINAN POLY PHARM	2MG/ML	A209864	001	Jan 25, 2019	Jan NEWA
>A>	AP			75MG/100ML	A209864	002	Jan 25, 2019	Jan NEWA

ESTRADIOL

FILM, EXTENDED RELEASE;TRANSDERMAL

ESTRADIOL

>A> AB1	AMNEAL PHARMS LLC	0.025MG/24HR	A211293	001	Feb 04, 2019	Jan NEWA
>A> AB1		0.0375MG/24HR	A211293	002	Feb 04, 2019	Jan NEWA
>A> AB1		0.05MG/24HR	A211293	003	Feb 04, 2019	Jan NEWA
>A> AB1		0.075MG/24HR	A211293	004	Feb 04, 2019	Jan NEWA
>A> AB1		0.1MG/24HR	A211293	005	Feb 04, 2019	Jan NEWA

GEL;TRANSDERMAL

DIVIGEL

>D>	+ VERTICAL PHARMS LLC	0.1%	N022038	001	Jun 04, 2007	Jan CHRS
>A>	+!	0.1%	N022038	001	Jun 04, 2007	Jan CHRS

ETHACRYNATE SODIUM

INJECTABLE;INJECTION

EDECRIN

>D> AP	+! ATON	EQ 50MG BASE/VIAL	N016093	001		Jan CAHN
>A> AP	+! VALEANT PHARMS INTL	EQ 50MG BASE/VIAL	N016093	001		Jan CAHN

ETHACRYNIC ACID

TABLET;ORAL

EDECRIN

>D> AB	+! ATON	25MG	N016092	001		Jan CAHN
>D>	@	50MG	N016092	002		Jan CAHN
>A> AB	+! VALEANT PHARMS INTL	25MG	N016092	001		Jan CAHN
>A>	@	50MG	N016092	002		Jan CAHN

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE

TABLET;ORAL-28

>A> LO-MALMOREDE

>A> AB	NOVAST LABS	0.035MG;1MG	A209548	001	Feb 11, 2019	Jan NEWA

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET;ORAL

>A> SYLEVIA

>A> AB	SUN PHARM INDS LTD	0.03MG;0.15MG	A202988	001	Feb 06, 2019	Jan NEWA

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

>A> TABLET;ORAL-21

>A> HAILEY 1.5/30

>A> AB	GLENMARK PHARMS	0.03MG;1.5MG	A209297	001	Jun 05, 2018	Jan CDFR

LOESTRIN 21 1.5/30

>D> AB	APIL	0.03MG;1.5MG	N017875	001		Jan CRLD
>A> AB	+	0.03MG;1.5MG	N017875	001		Jan CRLD

LOESTRIN 21 1/20

>D> AB	APIL	0.02MG;1MG	N017876	001		Jan CRLD
>A> AB	+	0.02MG;1MG	N017876	001		Jan CRLD

>D> TABLET;ORAL-28

>D> HAILEY 1.5/30

>D> AB	GLENMARK PHARMS	0.03MG;1.5MG	A209297	001	Jun 05, 2018	Jan CDFR

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET;ORAL-28

NORGESTIMATE AND ETHINYL ESTRADIOL

>D> AB	MYLAN LABS LTD	0.025MG,0.025MG,0.025MG;0.18MG,0.215MG,0.25MG	A202132	001	Sep 09, 2015	Jan DISC
>A>	@	0.025MG,0.025MG,0.025MG;0.18MG,0.215MG,0.25MG	A202132	001	Sep 09, 2015	Jan DISC

FENOFIBRATE

CAPSULE;ORAL

FENOFIBRATE (MICRONIZED)

>A> AB	AUSTARPHARMA	67MG	A207805	001	Nov 16, 2017	Jan CAHN
>A> AB		134MG	A207805	002	Nov 16, 2017	Jan CAHN
>A> AB		200MG	A207805	003	Nov 16, 2017	Jan CAHN
>D> AB	CNTY LINE PHARMS	67MG	A207805	001	Nov 16, 2017	Jan CAHN
>D> AB		134MG	A207805	002	Nov 16, 2017	Jan CAHN
>D> AB		200MG	A207805	003	Nov 16, 2017	Jan CAHN

TABLET;ORAL

FENOFIBRATE

>A> AB	AUSTARPHARMA	54MG	A207803	001	Dec 19, 2017	Jan CAHN

TABLET;ORAL
FENOFIBRATE

>A> AB		160MG	A207803	002	Dec 19, 2017	Jan CAHN
>D> AB	CNTY LINE PHARMS	54MG	A207803	001	Dec 19, 2017	Jan CAHN
>D> AB		160MG	A207803	002	Dec 19, 2017	Jan CAHN
>A> AB	ORIT LABS LLC	54MG	A209660	001	Feb 11, 2019	Jan NEWA
>A> AB		160MG	A209660	002	Feb 11, 2019	Jan NEWA

FLUOCINOLONE ACETONIDE
SOLUTION;TOPICAL
FLUOCINOLONE ACETONIDE

>A> AT	ENCUBE ETHICALS	0.01%	A209913	001	Feb 13, 2019	Jan NEWA
>D>	@ GLASSHOUSE PHARMS	0.01%	A209596	001	Dec 26, 2017	Jan CMFD
>A> AT		0.01%	A209596	001	Dec 26, 2017	Jan CMFD

FLUOXETINE HYDROCHLORIDE
TABLET;ORAL
FLUOXETINE HYDROCHLORIDE

>A> AB	APPCO PHARMA LLC	EQ 10MG BASE	A211696	001	Jan 30, 2019	Jan NEWA
>A> AB		EQ 20MG BASE	A211696	002	Jan 30, 2019	Jan NEWA
>A> AB	DR REDDYS LABS LTD	EQ 60MG BASE	A211721	001	Jan 25, 2019	Jan NEWA

FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE
POWDER;INHALATION
ADVAIR DISKUS 100/50

>D>	+! GLAXO GRP LTD	0.1MG/INH;EQ 0.05MG BASE/INH	N021077	001	Aug 24, 2000	Jan CFTG
>A> AB	+!	0.1MG/INH;EQ 0.05MG BASE/INH	N021077	001	Aug 24, 2000	Jan CFTG

ADVAIR DISKUS 250/50

>D>	+! GLAXO GRP LTD	0.25MG/INH;EQ 0.05MG BASE/INH	N021077	002	Aug 24, 2000	Jan CFTG
>A> AB	+!	0.25MG/INH;EQ 0.05MG BASE/INH	N021077	002	Aug 24, 2000	Jan CFTG

ADVAIR DISKUS 500/50

>D>	+! GLAXO GRP LTD	0.5MG/INH;EQ 0.05MG BASE/INH	N021077	003	Aug 24, 2000	Jan CFTG
>A> AB	+!	0.5MG/INH;EQ 0.05MG BASE/INH	N021077	003	Aug 24, 2000	Jan CFTG

>A> WIXELA INHUB

>A> AB	MYLAN PHARMS INC	0.1MG/INH;EQ 0.05MG BASE/INH	A208891	001	Jan 30, 2019	Jan NFTG
>A> AB		0.25MG/INH;EQ 0.05MG BASE/INH	A208891	002	Jan 30, 2019	Jan NFTG
>A> AB		0.5MG/INH;EQ 0.05MG BASE/INH	A208891	003	Jan 30, 2019	Jan NFTG

GALLIUM CITRATE GA-67
INJECTABLE;INJECTION
GALLIUM CITRATE GA 67

>A> BS	CURIUM	2mCi/ML	N018058	001		Jan CAHN
>D> BS	MALLINKRODT NUCLEAR	2mCi/ML	N018058	001		Jan CAHN

GEMCITABINE HYDROCHLORIDE
INJECTABLE;INJECTION
GEMCITABINE HYDROCHLORIDE

>D> AP	FRESENIUS KABI ONCOL	EQ 200MG BASE/VIAL	A090799	001	Jul 25, 2011	Jan CAHN
>D> AP		EQ 1GM BASE/VIAL	A090799	002	Jul 25, 2011	Jan CAHN
>D> AP		EQ 2GM BASE/VIAL	A090799	003	May 16, 2011	Jan CAHN
>A> AP	FRESENIUS KABI USA	EQ 200MG BASE/VIAL	A090799	001	Jul 25, 2011	Jan CAHN
>A> AP		EQ 1GM BASE/VIAL	A090799	002	Jul 25, 2011	Jan CAHN
>A> AP		EQ 2GM BASE/VIAL	A090799	003	May 16, 2011	Jan CAHN

GRANISETRON HYDROCHLORIDE
TABLET;ORAL
GRANISETRON HYDROCHLORIDE

>D> AB	! TEVA PHARMS	EQ 1MG BASE	A078080	001	Dec 31, 2007	Jan DISC
>A>	@	EQ 1MG BASE	A078080	001	Dec 31, 2007	Jan DISC
>D> AB	WEST-WARD PHARMS INT	EQ 1MG BASE	A077842	001	Dec 31, 2007	Jan CHRS
>A> AB	!	EQ 1MG BASE	A077842	001	Dec 31, 2007	Jan CHRS

HALOBETASOL PROPIONATE
LOTION;TOPICAL
BRYHALI

>D>	DOW PHARM	0.01%	N209355	001	Nov 06, 2018	Jan CHRS
>D>		0.01%	N209355	001	Nov 06, 2018	Jan CRLD
>A>	+!	0.01%	N209355	001	Nov 06, 2018	Jan CHRS
>A>	+	0.01%	N209355	001	Nov 06, 2018	Jan CRLD

HALOPERIDOL

TABLET;ORAL

HALOPERIDOL

>D>	AB		MYLAN	2MG	A070278	001	Jun 10, 1986	Jan CHRS
>D>	AB			2MG	A070278	001	Jun 10, 1986	Jan CTEC
>A>		!		2MG	A070278	001	Jun 10, 1986	Jan CTEC
>A>	AB	!		2MG	A070278	001	Jun 10, 1986	Jan CHRS
>D>	AB	!	SANDOZ	2MG	A071208	001	Nov 17, 1986	Jan DISC
>A>		@		2MG	A071208	001	Nov 17, 1986	Jan DISC

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP;ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

>D>		@	BIO-PHARM INC	1.5MG/5ML;5MG/5ML	A204765	001	Mar 06, 2017	Jan CAHN
>A>		@	TORRENT	1.5MG/5ML;5MG/5ML	A204765	001	Mar 06, 2017	Jan CAHN

HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL

TABLET;ORAL

OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE

>A>	AB		ACCORD HLTHCARE	12.5MG;20MG	A209281	001	Feb 07, 2019	Jan NEWA
>A>	AB			12.5MG;40MG	A209281	002	Feb 07, 2019	Jan NEWA
>A>	AB			25MG;40MG	A209281	003	Feb 07, 2019	Jan NEWA

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE;ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

>A>	AB		ZYDUS PHARMS USA INC	25MG;37.5MG	A208358	001	Feb 11, 2019	Jan NEWA

HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE

SOLUTION;ORAL

HYDROCODONE BITARTRATE AND PSEUDOEPHEDRINE HYDROCHLORIDE

>A>	AA		TORRENT	5MG/5ML;60MG/5ML	A206661	001	Jan 23, 2019	Jan NEWA

HYDROXYCHLOROQUINE SULFATE

TABLET;ORAL

HYDROXYCHLOROQUINE SULFATE

>A>	AB		LAURUS LABS LTD	200MG	A210959	001	Jan 15, 2019	Jan CAHN
>D>	AB		RISING PHARMS	200MG	A210959	001	Jan 15, 2019	Jan CAHN

HYDROXYPROPYL CELLULOSE

INSERT;OPHTHALMIC

LACRISERT

>D>		+!	ATON	5MG	N018771	001		Jan CAHN
>A>		+!	VALEANT PHARMS INTL	5MG	N018771	001		Jan CAHN

HYDROXYZINE HYDROCHLORIDE

TABLET;ORAL

HYDROXYZINE HYDROCHLORIDE

>D>	AB		ELITE LABS INC	10MG	A040604	002	Dec 28, 2004	Jan CAHN
>D>	AB			25MG	A040604	003	Dec 28, 2004	Jan CAHN
>D>	AB			50MG	A040604	001	Dec 28, 2004	Jan CAHN
>A>	AB		EPIC PHARMA LLC	10MG	A040604	002	Dec 28, 2004	Jan CAHN
>A>	AB			25MG	A040604	003	Dec 28, 2004	Jan CAHN
>A>	AB			50MG	A040604	001	Dec 28, 2004	Jan CAHN

IBUPROFEN

SOLUTION;INTRAVENOUS

CALDOLOR

>A>		+!	CUMBERLAND PHARMS	800MG/200ML (4MG/ML)	N022348	003	Jan 25, 2019	Jan NEWA

IMATINIB MESYLATE

TABLET;ORAL

IMATINIB MESYLATE

>A>	AB		SHILPA MEDICARE LTD	EQ 100MG BASE	A208302	001	Jan 17, 2019	Jan NEWA
>A>	AB			EQ 400MG BASE	A208302	002	Jan 17, 2019	Jan NEWA
>A>	AB		WOCKHARDT BIO AG	EQ 100MG BASE	A208429	001	Jan 17, 2019	Jan NEWA
>A>	AB			EQ 400MG BASE	A208429	002	Jan 17, 2019	Jan NEWA

INDIUM IN-111 CHLORIDE

INJECTABLE;INJECTION

INDIUM IN 111 CHLORIDE

>A>		+!	CURIUM	5mCi/0.5ML	N019841	001	Sep 27, 1994	Jan CAHN
>D>		+!	MALLINKRODT NUCLEAR	5mCi/0.5ML	N019841	001	Sep 27, 1994	Jan CAHN

INDIUM IN-111 PENTETREOTIDE KIT

INJECTABLE;INJECTION

OCTREOSCAN

>A>		+!	CURIUM	3mCi/ML	N020314	001	Jun 02, 1994	Jan CAHN
>D>		+!	MALLINKRODT NUCLEAR	3mCi/ML	N020314	001	Jun 02, 1994	Jan CAHN

IRINOTECAN HYDROCHLORIDE

INJECTABLE;INJECTION

IRINOTECAN HYDROCHLORIDE

>D>	AP		FRESENIUS KABI ONCOL	40MG/2ML (20MG/ML)	A078188	001	Feb 27, 2008	Jan CAHN
>D>	AP			100MG/5ML (20MG/ML)	A078188	002	Feb 27, 2008	Jan CAHN
>A>	AP		FRESENIUS KABI USA	40MG/2ML (20MG/ML)	A078188	001	Feb 27, 2008	Jan CAHN
>A>	AP			100MG/5ML (20MG/ML)	A078188	002	Feb 27, 2008	Jan CAHN

LABETALOL HYDROCHLORIDE

TABLET;ORAL

LABETALOL HYDROCHLORIDE

>A>	AB		INVATECH PHARMA	100MG	A207863	001	Feb 04, 2019	Jan NEWA
>A>	AB			200MG	A207863	002	Feb 04, 2019	Jan NEWA
>A>	AB			300MG	A207863	003	Feb 04, 2019	Jan NEWA

TRANDATE

>D>	AB		CNTY LINE PHARMS	100MG	N018716	001	May 24, 1985	Jan CRLD
>A>	AB	+		100MG	N018716	001	May 24, 1985	Jan CRLD
>D>	AB			200MG	N018716	002	Aug 01, 1984	Jan CRLD
>A>	AB	+		200MG	N018716	002	Aug 01, 1984	Jan CRLD
>D>	AB			300MG	N018716	003	Aug 01, 1984	Jan CRLD
>A>	AB	+		300MG	N018716	003	Aug 01, 1984	Jan CRLD

LACTULOSE

SOLUTION;ORAL

LACTULOSE

>D>		@	APOTEX INC	10GM/15ML	A075911	001	Feb 21, 2002	Jan CAHN
>A>		@	BAJAJ	10GM/15ML	A075911	001	Feb 21, 2002	Jan CAHN
>D>	AA		BIO-PHARM INC	10GM/15ML	A207786	001	Jun 11, 2018	Jan CAHN
>A>	AA		TORRENT	10GM/15ML	A207786	001	Jun 11, 2018	Jan CAHN

SOLUTION;ORAL, RECTAL

LACTULOSE

>D>		@	APOTEX INC	10GM/15ML	A076645	001	Jul 28, 2003	Jan CAHN
>A>		@	BAJAJ	10GM/15ML	A076645	001	Jul 28, 2003	Jan CAHN
>D>	AA		BIO-PHARM INC	10GM/15ML	A203762	001	Mar 27, 2015	Jan CAHN
>A>	AA		TORRENT	10GM/15ML	A203762	001	Mar 27, 2015	Jan CAHN

LAMIVUDINE; ZIDOVUDINE

TABLET;ORAL

LAMIVUDINE AND ZIDOVUDINE

>D>	AB		MYLAN PHARMS INC	150MG;300MG	A204005	001	Aug 28, 2014	Jan DISC
>A>		@		150MG;300MG	A204005	001	Aug 28, 2014	Jan DISC

LANSOPRAZOLE

CAPSULE, DELAYED REL PELLETS;ORAL

LANSOPRAZOLE

>A>	AB		ALKEM LABS LTD	15MG	A207394	001	Jan 18, 2019	Jan NEWA
>A>	AB			30MG	A207394	002	Jan 18, 2019	Jan NEWA

LEVOFLOXACIN

TABLET;ORAL

LEVOFLOXACIN

>A>	AB		HEC PHARM	250MG	A204968	001	Feb 05, 2019	Jan NEWA
>A>	AB			500MG	A204968	002	Feb 05, 2019	Jan NEWA
>A>	AB			750MG	A204968	003	Feb 05, 2019	Jan NEWA

LEVOMILNACIPRAN HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

FETZIMA

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

>A> LEVOMILNACIPRAN HYDROCHLORIDE

>A>	AB		AMNEAL PHARMS CO	EQ 20MG BASE	A210790	001	Feb 04, 2019	Jan NFTG
>A>	AB			EQ 40MG BASE	A210790	002	Feb 04, 2019	Jan NFTG
>A>	AB			EQ 80MG BASE	A210790	003	Feb 04, 2019	Jan NFTG
>A>	AB			EQ 120MG BASE	A210790	004	Feb 04, 2019	Jan NFTG

LEVOTHYROXINE SODIUM

SOLUTION;ORAL

TIROSINT-SOL

>D>		+ @	INSTITUT BIOCHIMIQUE	13MCG/ML	N206977	001	Dec 15, 2016	Jan CMFD
>A>		+		13MCG/ML	N206977	001	Dec 15, 2016	Jan CMFD
>D>		+ @		25MCG/ML	N206977	002	Dec 15, 2016	Jan CMFD
>A>		+		25MCG/ML	N206977	002	Dec 15, 2016	Jan CMFD
>D>		+ @		50MCG/ML	N206977	003	Dec 15, 2016	Jan CMFD
>A>		+		50MCG/ML	N206977	003	Dec 15, 2016	Jan CMFD
>D>		+ @		75MCG/ML	N206977	004	Dec 15, 2016	Jan CMFD
>A>		+		75MCG/ML	N206977	004	Dec 15, 2016	Jan CMFD
>D>		+ @		88MCG/ML	N206977	005	Dec 15, 2016	Jan CMFD
>A>		+		88MCG/ML	N206977	005	Dec 15, 2016	Jan CMFD
>D>		+ @		100MCG/ML	N206977	006	Dec 15, 2016	Jan CMFD
>A>		+		100MCG/ML	N206977	006	Dec 15, 2016	Jan CMFD
>D>		+ @		112MCG/ML	N206977	007	Dec 15, 2016	Jan CMFD
>A>		+		112MCG/ML	N206977	007	Dec 15, 2016	Jan CMFD
>D>		+ @		125MCG/ML	N206977	008	Dec 15, 2016	Jan CMFD
>A>		+		125MCG/ML	N206977	008	Dec 15, 2016	Jan CMFD
>D>		+ @		137MCG/ML	N206977	009	Dec 15, 2016	Jan CMFD
>A>		+		137MCG/ML	N206977	009	Dec 15, 2016	Jan CMFD
>D>		+ @		150MCG/ML	N206977	010	Dec 15, 2016	Jan CMFD
>A>		+		150MCG/ML	N206977	010	Dec 15, 2016	Jan CMFD
>D>		+ @		175MCG/ML	N206977	011	Dec 15, 2016	Jan CMFD
>A>		+		175MCG/ML	N206977	011	Dec 15, 2016	Jan CMFD
>D>		+ @		200MCG/ML	N206977	012	Dec 15, 2016	Jan CMFD
>A>		+!		200MCG/ML	N206977	012	Dec 15, 2016	Jan CMFD

LEVOTHYROXINE SODIUM **

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

TABLET;ORAL

LEVOTHYROXINE SODIUM

>A>	AB2		LUPIN ATLANTIS	0.025MG	A209713	001	Jan 18, 2019	Jan NEWA
>A>	AB2			0.05MG	A209713	002	Jan 18, 2019	Jan NEWA
>A>	AB2			0.075MG	A209713	003	Jan 18, 2019	Jan NEWA
>A>	AB2			0.088MG	A209713	004	Jan 18, 2019	Jan NEWA
>A>	AB2			0.1MG	A209713	005	Jan 18, 2019	Jan NEWA
>A>	AB2			0.112MG	A209713	006	Jan 18, 2019	Jan NEWA
>A>	AB2			0.125MG	A209713	007	Jan 18, 2019	Jan NEWA
>A>	AB2			0.137MG	A209713	008	Jan 18, 2019	Jan NEWA
>A>	AB2			0.15MG	A209713	009	Jan 18, 2019	Jan NEWA
>A>	AB2			0.175MG	A209713	010	Jan 18, 2019	Jan NEWA
>A>	AB2			0.2MG	A209713	011	Jan 18, 2019	Jan NEWA
>A>	AB2			0.3MG	A209713	012	Jan 18, 2019	Jan NEWA

MAGNESIUM SULFATE

SOLUTION;INTRAMUSCULAR, INTRAVENOUS

MAGNESIUM SULFATE

>D>		+!	FRESENIUS KABI USA	10GM/20ML (500MG/ML)	N019316	003	Jan 29, 2016	Jan CTEC
>A>	AP	+!		10GM/20ML (500MG/ML)	N019316	003	Jan 29, 2016	Jan CTEC
>D>			HOSPIRA INC	10GM/20ML (500MG/ML)	A202411	001	May 14, 2015	Jan CTEC
>A>	AP			10GM/20ML (500MG/ML)	A202411	001	May 14, 2015	Jan CTEC

MECLIZINE HYDROCHLORIDE

TABLET;ORAL

ANTIVERT

>D>		@	CASPER PHARMA LLC	12.5MG	N010721	006		Jan CRLD
>A>		+ @		12.5MG	N010721	006		Jan CRLD
>D>		@		25MG	N010721	004		Jan CRLD
>A>		+ @		25MG	N010721	004		Jan CRLD
>D>		@		50MG	N010721	001	Jan 20, 1982	Jan CRLD
>A>		+ @		50MG	N010721	001	Jan 20, 1982	Jan CRLD

MECLIZINE HYDROCHLORIDE

>D>	AA		AMNEAL PHARMS	12.5MG	A201451	001	Feb 23, 2011	Jan CHRS
>A>	AA	!		12.5MG	A201451	001	Feb 23, 2011	Jan CHRS
>D>	AA			25MG	A201451	002	Feb 23, 2011	Jan CHRS
>A>	AA	!		25MG	A201451	002	Feb 23, 2011	Jan CHRS

TABLET, CHEWABLE;ORAL

ANTIVERT

>D>		@	CASPER PHARMA LLC	25MG	N010721	005		Jan CRLD
>A>		+ @		25MG	N010721	005		Jan CRLD

MEDROXYPROGESTERONE ACETATE

INJECTABLE;INJECTION

MEDROXYPROGESTERONE ACETATE

>A>	AB		CIPLA	150MG/ML	A210335	001	Jan 25, 2019	Jan NEWA

MEMANTINE HYDROCHLORIDE

SOLUTION;ORAL

MEMANTINE HYDROCHLORIDE

>D>	AA	!	BIO-PHARM INC	2MG/ML	A205446	001	Dec 07, 2015	Jan CAHN
>A>	AA	!	TORRENT	2MG/ML	A205446	001	Dec 07, 2015	Jan CAHN

TABLET;ORAL

MEMANTINE HYDROCHLORIDE

>D>	AB		APOTEX INC	5MG	A090244	001	Jul 11, 2018	Jan DISC
>A>		@		5MG	A090244	001	Jul 11, 2018	Jan DISC
>D>	AB			10MG	A090244	002	Jul 11, 2018	Jan DISC
>A>		@		10MG	A090244	002	Jul 11, 2018	Jan DISC

MESALAMINE

TABLET, DELAYED RELEASE;ORAL

MESALAMINE

>A>	AB		SUN PHARM INDS LTD	1.2GM	A211858	001	Jan 25, 2019	Jan NEWA

METHYLPHENIDATE HYDROCHLORIDE

FOR SUSPENSION, EXTENDED RELEASE;ORAL

METHYLPHENIDATE HYDROCHLORIDE

>D>	AB		ACTAVIS LABS FL INC	5MG/ML	A206049	001	May 17, 2018	Jan DISC
>A>		@		5MG/ML	A206049	001	May 17, 2018	Jan DISC

QUILLIVANT XR

>D>	AB	+!	NEXTWAVE PHARMS	5MG/ML	N202100	001	Sep 27, 2012	Jan CTEC
>A>		+!		5MG/ML	N202100	001	Sep 27, 2012	Jan CTEC

TABLET;ORAL

METHYLPHENIDATE HYDROCHLORIDE

>A>	AB		CEDIPROF INC	5MG	A208737	001	Feb 01, 2019	Jan NEWA
>A>	AB			10MG	A208737	002	Feb 01, 2019	Jan NEWA
>A>	AB			20MG	A208737	003	Feb 01, 2019	Jan NEWA
>D>	AB		LANNETT CO INC	5MG	A086429	001		Jan DISC
>A>		@		5MG	A086429	001		Jan DISC
>D>	AB			10MG	A085799	001		Jan DISC
>A>		@		10MG	A085799	001		Jan DISC
>D>	AB			20MG	A086428	001		Jan DISC
>A>		@		20MG	A086428	001		Jan DISC

TABLET, EXTENDED RELEASE;ORAL

>D>			METADATE ER					
>D>	AB	!	LANNETT CO INC	20MG	A089601	001	Jun 01, 1988	Jan DISC
>A>		@		20MG	A089601	001	Jun 01, 1988	Jan DISC

METHYLPHENIDATE HYDROCHLORIDE

>A>	AB	!	ABHAI LLC	20MG	A207488	002	Jun 09, 2015	Jan NEWA

MINOCYCLINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

MINOCYCLINE HYDROCHLORIDE

>D>	@ BARR LABS INC	EQ 80MG BASE	A065485	007	Apr 26, 2017	Jan	CMFD
>A> AB		EQ 80MG BASE	A065485	007	Apr 26, 2017	Jan	CMFD
>D>	@	EQ 105MG BASE	A065485	008	Apr 26, 2017	Jan	CMFD
>A> AB		EQ 105MG BASE	A065485	008	Apr 26, 2017	Jan	CMFD

MITOMYCIN

INJECTABLE;INJECTION

MITOMYCIN

>D>	@ WEST-WARD PHARMS INT	20MG/VIAL	A064117	002	Apr 19, 1995	Jan	CMFD
>A> AP		20MG/VIAL	A064117	002	Apr 19, 1995	Jan	CMFD
>D>	@	40MG/VIAL	A064117	003	Jun 02, 1999	Jan	CMFD
>A> AP		40MG/VIAL	A064117	003	Jun 02, 1999	Jan	CMFD

MORPHINE SULFATE

SOLUTION;ORAL

MORPHINE SULFATE

>D> AA	LANNETT CO INC	20MG/5ML	A202310	001	Oct 30, 2015	Jan	DISC
>A>	@	20MG/5ML	A202310	001	Oct 30, 2015	Jan	DISC
>D>		100MG/5ML	N201517	001	Jun 23, 2011	Jan	DISC
>A>	@	100MG/5ML	N201517	001	Jun 23, 2011	Jan	DISC

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

MOXIFLOXACIN HYDROCHLORIDE

>A> AT1	ALEMBIC PHARMS LTD	EQ 0.5% BASE	A209469	001	Feb 13, 2019	Jan	NEWA

MYCOPHENOLATE MOFETIL

SUSPENSION;ORAL

MYCOPHENOLATE MOFETIL

>A> AB	VISTAPHARM	200MG/ML	A210370	001	Feb 12, 2019	Jan	NEWA

NALBUPHINE HYDROCHLORIDE

INJECTABLE;INJECTION

NALBUPHINE HYDROCHLORIDE

>A> AP	MYLAN LABS LTD	10MG/ML	A206506	001	Feb 06, 2019	Jan	NEWA
>A> AP		20MG/ML	A206506	002	Feb 06, 2019	Jan	NEWA

NEOSTIGMINE METHYLSULFATE

SOLUTION;INTRAVENOUS

NEOSTIGMINE METHYLSULFATE

>A> AP	AMRING PHARMS	5MG/10ML (0.5MG/ML)	A210989	001	Aug 22, 2018	Jan	CAHN
>A> AP		10MG/10ML (1MG/ML)	A210989	002	Aug 22, 2018	Jan	CAHN
>D> AP	RENAISSANCE SSA LLC	5MG/10ML (0.5MG/ML)	A210989	001	Aug 22, 2018	Jan	CAHN
>D> AP		10MG/10ML (1MG/ML)	A210989	002	Aug 22, 2018	Jan	CAHN

NYSTATIN

OINTMENT;TOPICAL

NYSTATIN

>A> AT	TORRENT PHARMS LTD	100,000 UNITS/GM	A211838	001	Jan 28, 2019	Jan	NEWA

OCTREOTIDE ACETATE

INJECTABLE;INJECTION

OCTREOTIDE ACETATE

>A> AP	HERITAGE PHARMS INC	EQ 0.2MG BASE/ML	A203765	001	Sep 07, 2018	Jan	CAHN
>A> AP		EQ 1MG BASE/ML	A203765	002	Sep 07, 2018	Jan	CAHN
>D> AP	USV NORTH AMERICA	EQ 0.2MG BASE/ML	A203765	001	Sep 07, 2018	Jan	CAHN
>D> AP		EQ 1MG BASE/ML	A203765	002	Sep 07, 2018	Jan	CAHN

ORPHENADRINE CITRATE

INJECTABLE;INJECTION

NORFLEX

>D>	@ TELIGENT	30MG/ML	N013055	001		Jan	CRLD
>A>	+ @	30MG/ML	N013055	001		Jan	CRLD

OXYBUTYNIN CHLORIDE

TABLET;ORAL

OXYBUTYNIN CHLORIDE

>A>	AB		INVATECH PHARMA	5MG	A211062	001	Feb 06, 2019	Jan NEWA

OXYCODONE HYDROCHLORIDE

SOLUTION;ORAL

OXYCODONE HYDROCHLORIDE

>A>	AA		ALKEM LABS LTD	100MG/5ML	A211749	001	Feb 04, 2019	Jan NEWA
>D>	AA		LANNETT CO INC	100MG/5ML	A204085	001	Sep 09, 2014	Jan DISC
>A>		@		100MG/5ML	A204085	001	Sep 09, 2014	Jan DISC
>A>	AA		PHARM ASSOC	5MG/ML	A206914	001	Feb 01, 2019	Jan NEWA

PAMIDRONATE DISODIUM

INJECTABLE;INJECTION

PAMIDRONATE DISODIUM

>D>	AP		SUN PHARMA GLOBAL	30MG/VIAL	A077703	001	Dec 24, 2008	Jan DISC
>A>		@		30MG/VIAL	A077703	001	Dec 24, 2008	Jan DISC
>D>	AP			90MG/VIAL	A077703	002	Dec 24, 2008	Jan DISC
>A>		@		90MG/VIAL	A077703	002	Dec 24, 2008	Jan DISC

PENICILLAMINE

CAPSULE;ORAL

CUPRIMINE

>D>		@	ATON	125MG	N019853	002		Jan CAHN
>D>		+!		250MG	N019853	001		Jan CAHN
>A>		@	VALEANT PHARMS INTL	125MG	N019853	002		Jan CAHN
>A>		+!		250MG	N019853	001		Jan CAHN

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION;INTRAVENOUS

PHENYLEPHRINE HYDROCHLORIDE

>A>	AP		FRESENIUS KABI USA	10MG/ML (10MG/ML)	A210665	001	Jan 29, 2019	Jan NEWA
>A>	AP			50MG/5ML (10MG/ML)	A210666	001	Jan 30, 2019	Jan NEWA
>A>	AP			100MG/10ML (10MG/ML)	A210666	002	Jan 30, 2019	Jan NEWA
>A>	AP		SANDOZ INC	10MG/ML (10MG/ML)	A208905	001	Jan 31, 2019	Jan NEWA
>A>	AP			50MG/5ML (10MG/ML)	A208905	002	Jan 31, 2019	Jan NEWA
>A>	AP			100MG/10ML (10MG/ML)	A208905	003	Jan 31, 2019	Jan NEWA

SOLUTION/DROPS;OPHTHALMIC

PHENYLEPHRINE HYDROCHLORIDE

>D>		+!	AKORN INC	2.5%	N207926	001	Jan 15, 2015	Jan CTEC
>A>	AT	+!		2.5%	N207926	001	Jan 15, 2015	Jan CTEC
>D>		+!		10%	N207926	002	Jan 15, 2015	Jan CTEC
>A>	AT	+!		10%	N207926	002	Jan 15, 2015	Jan CTEC
>D>		+!	PARAGON BIOTECK	2.5%	N203510	001	Mar 21, 2013	Jan CTEC
>A>	AT	+!		2.5%	N203510	001	Mar 21, 2013	Jan CTEC
>D>		+!		10%	N203510	002	Mar 21, 2013	Jan CTEC
>A>	AT	+!		10%	N203510	002	Mar 21, 2013	Jan CTEC

PHYTONADIONE

TABLET;ORAL

MEPHYTON

>D>	AB	+!	VALEANT PHARMS	5MG	N010104	003		Jan CAHN
>A>	AB	+!	VALEANT PHARMS INTL	5MG	N010104	003		Jan CAHN

PIMAVANSERIN TARTRATE

TABLET;ORAL

NUPLAZID

>D>		+!	ACADIA PHARMS INC	EQ 17MG BASE	N207318	001	Apr 29, 2016	Jan DISC
>A>		+ @		EQ 17MG BASE	N207318	001	Apr 29, 2016	Jan DISC

PIROXICAM

CAPSULE;ORAL

PIROXICAM

>D>	AB		BRECKENRIDGE PHARM	10MG	A208991	001	Feb 21, 2018	Jan DISC
>A>		@		10MG	A208991	001	Feb 21, 2018	Jan DISC
>D>	AB			20MG	A208991	002	Feb 21, 2018	Jan DISC
>A>		@		20MG	A208991	002	Feb 21, 2018	Jan DISC

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE;ORAL

POTASSIUM CHLORIDE

>A> AB2	PII	8MEQ	A206881	001	Jan 22, 2019	Jan NEWA
>A> AB2		10MEQ	A206881	002	Jan 22, 2019	Jan NEWA

PREDNISONE

TABLET;ORAL

PREDNISONE

>A> AB	SUN PHARM INDUSTRIES	5MG	A089247	002	Dec 04, 1985	Jan CMS1
>A> AB		10MG	A089247	003	Dec 04, 1985	Jan CMS1

RANITIDINE HYDROCHLORIDE

SYRUP;ORAL

RANITIDINE HYDROCHLORIDE

>D> AA	BIO PHARM INC	EQ 15MG BASE/ML	A090102	001	May 26, 2009	Jan CAHN
>A> AA	TORRENT	EQ 15MG BASE/ML	A090102	001	May 26, 2009	Jan CAHN

TABLET;ORAL

RANITIDINE HYDROCHLORIDE

>A> AB	VKT PHARMA PVT LTD	EQ 150MG BASE	A211289	001	Jan 31, 2019	Jan NEWA
>A> AB		EQ 300MG BASE	A211289	002	Jan 31, 2019	Jan NEWA

RISPERIDONE

SOLUTION;ORAL

RISPERIDONE

>D> AA	BIO PHARM INC	1MG/ML	A078909	001	Jul 29, 2009	Jan CAHN
>A> AA	TORRENT	1MG/ML	A078909	001	Jul 29, 2009	Jan CAHN

SIROLIMUS

SOLUTION;ORAL

RAPAMUNE

>D>	+! PF PRISM CV	1MG/ML	N021083	001	Sep 15, 1999	Jan CFTG
>A> AA	+!	1MG/ML	N021083	001	Sep 15, 1999	Jan CFTG

>A> SIROLIMUS

>A> AA	NOVITIUM PHARMA	1MG/ML	A211040	001	Jan 28, 2019	Jan NFTG

SODIUM CHROMATE CR-51

INJECTABLE;INJECTION

SODIUM CHROMATE CR 51

>A>	@ CURIUM	100uCi/ML	N016708	001		Jan CAHN
>D>	@ MALLINKRODT NUCLEAR	100uCi/ML	N016708	001		Jan CAHN

SODIUM IODIDE I-131

CAPSULE;ORAL

SODIUM IODIDE I 131

>A>	@ CURIUM	0.8-100mCi	N016515	002		Jan CAHN
>A>	+ @	0.8-100mCi	N016517	001		Jan CAHN
>A>	@	15-100uCi	N016517	002		Jan CAHN
>D>	@ MALLINKRODT NUCLEAR	0.8-100mCi	N016515	002		Jan CAHN
>D>	+ @	0.8-100mCi	N016517	001		Jan CAHN
>D>	@	15-100uCi	N016517	002		Jan CAHN

SOLUTION;ORAL

SODIUM IODIDE I 131

>A>	+ @ CURIUM	3.5-150mCi/VIAL	N016515	001		Jan CAHN
>D>	+ @ MALLINKRODT NUCLEAR	3.5-150mCi/VIAL	N016515	001		Jan CAHN

STRONTIUM CHLORIDE SR-89

INJECTABLE;INJECTION

METASTRON

>D> AP	+! GE HEALTHCARE	1mCi/ML	N020134	001	Jun 18, 1993	Jan CAHN
>A> AP	+! Q BIOMED	1mCi/ML	N020134	001	Jun 18, 1993	Jan CAHN

SUCCINYLCHOLINE CHLORIDE

INJECTABLE;INJECTION

SUCCINYLCHOLINE CHLORIDE

>A> AP	AMRING PHARMS	20MG/ML	A210231	001	Jun 04, 2018	Jan CAHN
>D> AP	RENAISSANCE SSA LLC	20MG/ML	A210231	001	Jun 04, 2018	Jan CAHN

SUMATRIPTAN

SPRAY;NASAL

TOSYMRA

>A>	+!	DR REDDYS LABS LTD	10MG/SPRAY	N210884	001	Jan 25, 2019	Jan NEWA

TACROLIMUS

OINTMENT;TOPICAL

TACROLIMUS

>A> AB		ACCORD HLTHCARE	0.03%	A211688	001	Jan 31, 2019	Jan NEWA
>A> AB			0.1%	A211688	002	Jan 31, 2019	Jan NEWA

TADALAFIL

TABLET;ORAL

ALYQ

>A> AB2		TEVA PHARMS USA	20MG	A209942	001	Feb 05, 2019	Jan NEWA

TADALAFIL

>A> AB2		AJANTA PHARMA LTD	20MG	A210392	001	Feb 05, 2019	Jan NEWA
>A> AB2		AUROBINDO PHARMA LTD	20MG	A206286	001	Feb 05, 2019	Jan NEWA
>A> AB2		CIPLA	20MG	A210255	001	Feb 05, 2019	Jan NEWA
>A> AB2		DR REDDYS LABS LTD	20MG	A210145	001	Feb 05, 2019	Jan NEWA
>A> AB2		HETERO LABS LTD III	20MG	A209907	001	Feb 05, 2019	Jan NEWA
>A> AB2		LUPIN LTD	20MG	A210572	001	Feb 05, 2019	Jan NEWA

TAZAROTENE

CREAM;TOPICAL

TAZAROTENE

>A> AB		FOUGERA PHARMS INC	1%	A211175	001	Jan 28, 2019	Jan NEWA

TECHNETIUM TC-99M MERTIATIDE KIT

INJECTABLE;INJECTION

TECHNESCAN MAG3

>A>	+!	CURIUM	N/A	N019882	001	Jun 15, 1990	Jan CAHN
>D>	+!	MALLINKRODT NUCLEAR	N/A	N019882	001	Jun 15, 1990	Jan CAHN

TECHNETIUM TC-99M OXIDRONATE KIT

INJECTABLE;INJECTION

TECHNESCAN

>A>	+!	CURIUM	N/A	N018321	001		Jan CAHN
>D>	+!	MALLINKRODT NUCLEAR	N/A	N018321	001		Jan CAHN

TECHNETIUM TC-99M PYROPHOSPHATE KIT

INJECTABLE;INJECTION

TECHNESCAN PYP KIT

>A> AP		CURIUM	N/A	N017538	001		Jan CAHN
>D> AP		MALLINKRODT NUCLEAR	N/A	N017538	001		Jan CAHN

TECHNETIUM TC-99M RED BLOOD CELL KIT

INJECTABLE;INJECTION

ULTRATAG

>A>	+!	CURIUM	N/A	N019981	001	Jun 10, 1991	Jan CAHN
>D>	+!	MALLINKRODT NUCLEAR	N/A	N019981	001	Jun 10, 1991	Jan CAHN

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION;INTRAVENOUS

ULTRA-TECHNEKOW FM

>A>	+!	CURIUM	1-19 CI/GENERATOR	N017243	003	Feb 18, 2014	Jan CAHN
>A>	@		0.25-3 CI/GENERATOR	N017243	002		Jan CAHN
>D>	+!	MALLINKRODT NUCLEAR	1-19 CI/GENERATOR	N017243	003	Feb 18, 2014	Jan CAHN
>D>	@		0.25-3 CI/GENERATOR	N017243	002		Jan CAHN

TEMOZOLOMIDE

CAPSULE;ORAL

TEMOZOLOMIDE

>D> AB		APOTEX INC	5MG	A204159	001	Jul 05, 2018	Jan DISC
>A>	@		5MG	A204159	001	Jul 05, 2018	Jan DISC
>D> AB			20MG	A204159	002	Jul 05, 2018	Jan DISC
>A>	@		20MG	A204159	002	Jul 05, 2018	Jan DISC
>D> AB			100MG	A204159	003	Jul 05, 2018	Jan DISC
>A>	@		100MG	A204159	003	Jul 05, 2018	Jan DISC
>D> AB			140MG	A204159	004	Jul 05, 2018	Jan DISC
>A>	@		140MG	A204159	004	Jul 05, 2018	Jan DISC

CAPSULE;ORAL
TEMOZOLOMIDE

>D>	AB			180MG	A204159	005	Jul 05, 2018	Jan DISC
>A>		@		180MG	A204159	005	Jul 05, 2018	Jan DISC
>D>	AB			250MG	A204159	006	Jul 05, 2018	Jan DISC
>A>		@		250MG	A204159	006	Jul 05, 2018	Jan DISC

TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL
TENOFOVIR DISOPROXIL FUMARATE

>D>	AB		APOTEX INC	300MG	A206481	001	Jul 26, 2018	Jan DISC
>A>		@		300MG	A206481	001	Jul 26, 2018	Jan DISC

TERIFLUNOMIDE

TABLET;ORAL
TERIFLUNOMIDE

>D>	AB		APOTEX INC	7MG	A209601	001	Nov 02, 2018	Jan DISC
>A>		@		7MG	A209601	001	Nov 02, 2018	Jan DISC
>D>	AB			14MG	A209601	002	Nov 02, 2018	Jan DISC
>A>		@		14MG	A209601	002	Nov 02, 2018	Jan DISC

THALLOUS CHLORIDE TL-201

INJECTABLE;INJECTION
THALLOUS CHLORIDE TL 201

>A>	AP	+!	CURIUM	1mCi/ML	N018150	001		Jan CAHN
>D>	AP	+!	MALLINKRODT NUCLEAR	1mCi/ML	N018150	001		Jan CAHN

TICAGRELOR

TABLET;ORAL
TICAGRELOR

>A>	AB		AMNEAL PHARMS CO	90MG	A208531	001	Jan 23, 2019	Jan NEWA
>A>	AB		HISUN PHARM HANGZHOU	90MG	A208575	001	Jan 23, 2019	Jan NEWA

TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC
TIMOPTIC

>D>	AT	+	ATON	EQ 0.25% BASE	N018086	001		Jan CAHN
>D>	AT1	+		EQ 0.5% BASE	N018086	002		Jan CAHN
>A>	AT	+	VALEANT PHARMS INTL	EQ 0.25% BASE	N018086	001		Jan CAHN
>A>	AT1	+		EQ 0.5% BASE	N018086	002		Jan CAHN

TIMOPTIC IN OCUDOSE

>D>		+!	ATON	EQ 0.25% BASE	N019463	001	Nov 05, 1986	Jan CAHN
>D>		+!		EQ 0.5% BASE	N019463	002	Nov 05, 1986	Jan CAHN
>A>		+!	VALEANT PHARMS INTL	EQ 0.25% BASE	N019463	001	Nov 05, 1986	Jan CAHN
>A>		+!		EQ 0.5% BASE	N019463	002	Nov 05, 1986	Jan CAHN

TIZANIDINE HYDROCHLORIDE

TABLET;ORAL
TIZANIDINE HYDROCHLORIDE

>A>	AB		ALKEM LABS LTD	EQ 2MG BASE	A211798	001	Jan 25, 2019	Jan NEWA
>A>	AB			EQ 4MG BASE	A211798	002	Jan 25, 2019	Jan NEWA

TOBRAMYCIN

SOLUTION;INHALATION
TOBRAMYCIN

>D>	AN		DR REDDYS LABS SA	300MG/5ML	A207080	001	Jul 09, 2018	Jan DISC
>A>		@		300MG/5ML	A207080	001	Jul 09, 2018	Jan DISC

TRETINOIN

CREAM;TOPICAL
TRETINOIN

>A>	AB1		TARO PHARMS	0.05%	A211644	001	Jan 25, 2019	Jan NEWA
>A>	AB			0.1%	A211645	001	Jan 22, 2019	Jan NEWA

TRIAMCINOLONE ACETONIDE

CREAM;TOPICAL
TRIAMCINOLONE ACETONIDE

>A>	AT		STRIDES PHARMA	0.025%	A210346	001	Feb 11, 2019	Jan NEWA
>A>	AT			0.1%	A210346	002	Feb 11, 2019	Jan NEWA
>A>	AT			0.5%	A210346	003	Feb 11, 2019	Jan NEWA

CETIRIZINE HYDROCHLORIDE

SYRUP;ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

>D>	BIO PHARM INC	5MG/5ML	A090474	002	Mar 30, 2009	Jan	CAHN
>A>	TORRENT	5MG/5ML	A090474	002	Mar 30, 2009	Jan	CAHN

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

>D>	BIO PHARM INC	5MG/5ML	A090474	001	Mar 30, 2009	Jan	CAHN
>A>	TORRENT	5MG/5ML	A090474	001	Mar 30, 2009	Jan	CAHN

CHLORHEXIDINE GLUCONATE

SOLUTION;TOPICAL

DYNA-HEX

>D>	@ BAJAJ	0.75%	N020111	001	Sep 11, 1997	Jan	CMFD
>A>		0.75%	N020111	001	Sep 11, 1997	Jan	CMFD

CHLORPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE;ORAL

>D>	CHLOR-TRIMETON						
>D>	+! BAYER HEALTHCARE LLC	12MG	N007638	002		Jan	DISC
>A>	+ @	12MG	N007638	002		Jan	DISC

CHLORPHENIRAMINE MALEATE

>D>	AVANTHI INC	12MG	A040829	001	May 13, 2009	Jan	CHRS
>A>	!	12MG	A040829	001	May 13, 2009	Jan	CHRS

DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN

CAPSULE;ORAL

IBUPROFEN AND DIPHENHYDRAMINE HYDROCHLORIDE

>A>	AUROBINDO PHARMA LTD	25MG;EQ 200MG FREE ACID AND POTASSIUM SALT	A210676	001	Feb 14, 2019	Jan	NEWA

DIPHENHYDRAMINE HYDROCHLORIDE; NAPROXEN SODIUM

TABLET;ORAL

NAPROXEN SODIUM AND DIPHENHYDRAMINE HYDROCHLORIDE

>A>	ACTAVIS ELIZABETH	25MG;220MG	A207597	001	Jan 25, 2019	Jan	NEWA

KETOCONAZOLE

SHAMPOO;TOPICAL

NIZORAL A-D

>D>	+! JOHNSON AND JOHNSON	1%	N020310	001	Oct 10, 1997	Jan	CAHN
>A>	+! KRAMER	1%	N020310	001	Oct 10, 1997	Jan	CAHN

LEVONORGESTREL

TABLET;ORAL

LEVONORGESTREL

>D>	APOTEX INC	1.5MG	A205329	001	Sep 18, 2018	Jan	DISC
>A>	@	1.5MG	A205329	001	Sep 18, 2018	Jan	DISC

OMEPRAZOLE

TABLET, DELAYED RELEASE;ORAL

OMEPRAZOLE

>A>	APOTEX INC	20MG	A210070	001	Feb 11, 2019	Jan	NEWA

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

CUMULATIVE SUPPLEMENT NUMBER 01 JANUARY 2019

NO JANUARY 2019 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of Orphan Designations and Approvals is available at:

http://www.fda.gov/orphan/designat/list.htm

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

NO JANUARY 2019 ADDITIONS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2019

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ABIRATERONE ACETATE - ABIRATERONE ACETATE						
A 208327 001					>A> PC	Apr 29, 2019
ACALABRUTINIB - CALQUENCE						
N 210259 001	>A> 10167291	Jul 01, 2036	DP		U-2145	
ACETAMINOPHEN; BENZHYDROCODONE HYDROCHLORIDE - APADAZ						
N 208653 002	>A> 8461137	Feb 22, 2031	DS DP			
	>A> 8748413	Jul 10, 2030	DS DP			
	>A> 8828978	Jul 01, 2030	DP			
	>A> 9132125	Jul 01, 2030	DS DP		U-2249	
	>A> 9549923	Jul 01, 2030	DS DP			
ACETAMINOPHEN; BENZHYDROCODONE HYDROCHLORIDE - APADAZ						
N 208653 003	>A> 8461137	Feb 22, 2031	DS DP			
	>A> 8748413	Jul 10, 2030	DS DP			
	>A> 8828978	Jul 01, 2030	DP			
	>A> 9132125	Jul 01, 2030	DS DP		U-2249	
	>A> 9549923	Jul 01, 2030	DS DP			
ALBUTEROL SULFATE - PROAIR RESPICLICK						
N 205636 001	>A> 10124131	May 18, 2031	DP			
ALBUTEROL SULFATE - PROAIR DIGIHALER						
N 205636 002	>A> 10022510	May 18, 2031	DP			
	>A> 10124131	May 18, 2031	DP			
	>A> 6701917	Jun 23, 2021	DP			
	>A> 6718972	Jun 23, 2021	DP			
	>A> 6748947	Jun 23, 2021	DP			
	>A> 6871646	Jun 23, 2021	DP			
	>A> 7540282	May 06, 2023	DP			
	>A> 8006690	Jun 23, 2021	DP			
	>A> 8651103	Mar 26, 2028	DP			
	>A> 8978966	Jan 13, 2032	DP			
	>A> 9216260	Jun 28, 2031	DP			
	>A> 9463288	May 19, 2025	DP			
	>A> 9731087	May 18, 2031	DP			
	>A> 9782550	Aug 28, 2035	DP			
	>A> 9782551	Aug 28, 2035	DP			
AMPHETAMINE SULFATE - EVEKEO ODT						
N 209905 001	>A> 10130580	Apr 19, 2024	DP			
AMPHETAMINE SULFATE - EVEKEO ODT						
N 209905 002	>A> 10130580	Apr 19, 2024	DP			
AMPHETAMINE SULFATE - EVEKEO ODT						
N 209905 003	>A> 10130580	Apr 19, 2024	DP			
AMPHETAMINE SULFATE - EVEKEO ODT						
N 209905 004	>A> 10130580	Apr 19, 2024	DP			
BETAMETHASONE DIPROPIONATE - SERNIVO						
N 208079 001	>A> 10179137	Aug 31, 2030	DP		U-1858	
BRIGATINIB - ALUNBRIG						
N 208772 001	>A> 9012462	Jul 31, 2030	DS			
BRIGATINIB - ALUNBRIG						
N 208772 002	>A> 9012462	Jul 31, 2030	DS			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2019

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BRIGATINIB - ALUNBRIG						
N 208772 003	>A> 9012462	Jul 31, 2030	DS			
BRIMONIDINE TARTRATE - MIRVASO						
N 204708 001	>A> 10201517	Jun 13, 2031	DS DP			
CABOZANTINIB S-MALATE - CABOMETYX						
N 208692 001	>A> 10034873	Jul 18, 2031	U-2488			
	>A> 8497284	Sep 24, 2024	U-1220			
	>A> 8497284	Sep 24, 2024	U-1480			
	>A> 8497284	Sep 24, 2024	U-2488			
CABOZANTINIB S-MALATE - CABOMETYX						
N 208692 002	>A> 10034873	Jul 18, 2031	U-2488			
	>A> 8497284	Sep 24, 2024	U-1220			
	>A> 8497284	Sep 24, 2024	U-1480			
	>A> 8497284	Sep 24, 2024	U-2488			
CABOZANTINIB S-MALATE - CABOMETYX						
N 208692 003	>A> 10034873	Jul 18, 2031	U-2488			
	>A> 8497284	Sep 24, 2024	U-1220			
	>A> 8497284	Sep 24, 2024	U-1480			
	>A> 8497284	Sep 24, 2024	U-2488			
DALFAMPRIDINE - DALFAMPRIDINE						
A 206863 001					>A> PC	Mar 09, 2019
DEFERIPRONE - FERRIPROX						
N 208030 002	>A> 7049328	Jun 28, 2021	U-735			
	>A> 8703156	Oct 29, 2029	DP U-735			
DEXAMETHASONE - DEXTENZA						
N 208742 001	>A> 8409606	May 14, 2030	DP		>A> NP	Nov 30, 2021
	>A> 8563027	Feb 12, 2030	U-2487			
	>A> 9254267	Sep 11, 2024	DP			
DEXAMETHASONE - DEXYCU KIT						
N 208912 001	>A> 10159683	May 23, 2034	DP			
FERRIC CITRATE - AURYXIA						
N 205874 001					>A> I-790	Nov 06, 2020
FERRIC PYROPHOSPHATE CITRATE - TRIFERIC						
N 208551 001	>A> 7816404	Apr 17, 2029	U-1656			
	>A> 7857977	Sep 08, 2027	U-1656			
FLUTICASONE PROPIONATE - XHANCE						
N 209022 001	>A> 10179216	Jul 08, 2033	DP U-2133			
GILTERITINIB FUMARATE - XOSPATA						
N 211349 001					>A> NCE	Nov 28, 2023
HYDROCORTISONE VALERATE - HYDROCORTISONE VALERATE						
A 211750 001					>A> CGT	Jul 16, 2019
IBRUTINIB - IMBRUVICA						
N 205552 001					>A> M-236	Jan 25, 2022
IBRUTINIB - IMBRUVICA						
N 205552 002					>A> M-236	Jan 25, 2022

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2019

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IBRUTINIB - IMBRUVICA						
N 210563 001					>A> M-236	Jan 25, 2022
IBRUTINIB - IMBRUVICA						
N 210563 002					>A> M-236	Jan 25, 2022
IBRUTINIB - IMBRUVICA						
N 210563 003					>A> M-236	Jan 25, 2022
IBRUTINIB - IMBRUVICA						
N 210563 004					>A> M-236	Jan 25, 2022
INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT - NOVOLOG MIX 70/30 FLEXPEN						
N 021172 004	>A> 7762994	May 23, 2024	DP			
	>A> 8579869	Jun 30, 2023	DP			
INSULIN ASPART RECOMBINANT - NOVOLOG PENFILL						
N 020986 002	>A> 7762994	May 23, 2024	DP			
	>A> 8579869	Jun 30, 2023	DP			
INSULIN ASPART RECOMBINANT - NOVOLOG FLEXPEN						
N 020986 003	>A> 7762994	May 23, 2024	DP			
	>A> 8579869	Jun 30, 2023	DP			
INSULIN ASPART RECOMBINANT - NOVOLOG FLEXTOUCH						
N 020986 005	>A> 7762994	May 23, 2024	DP			
	>A> 8579869	Jun 30, 2023	DP			
INSULIN ASPART; INSULIN DEGLUDEC - RYZODEG 70/30						
N 203313 001	>A> 7762994	May 23, 2024	DP			
	>A> 8579869	Jun 30, 2023	DP			
INSULIN DEGLUDEC - TRESIBA						
N 203314 001	>A> 8579869	Jun 30, 2023	DP			
INSULIN DEGLUDEC - TRESIBA						
N 203314 002	>A> 8579869	Jun 30, 2023	DP			
INSULIN DEGLUDEC; LIRAGLUTIDE - XULTOPHY 100/3.6						
N 208583 001	>A> 8579869	Jun 30, 2023	DP			
INSULIN DETEMIR RECOMBINANT - LEVEMIR FLEXTOUCH						
N 021536 005	>A> 7762994	May 23, 2024	DP			
	>A> 8579869	Jun 30, 2023	DP			
LAROTRECTINIB - VITRAKVI						
N 210861 001					>A> NCE	Nov 26, 2023
LAROTRECTINIB - VITRAKVI						
N 210861 002					>A> NCE	Nov 26, 2023
LAROTRECTINIB - VITRAKVI						
N 211710 001					>A> NCE	Nov 26, 2023
LEVODOPA - INBRIJA						
N 209184 001	>A> 6514482	Sep 19, 2020	DP U-2484		>A> NP	Dec 21, 2021
	>A> 6613308	Sep 19, 2020	U-2484			
	>A> 6858199	Nov 04, 2021	U-2485			
	>A> 6921528	Jun 19, 2020	U-2485			
	>A> 6979437	Sep 19, 2020	U-2484			
	>A> 7146978	Apr 16, 2021	U-2486			

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LEVODOPA - INBRIJA							
N 209184	001	>A> 7182961	Feb 22, 2024	DP			
		>A> 7384649	Nov 20, 2022	DP			
		>A> 7556798	Nov 04, 2021			U-2485	
		>A> 8404276	Mar 19, 2023			U-2484	
		>A> 8545878	Nov 16, 2032	DP			
		>A> 8586093	Mar 19, 2023			U-2484	
		>A> 8628754	Jun 19, 2020			U-2485	
		>A> 8685442	Nov 16, 2032	DP			
		>A> 8945612	Nov 16, 2032	DP			
		>A> 9155699	Mar 19, 2023	DP			
		>A> 9393210	Nov 16, 2032	DP			
		>A> RE43711	Feb 03, 2029			U-2484	
LIRAGLUTIDE RECOMBINANT - SAXENDA							
N 206321	001	>A> 8579869	Jun 30, 2023	DP			
METFORMIN HYDROCHLORIDE - RIOMET							
N 021591	001	>A> 6890957	Aug 07, 2021	DP			
METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM							
N 209311	001	>A> 10182995	Mar 23, 2032	DP			
METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM							
N 209311	002	>A> 10182995	Mar 23, 2032	DP			
METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM							
N 209311	003	>A> 10182995	Mar 23, 2032	DP			
METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM							
N 209311	004	>A> 10182995	Mar 23, 2032	DP			
METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM							
N 209311	005	>A> 10182995	Mar 23, 2032	DP			
MIFEPRISTONE - KORLYM							
N 202107	001	>A> 10195214	Jun 19, 2037			U-1643	
OLAPARIB - LYNPARZA							
N 208558	001	>A> 8143241	Aug 12, 2027			U-2101	
		>A> 8143241	Aug 12, 2027			U-2103	
		>A> 8143241	Aug 12, 2027			U-2480	
		>A> 8143241	Aug 12, 2027			U-2481	
		>A> 8143241	Aug 12, 2027			U-2482	
		>A> 8143241	Aug 12, 2027			U-2483	
		>A> 8859562	Aug 04, 2031			U-2101	
		>A> 8859562	Aug 04, 2031			U-2480	
		>A> 8859562	Aug 04, 2031			U-2481	
		>A> 8859562	Aug 04, 2031			U-2482	
		>A> 8859562	Aug 04, 2031			U-2483	
		>A> 8912187	Mar 12, 2024			U-2101	
		>A> 8912187	Mar 12, 2024			U-2480	
		>A> 8912187	Mar 12, 2024			U-2481	
		>A> 8912187	Mar 12, 2024			U-2482	
		>A> 8912187	Mar 12, 2024			U-2483	
OLAPARIB - LYNPARZA							
N 208558	002	>A> 8143241	Aug 12, 2027			U-2101	
		>A> 8143241	Aug 12, 2027			U-2103	
		>A> 8143241	Aug 12, 2027			U-2480	
		>A> 8143241	Aug 12, 2027			U-2481	
		>A> 8143241	Aug 12, 2027			U-2482	
		>A> 8143241	Aug 12, 2027			U-2483	
		>A> 8859562	Aug 04, 2031			U-2101	

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2019

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OLAPARIB - LYNPARZA								
N 208558	002	>A>	8859562	Aug 04, 2031	U-2480			
		>A>	8859562	Aug 04, 2031	U-2481			
		>A>	8859562	Aug 04, 2031	U-2482			
		>A>	8859562	Aug 04, 2031	U-2483			
		>A>	8912187	Mar 12, 2024	U-2101			
		>A>	8912187	Mar 12, 2024	U-2480			
		>A>	8912187	Mar 12, 2024	U-2481			
		>A>	8912187	Mar 12, 2024	U-2482			
		>A>	8912187	Mar 12, 2024	U-2483			
OSIMERTINIB MESYLATE - TAGRISSO								
N 208065	001	>A>	10183020	Jan 02, 2035	DP U-1777			
		>A>	10183020	Jan 02, 2035	DP U-2289			
OSIMERTINIB MESYLATE - TAGRISSO								
N 208065	002	>A>	10183020	Jan 02, 2035	DP U-1777			
		>A>	10183020	Jan 02, 2035	DP U-2289			
OSPEMIFENE - OSPHENA								
N 203505	001	>A>	6245819	Jul 21, 2025	U-1370			
		>A>	6245819	Jul 21, 2025	U-905			
			8236861	Aug 11, 2026	U-1369			
			8236861	Aug 11, 2026	U-1370			
			8236861	Aug 11, 2026	U-905			
		>A>	8470890	Feb 13, 2024	U-1369			
		>A>	8470890	Feb 13, 2024	U-1370			
		>A>	8470890	Feb 13, 2024	U-905			
		>A>	8772353	Feb 13, 2024	U-1369			
		>A>	8772353	Feb 13, 2024	U-1370			
		>A>	8772353	Feb 13, 2024	U-905			
		>A>	9241915	Feb 13, 2024	U-1369			
		>A>	9241915	Feb 13, 2024	U-1370			
		>A>	9241915	Feb 13, 2024	U-905			
		>A>	9855224	Feb 13, 2024	U-1369			
		>A>	9855224	Feb 13, 2024	U-1370			
		>A>	9855224	Feb 13, 2024	U-905			
OXCARBAZEPINE - OXTELLAR XR								
N 202810	001	>A>	7910131	Apr 13, 2027	U-2041			
		>A>	9119791	Apr 13, 2027	U-2041			
OXCARBAZEPINE - OXTELLAR XR								
N 202810	002	>A>	7910131	Apr 13, 2027	U-2041			
		>A>	9119791	Apr 13, 2027	U-2041			
OXCARBAZEPINE - OXTELLAR XR								
N 202810	003	>A>	7910131	Apr 13, 2027	U-2041			
		>A>	9119791	Apr 13, 2027	U-2041			
OXYCODONE - XTAMPZA ER								
N 208090	001	>A>	10188644	Sep 02, 2036	DP U-1556			
OXYCODONE - XTAMPZA ER								
N 208090	002	>A>	10188644	Sep 02, 2036	DP U-1556			
OXYCODONE - XTAMPZA ER								
N 208090	003	>A>	10188644	Sep 02, 2036	DP U-1556			
OXYCODONE - XTAMPZA ER								
N 208090	004	>A>	10188644	Sep 02, 2036	DP U-1556			

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APPL/PROD NO			PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
OXYCODONE - XTAMPZA ER								
N 208090	005	>A>	10188644	Sep 02, 2036	DP U-1556			
SODIUM ZIRCONIUM CYCLOSILICATE - LOKELMA								
N 207078	001	>A>	9913860	Oct 22, 2033	DS U-2312			
SODIUM ZIRCONIUM CYCLOSILICATE - LOKELMA								
N 207078	002	>A>	9913860	Oct 22, 2033	DS U-2312			
SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO								
N 021148	008	>A>	7762994	May 23, 2024	DP			
SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO								
N 021148	009	>A>	7762994	May 23, 2024	DP			
SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO								
N 021148	010	>A>	7762994	May 23, 2024	DP			
SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO								
N 021148	011	>A>	7762994	May 23, 2024	DP			
SUNITINIB MALATE - SUTENT								
N 021938	001	>A>	6573293	Feb 15, 2021	DS DP U-1154		>A> I-755	Nov 16, 2020
		>A>	6573293	Feb 15, 2021	DS DP U-2171		>A> PED	May 16, 2021
		>A>	6573293*PED	Aug 15, 2021				
		>A>	7125905	Feb 15, 2021	DS DP			
		>A>	7125905*PED	Aug 15, 2021				
		>A>	7211600	Dec 22, 2020	U-883			
		>A>	7211600*PED	Jun 22, 2021				
SUNITINIB MALATE - SUTENT								
N 021938	002	>A>	6573293	Feb 15, 2021	DS DP U-1154		>A> I-755	Nov 16, 2020
		>A>	6573293	Feb 15, 2021	DS DP U-2171		>A> PED	May 16, 2021
		>A>	6573293*PED	Aug 15, 2021				
		>A>	7125905	Feb 15, 2021	DS DP			
		>A>	7125905*PED	Aug 15, 2021				
		>A>	7211600	Dec 22, 2020	U-883			
		>A>	7211600*PED	Jun 22, 2021				
SUNITINIB MALATE - SUTENT								
N 021938	003	>A>	6573293	Feb 15, 2021	DS DP U-1154		>A> I-755	Nov 16, 2020
		>A>	6573293	Feb 15, 2021	DS DP U-2171		>A> PED	May 16, 2021
		>A>	6573293*PED	Aug 15, 2021				
		>A>	7125905	Feb 15, 2021	DS DP			
		>A>	7125905*PED	Aug 15, 2021				
		>A>	7211600	Dec 22, 2020	U-883			
		>A>	7211600*PED	Jun 22, 2021				
SUNITINIB MALATE - SUTENT								
N 021938	004	>A>	6573293	Feb 15, 2021	DS DP U-1154		>A> I-755	Nov 16, 2020
		>A>	6573293	Feb 15, 2021	DS DP U-2171		>A> PED	May 16, 2021
		>A>	6573293*PED	Aug 15, 2021				
		>A>	7125905	Feb 15, 2021	DS DP			
		>A>	7125905*PED	Aug 15, 2021				
		>A>	7211600	Dec 22, 2020	U-883			
		>A>	7211600*PED	Jun 22, 2021				
TRIPTORELIN PAMOATE - TRELSTAR								
N 022437	001	>A>	10166181	Feb 10, 2029	DP			

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APPL/PROD NO			PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
TRIPTORELIN PAMOATE - TRIPTODUR KIT								
N 208956	001	>A>	10166181	Feb 10, 2029	DP			
URIDINE TRIACETATE - VISTOGARD								
N 208159	001	>A>	6258795	Jul 10, 2023	DP			
URIDINE TRIACETATE - XURIDEN								
N 208169	001	>A>	6258795	Jul 10, 2023	DP			

Footnote:

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

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

PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 39th 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