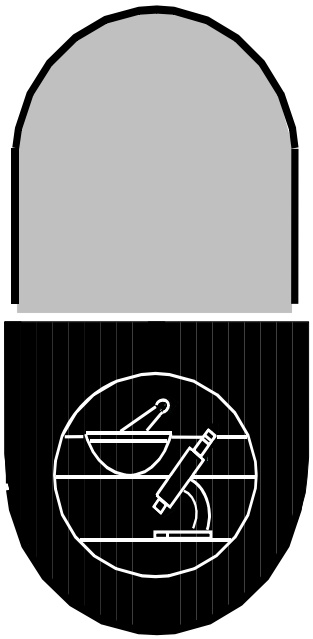
CUMULATIVE SUPPLEMENT 1
JANUARY 2013



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

33rd EDITION

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs

2013

Prepared By
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

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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, 30th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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, 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, or have been discontinued from marketing 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 the 32nd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 33rd Edition. The current Edition Section 2., How To Use The Drug Product Lists, describes the layout and usage of the List.

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

- All product changes received and processed as of the date of publication.
  - o Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
  - o Discontinued products will be processed as of the date of publication. There will be circumstances where a product is discontinued in one month, however, it will be reported in a different month's CS. For example, the Orange Book Staff received a letter November 7 that the product has been discontinued from manufacturing and marketing. The Orange Book subsequently publishes the October CS on November 14. The product will show in the October CS that it is discontinued even though the date of discontinuance is the day that the Orange Book Staff receives notification (November 7).

- New Drug Application (NDA) approvals (20,000 and 50,000 series) 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 drugproducts@fda.hhs.gov. Send Changes by FAX: 240-276-8974; mail to:

FDA/CDER Orange Book Staff
Office of Generic Drugs, HFD-610
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 76187) and Levo-T (Alara NDA 21342) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets. Levo-T (Alara NDA 021342), Levothyroxine Sodium (Mylan ANDA 76187), Unithroid (Jerome Stevens NDA 021210), and Levothyroxine Sodium (Merck KGAA ANDA 76752)tablets have been determined to be therapeutically

equivalent to corresponding strengths of Synthroid (Abbott NDA 021402) tablets.

Levo-T (Alara NDA 021342), Unithroid (Jerome Stevens NDA 021210), Levothyroxine Sodium (Mylan ANDA 076187), and Levothyroxine Sodium (Merck KGAA ANDA 76752) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King Pharms NDA 021301) tablets.

Levothyroxine Sodium (Mylan ANDA 76187) 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. 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	Potency	TE Code	Appl No	Product No
UNITHROID	STEVENS J	0.025MG	AB1	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB1	76187	001
LEVOXYL	KING PHARMS	0.025MG	AB1	21301	001
SYNTHROID	ABBOTT	0.025MG	AB1	21402	001
LEVO-T	ALARA PHARM	0.025MG	AB1	21342	001
SYNTHROID	ABBOTT	0.025MG	AB2	21402	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB2	76187	001
LEVO-T	ALARA PHARM	0.025MG	AB2	21342	001
UNITHROID	STEVENS J	0.025MG	AB2	21210	001
LEVOTHYROXINE SODIUM	MERCK KGAA	0.025MG	AB2	76752	001
LEVOXYL	KUNG PHARMS	0.025MG	AB3	21301	001
LEVO-T	ALARA PHARM	0.025MG	AB3	21342	001
UNITHROID	STEVENS J	0.025MG	AB3	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB3	76187	001
LEVOTHYROXINE SODIUM	MERCK KGAA	0.025MG	AB3	76752	001
LEVOTHROID	LLOYD	0.025MG	AB4	21116	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB4	76187	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 (Dec 2011) 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 2012	MAR 2013	JUN 2013	SEPT 2013	DEC 2013
DRUG PRODUCTS LISTED	15343				
SINGLE SOURCE	2400 (15.9%)				
MULTISOURCE	12825 (83.6%)				
THERAPEUTICALLY EQUIVALENT	12683 (82.7%)				
NOT THERAPEUTICALLY EQUIVALENT	142 (0.9%)				
EXCEPTIONS[1]	78 (0.5%)				
NEW MOLECULAR ENTITIES APPROVED	17				
NUMBER OF APPLICANTS	835				

[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 and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug 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; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

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

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.

CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
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.

ACETAZOLAMIDE

TABLET; ORAL
ACETAZOLAMIDE

>D>	AB		WATSON LABS	250MG	A088882	001	Oct 22, 1985	Jan	DISC
>A>			@	250MG	A088882	001	Oct 22, 1985	Jan	DISC

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION
ACETAZOLAMIDE SODIUM

>A>	AP		SAGENT AGILA	EQ 500MG BASE/VIAL	A200880	001	May 09, 2012	Jan	CAHN
>D>	AP		SAGENT STRIDES	EQ 500MG BASE/VIAL	A200880	001	May 09, 2012	Jan	CAHN

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

>D>	AN	+	DEY	EQ 0.083% BASE	A072652	001	Feb 21, 1992	Jan	CAHN
>A>	AN	+	MYLAN SPECLT	EQ 0.083% BASE	A072652	001	Feb 21, 1992	Jan	CAHN

>A> ALOGLIPTIN BENZOATE

>A> TABLET; ORAL
>A> NESINA

>A>			TAKEDA PHARMS USA	EQ 6.25MG BASE	N022271	001	Jan 25, 2013	Jan	NEWA
>A>				EQ 12.5MG BASE	N022271	002	Jan 25, 2013	Jan	NEWA
>A>		+		EQ 25MG BASE	N022271	003	Jan 25, 2013	Jan	NEWA

>A> ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE

>A> TABLET; ORAL
>A> KAZANO

>A>			TAKEDA PHARMS USA	EQ 12.5MG BASE;500MG	N203414	001	Jan 25, 2013	Jan	NEWA
>A>		+		EQ 12.5MG BASE;1GM	N203414	002	Jan 25, 2013	Jan	NEWA

>A> ALOGLIPTIN BENZOATE; PIOGLITAZONE

>A> TABLET; ORAL
>A> OSENI

>A>			TAKEDA PHARMS USA	EQ 12.5MG BASE;EQ 15MG BASE	N022426	004	Jan 25, 2013	Jan	NEWA
>A>				EQ 12.5MG BASE;EQ 30MG BASE	N022426	005	Jan 25, 2013	Jan	NEWA
>A>				EQ 12.5MG BASE;EQ 45MG BASE	N022426	006	Jan 25, 2013	Jan	NEWA
>A>				EQ 25MG BASE;EQ 15MG BASE	N022426	001	Jan 25, 2013	Jan	NEWA
>A>				EQ 25MG BASE;EQ 30MG BASE	N022426	002	Jan 25, 2013	Jan	NEWA
>A>		+		EQ 25MG BASE;EQ 45MG BASE	N022426	003	Jan 25, 2013	Jan	NEWA

AMOXICILLIN

>D> TABLET, FOR SUSPENSION; ORAL
>D> AMOXICILLIN

>D>	AB		AUROBINDO PHARMA	200MG	A065324	001	Jan 17, 2007	Jan	DISC
>D>	AB			400MG	A065324	002	Jan 17, 2007	Jan	DISC
>A>			@ AUROBINDO PHARMA LTD	200MG	A065324	001	Jan 17, 2007	Jan	DISC
>A>			@	400MG	A065324	002	Jan 17, 2007	Jan	DISC

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL
DEXTROAMP SACCHARATE,AMP ASPARTATE,DEXTROAMP SULFATE AND AMP SULFATE

>A>	AB		BARR LABS INC	1.25MG;1.25MG;1.25MG;1.25MG	A076536	001	Feb 12, 2013	Jan	NEWA

CAPSULE, EXTENDED RELEASE; ORAL
DEXTROAMP SACCHARATE,AMP ASPARTATE,DEXTROAMP SULFATE AND AMP SULFATE

>A>	AB	BARR LABS INC	2.5MG;2.5MG;2.5MG;2.5MG	A076536	002	Feb 12, 2013	Jan	NEWA
>A>	AB		3.75MG;3.75MG;3.75MG;3.75MG	A076536	003	Feb 12, 2013	Jan	NEWA
>A>	AB		5MG;5MG;5MG;5MG	A076536	004	Feb 12, 2013	Jan	NEWA
>A>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A076536	005	Feb 12, 2013	Jan	NEWA
>A>	AB		7.5MG;7.5MG;7.5MG;7.5MG	A076536	006	Feb 12, 2013	Jan	NEWA

TABLET; ORAL
DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>D>	AB	TEVA PHARMS	1.25MG;1.25MG;1.25MG;1.25MG	A040472	001	Sep 30, 2003	Jan	DISC
>A>		@	1.25MG;1.25MG;1.25MG;1.25MG	A040472	001	Sep 30, 2003	Jan	DISC
>D>	AB		2.5MG;2.5MG;2.5MG;2.5MG	A040472	002	Sep 30, 2003	Jan	DISC
>A>		@	2.5MG;2.5MG;2.5MG;2.5MG	A040472	002	Sep 30, 2003	Jan	DISC
>D>	AB		5MG;5MG;5MG;5MG	A040472	003	Sep 30, 2003	Jan	DISC
>A>		@	5MG;5MG;5MG;5MG	A040472	003	Sep 30, 2003	Jan	DISC
>D>	AB		7.5MG;7.5MG;7.5MG;7.5MG	A040472	004	Sep 30, 2003	Jan	DISC
>A>		@	7.5MG;7.5MG;7.5MG;7.5MG	A040472	004	Sep 30, 2003	Jan	DISC

BENZTROPINE MESYLATE

INJECTABLE; INJECTION
BENZTROPINE MESYLATE

>A>	AP	NAVINTA LLC	1MG/ML	A091525	001	Feb 05, 2013	Jan	NEWA

BUDESONIDE

TABLET, EXTENDED RELEASE; ORAL

>A>		UCERIS						
>A>	+	SANTARUS	9MG	N203634	001	Jan 14, 2013	Jan	NEWA

CAFFEINE; ERGOTAMINE TARTRATE

TABLET; ORAL
ERGOTAMINE TARTRATE AND CAFFEINE

>D>	AA	MIKART	100MG;1MG	A040590	001	Sep 16, 2005	Jan	DISC
>A>		@	100MG;1MG	A040590	001	Sep 16, 2005	Jan	DISC

CALCIUM ACETATE

CAPSULE; ORAL
CALCIUM ACETATE

>A>	AB	INVAGEN PHARMS	EQ 169MG CALCIUM	A203135	001	Feb 07, 2013	Jan	NEWA

TABLET; ORAL
CALCIUM ACETATE

>A>	AB	INVAGEN PHARMS	EQ 169MG CALCIUM	A202420	001	Feb 05, 2013	Jan	NEWA

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL
CARBIDOPA AND LEVODOPA

>A>	AB	ACCORD HLTHCARE	25MG;100MG	A202323	001	Feb 08, 2013	Jan	NEWA
>A>	AB		50MG;200MG	A202323	002	Feb 08, 2013	Jan	NEWA

CARMUSTINE

INJECTABLE; INJECTION
BICNU

>D>	+	BRISTOL	100MG/VIAL	N017422	001		Jan	CAHN
>A>	+	EMCURE PHARMS LTD	100MG/VIAL	N017422	001		Jan	CAHN

CHLOROTHIAZIDE

TABLET; ORAL

DIURIL

>D>			@ LUNDBECK INC	250MG	N011145	004		Jan	CAHN
>A>			@ OAK PHARMS AKORN	250MG	N011145	004		Jan	CAHN
>D>			@	500MG	N011145	002		Jan	CAHN
>A>			@	500MG	N011145	002		Jan	CAHN

CHLOROTHIAZIDE SODIUM

INJECTABLE; INJECTION

DIURIL

>D>	AP	+	LUNDBECK INC	EQ 500MG BASE/VIAL	N011145	005		Jan	CAHN
>A>	AP	+	OAK PHARMS AKORN	EQ 500MG BASE/VIAL	N011145	005		Jan	CAHN

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

>D>	AB		WATSON LABS	100MG	A088852	001	Sep 26, 1984	Jan	DISC
>D>	AB			250MG	A088826	001	Sep 26, 1984	Jan	DISC
>A>			@ WATSON LABS INC	100MG	A088852	001	Sep 26, 1984	Jan	DISC
>A>			@	250MG	A088826	001	Sep 26, 1984	Jan	DISC

CICLOPIROX

SOLUTION; TOPICAL

CICLOPIROX

>D>	AT		TEVA PHARMS	8%	A078079	001	Sep 18, 2007	Jan	DISC
>A>			@	8%	A078079	001	Sep 18, 2007	Jan	DISC

CISPLATIN

INJECTABLE; INJECTION

PLATINOL

>D>			@ CORDEN PHARMA	10MG/VIAL	N018057	001		Jan	CAHN
>D>			@	50MG/VIAL	N018057	002		Jan	CAHN
>A>			@ HQ SPCLT PHARMA	10MG/VIAL	N018057	001		Jan	CAHN
>A>			@	50MG/VIAL	N018057	002		Jan	CAHN

PLATINOL-AQ

>D>			@ CORDEN PHARMA	0.5MG/ML	N018057	003	Jul 18, 1984	Jan	CAHN
>D>			@	1MG/ML	N018057	004	Nov 08, 1988	Jan	CAHN
>A>			@ HQ SPCLT PHARMA	0.5MG/ML	N018057	003	Jul 18, 1984	Jan	CAHN
>A>			@	1MG/ML	N018057	004	Nov 08, 1988	Jan	CAHN

CYCLOBENZAPRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

AMRIX

>A>	AB		IVAX INTL	15MG	N021777	001	Feb 01, 2007	Jan	CAHN
>A>	AB	+		30MG	N021777	002	Feb 01, 2007	Jan	CAHN
>D>	AB		TEVA	15MG	N021777	001	Feb 01, 2007	Jan	CAHN
>D>	AB	+		30MG	N021777	002	Feb 01, 2007	Jan	CAHN

CYCLOBENZAPRINE HYDROCHLORIDE

>A>	AB		TWI PHARMS INC	15MG	A091281	001	Jan 31, 2013	Jan	NEWA
>A>	AB			30MG	A091281	002	Jan 31, 2013	Jan	NEWA

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

>A>		CYTOXAN (LYOPHILIZED)						
>A>		@ BAXTER HLTHCARE	500MG/VIAL	N012142	008	Jan 04, 1984	Jan	CTNA
>A>		@	1GM/VIAL	N012142	010	Sep 24, 1985	Jan	CTNA
>A>		@	2GM/VIAL	N012142	009	Dec 10, 1985	Jan	CTNA
>D>		LYOPHILIZED CYTOXAN						
>D>		@ BAXTER HLTHCARE	500MG/VIAL	N012142	008	Jan 04, 1984	Jan	CTNA
>D>		@	1GM/VIAL	N012142	010	Sep 24, 1985	Jan	CTNA
>D>		@	2GM/VIAL	N012142	009	Dec 10, 1985	Jan	CTNA

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION

		DESMOPRESSIN ACETATE						
>A>	AP	SUN PHARM INDS LTD	0.004MG/ML	A091280	001	Jan 25, 2013	Jan	NEWA

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION; OPHTHALMIC

>D>		NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE						
>D>	AT	ALCON PHARMS LTD	0.1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	A062721	001	Nov 17, 1986	Jan	DISC

SUSPENSION/DROPS; OPHTHALMIC

>D>		NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE						
>A>		@ ALCON PHARMS LTD	0.1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	A062721	001	Nov 17, 1986	Jan	DISC

DEXTROSE; POTASSIUM CHLORIDE

INJECTABLE; INJECTION

>D>		POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% IN PLASTIC CONTAINER						
>D>		B BRAUN	5GM/100ML;220MG/100ML	N018744	003	Nov 09, 1982	Jan	DISC
>A>		@	5GM/100ML;220MG/100ML	N018744	003	Nov 09, 1982	Jan	DISC

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

		DILTIAZEM HYDROCHLORIDE						
>D>	AB3	ACTAVIS ELIZABETH	120MG	A074984	001	Dec 20, 1999	Jan	CAHN
>D>	AB3		180MG	A074984	002	Dec 20, 1999	Jan	CAHN
>D>	AB3		240MG	A074984	003	Dec 20, 1999	Jan	CAHN
>D>	AB3		300MG	A074984	004	Dec 20, 1999	Jan	CAHN
>A>	AB3	PAR PHARM	120MG	A074984	001	Dec 20, 1999	Jan	CAHN
>A>	AB3		180MG	A074984	002	Dec 20, 1999	Jan	CAHN
>A>	AB3		240MG	A074984	003	Dec 20, 1999	Jan	CAHN
>A>	AB3		300MG	A074984	004	Dec 20, 1999	Jan	CAHN

TABLET; ORAL

		DILTIAZEM HYDROCHLORIDE						
>D>	AB	DAVA PHARMS INC	30MG	A074093	001	Nov 05, 1992	Jan	DISC
>A>		@	30MG	A074093	001	Nov 05, 1992	Jan	DISC
>D>	AB		60MG	A074093	002	Nov 05, 1992	Jan	DISC
>A>		@	60MG	A074093	002	Nov 05, 1992	Jan	DISC
>D>	AB		90MG	A074093	003	Nov 05, 1992	Jan	DISC
>A>		@	90MG	A074093	003	Nov 05, 1992	Jan	DISC
>D>	AB		120MG	A074093	004	Nov 05, 1992	Jan	DISC
>A>		@	120MG	A074093	004	Nov 05, 1992	Jan	DISC

DONEPEZIL HYDROCHLORIDE

TABLET; ORAL
DONEPEZIL HYDROCHLORIDE

>D>	AB		ACCORD HLTHCARE	5MG	A201335	001	Aug 29, 2011	Jan	DISC
>A>			@	5MG	A201335	001	Aug 29, 2011	Jan	DISC
>D>	AB			10MG	A201335	002	Aug 29, 2011	Jan	DISC
>A>			@	10MG	A201335	002	Aug 29, 2011	Jan	DISC

DOXAZOSIN MESYLATE

TABLET; ORAL
DOXAZOSIN MESYLATE

>D>	AB		WATSON LABS	EQ 1MG BASE	A075426	001	Oct 18, 2000	Jan	DISC
>D>	AB			EQ 2MG BASE	A075426	002	Oct 18, 2000	Jan	DISC
>D>	AB			EQ 4MG BASE	A075426	003	Oct 18, 2000	Jan	DISC
>D>	AB			EQ 8MG BASE	A075426	004	Oct 18, 2000	Jan	DISC
>A>			@ WATSON LABS INC	EQ 1MG BASE	A075426	001	Oct 18, 2000	Jan	DISC
>A>			@	EQ 2MG BASE	A075426	002	Oct 18, 2000	Jan	DISC
>A>			@	EQ 4MG BASE	A075426	003	Oct 18, 2000	Jan	DISC
>A>			@	EQ 8MG BASE	A075426	004	Oct 18, 2000	Jan	DISC

DOXORUBICIN HYDROCHLORIDE

INJECTABLE, LIPOSOMAL; INJECTION
DOXIL

>D>		+	JANSSEN R AND D	20MG/10ML (2MG/ML)	N050718	001	Nov 17, 1995	Jan	CFTG
>D>		+		50MG/25ML (2MG/ML)	N050718	002	Jun 13, 2000	Jan	CFTG
>A>	AB	+	JANSSEN RES AND DEV	20MG/10ML (2MG/ML)	N050718	001	Nov 17, 1995	Jan	CFTG
>A>	AB	+		50MG/25ML (2MG/ML)	N050718	002	Jun 13, 2000	Jan	CFTG

>A> DOXORUBICIN HYDROCHLORIDE

>A>	AB		SUN PHARMA GLOBAL	20MG/10ML (2MG/ML)	A203263	001	Feb 04, 2013	Jan	NEWA
>A>	AB			50MG/25ML (2MG/ML)	A203263	002	Feb 04, 2013	Jan	NEWA

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-28
LEVONORGESTREL AND ETHINYL ESTRADIOL

>A>	AB1		LUPIN LTD	0.02MG;0.1MG	A091425	001	Jan 18, 2013	Jan	NEWA

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL
FEMHRT

>D>	AB	+	WARNER CHILCOTT LLC	0.005MG;1MG	N021065	002	Oct 15, 1999	Jan	DISC
>A>			@	0.005MG;1MG	N021065	002	Oct 15, 1999	Jan	DISC

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL

>D>	AB		BARR	0.005MG;1MG	A076221	001	Nov 06, 2009	Jan	CRLD
>A>		+	BARR LABS INC	0.005MG;1MG	A076221	001	Nov 06, 2009	Jan	CRLD

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28

>A> ESTARYLLA

>A>	AB		SANDOZ	0.035MG;0.25MG	A090794	001	Jan 30, 2013	Jan	NEWA

>A> TRI-ESTARYLLA

>A>	AB		SANDOZ	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A090793	001	Jan 30, 2013	Jan	NEWA

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION
FLUDARABINE PHOSPHATE

>D>	AP		FRESENIUS KABI USA	50MG/2ML (25MG/ML)	A078393	001	Oct 15, 2007	Jan	CRLD
>A>	AP	+		50MG/2ML (25MG/ML)	A078393	001	Oct 15, 2007	Jan	CRLD
>D>	AP	+	TEVA PARENTERAL	50MG/2ML (25MG/ML)	A076661	001	Apr 28, 2004	Jan	CRLD
>A>	AP			50MG/2ML (25MG/ML)	A076661	001	Apr 28, 2004	Jan	CRLD

FLUDEOXYGLUCOSE F-18

INJECTABLE; INTRAVENOUS
FLUDEOXYGLUCOSE F18

>D>		+	FEINSTEIN	20-300mCi/ML	N021870	002	Nov 21, 2008	Jan	CFTG
>A>		+		20-300mCi/ML	N021870	002	Nov 21, 2008	Jan	CFTG
>A>			HOUSTON CYCLOTRON	20-500mCi/ML	A203665	001	Feb 14, 2013	Jan	NEWA

FLUOCINONIDE

CREAM; TOPICAL
LIDEX

>A>			@ CNTY LINE PHARMS	0.05%	N016908	002		Jan	CAHN
>D>			@ MEDICIS	0.05%	N016908	002		Jan	CAHN

LIDEX-E

>A>			@ CNTY LINE PHARMS	0.05%	N016908	003		Jan	CAHN
>D>			@ MEDICIS	0.05%	N016908	003		Jan	CAHN

GEL; TOPICAL
FLUOCINONIDE

>D>	AB		TARO	0.05%	A074935	001	Jul 29, 1997	Jan	CRLD
>A>	AB	+		0.05%	A074935	001	Jul 29, 1997	Jan	CRLD

LIDEX

>A>			@ CNTY LINE PHARMS	0.05%	N017373	001		Jan	CAHN
>D>	AB	+	MEDICIS	0.05%	N017373	001		Jan	CAHN

OINTMENT; TOPICAL
FLUOCINONIDE

>D>	AB		TARO	0.05%	A075008	001	Jun 30, 1999	Jan	CRLD
>A>	AB	+		0.05%	A075008	001	Jun 30, 1999	Jan	CRLD

LIDEX

>A>			@ CNTY LINE PHARMS	0.05%	N016909	002		Jan	CAHN
>D>	AB	+	MEDICIS	0.05%	N016909	002		Jan	CAHN

SOLUTION; TOPICAL
FLUOCINONIDE

>D>	AT		TARO	0.05%	A074799	001	Dec 31, 1996	Jan	CRLD
>A>	AT	+		0.05%	A074799	001	Dec 31, 1996	Jan	CRLD

>D>			LIDEX						
>D>	AT	+	MEDICIS	0.05%	N018849	001	Apr 06, 1984	Jan	DISC
>A>			@	0.05%	N018849	001	Apr 06, 1984	Jan	DISC

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

>D>	AP		INTL MEDICATION	10MG/ML	N018025	001		Jan	DISC
>A>			@	10MG/ML	N018025	001		Jan	DISC

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

>D>	AB		WATSON LABS	50MG;75MG	A071969	001	Apr 17, 1988	Jan	DISC

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

>A>		@ WATSON LABS	50MG;75MG	A071969	001	Apr 17, 1988	Jan	DISC

HYDROMORPHONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
EXALGO

>D>		+ MALLINCKRODT INC	16MG	N021217	003	Mar 01, 2010	Jan	CRLD
>A>			16MG	N021217	003	Mar 01, 2010	Jan	CRLD
>D>			32MG	N021217	004	Aug 24, 2012	Jan	CRLD
>A>		+	32MG	N021217	004	Aug 24, 2012	Jan	CRLD

LABETALOL HYDROCHLORIDE

TABLET; ORAL
LABETALOL HYDROCHLORIDE

>D>	AB	SANDOZ	200MG	A075113	002	Aug 04, 1998	Jan	CRLD
>A>	AB	+	200MG	A075113	002	Aug 04, 1998	Jan	CRLD
>D>		TRANDATE						
>D>	AB	PROMETHEUS LABS	100MG	N018716	001	May 24, 1985	Jan	DISC
>A>		@	100MG	N018716	001	May 24, 1985	Jan	DISC
>D>	AB	+	200MG	N018716	002	Aug 01, 1984	Jan	DISC
>A>		@	200MG	N018716	002	Aug 01, 1984	Jan	DISC

LAMOTRIGINE

TABLET, EXTENDED RELEASE; ORAL
LAMOTRIGINE

>A>	AB	PAR PHARM	25MG	A201791	001	Jan 18, 2013	Jan	NEWA
>A>	AB		50MG	A201791	002	Jan 18, 2013	Jan	NEWA
>A>	AB		100MG	A201791	003	Jan 18, 2013	Jan	NEWA
>A>	AB		200MG	A201791	004	Jan 18, 2013	Jan	NEWA
>A>	AB		250MG	A201791	005	Jan 18, 2013	Jan	NEWA
>A>	AB		300MG	A201791	006	Jan 18, 2013	Jan	NEWA

LATANOPROST

SOLUTION/DROPS; OPHTHALMIC
LATANOPROST

>A>	AT	DR REDDYS LABS LTD	0.005%	A202077	001	Feb 11, 2013	Jan	NEWA

LEVETIRACETAM

TABLET, EXTENDED RELEASE; ORAL
LEVETIRACETAM

>A>	AB	VINTAGE PHARMS LLC	500MG	A202533	001	Jul 20, 2012	Jan	NEWA
>A>	AB		750MG	A202533	002	Jul 20, 2012	Jan	NEWA

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET; ORAL
LEVOCETIRIZINE DIHYDROCHLORIDE

>A>	AB	SUN PHARMA GLOBAL	5MG	A090362	001	Jan 31, 2013	Jan	NEWA

LEVOFLOXACIN

INJECTABLE; INJECTION
LEVOFLOXACIN

>A>	AP	AUROBINDO PHARMA LTD	EQ 500MG/20ML (EQ 25MG/ML)	A202328	001	Jan 24, 2013	Jan	NEWA
>A>	AP		EQ 750MG/30ML (EQ 25MG/ML)	A202328	002	Jan 24, 2013	Jan	NEWA
>A>	AP	EMCURE PHARMS LTD	EQ 500MG/20ML (EQ 25MG/ML)	A202590	001	Jan 24, 2013	Jan	NEWA
>A>	AP		EQ 750MG/30ML (EQ 25MG/ML)	A202590	002	Jan 24, 2013	Jan	NEWA

LEVONORGESTREL

>A>		INTRAUTERINE DEVICE; INTRAUTERINE							
>A>		SKYLA							
>A>		+ BAYER HLTHCARE	13.5MG	N203159	001	Jan 09, 2013	Jan	NEWA	
		TABLET; ORAL							
		LEVONORGESTREL							
>A>	AB	LUPIN LTD	0.75MG	A091328	001	Jan 23, 2013	Jan	NEWA	

LISINOPRIL

		TABLET; ORAL							
		LISINOPRIL							
>D>		@ LEK PHARMS	2.5MG	A075999	001	Jul 01, 2002	Jan	CAHN	
>D>		@	5MG	A075999	002	Jul 01, 2002	Jan	CAHN	
>D>		@	10MG	A075999	003	Jul 01, 2002	Jan	CAHN	
>D>		@	20MG	A075999	004	Jul 01, 2002	Jan	CAHN	
>D>		@	30MG	A075999	005	Jul 01, 2002	Jan	CAHN	
>D>		@	40MG	A075999	006	Jul 01, 2002	Jan	CAHN	
>A>		@ SANDOZ	2.5MG	A075999	001	Jul 01, 2002	Jan	CAHN	
>A>		@	5MG	A075999	002	Jul 01, 2002	Jan	CAHN	
>A>		@	10MG	A075999	003	Jul 01, 2002	Jan	CAHN	
>A>		@	20MG	A075999	004	Jul 01, 2002	Jan	CAHN	
>A>		@	30MG	A075999	005	Jul 01, 2002	Jan	CAHN	
>A>		@	40MG	A075999	006	Jul 01, 2002	Jan	CAHN	

MAFENIDE ACETATE

		FOR SOLUTION; TOPICAL							
>A>		MAFENIDE ACETATE							
>A>	AB	PAR FORM	5%	A201511	001	Feb 12, 2013	Jan	NEWA	
		SULFAMYLON							
>D>		+ MYLAN LLC	5%	N019832	003	Jun 05, 1998	Jan	CFTG	
>A>	AB	+	5%	N019832	003	Jun 05, 1998	Jan	CFTG	

>A> MAGNESIUM SULFATE, POTASSIUM SULFATE, SODIUM SULFATE;PEG-3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE

>A>		SOLUTION, FOR SOLUTION;ORAL							
>A>		SUCLEAR							
>A>		+ BRAINTREE LABS	1.6GM/BOT,3.13GM/BOT,1.75GM/BOT;210GM,0.74GM,2.86GM,5.6GM	N203595	001	Jan 18, 2013	Jan	NEWA	

MANNITOL

		INJECTABLE; INJECTION							
		MANNITOL 20%							
>D>	AP	B BRAUN	20GM/100ML	N014738	001		Jan	DISC	
>A>		@	20GM/100ML	N014738	001		Jan	DISC	

MEFENAMIC ACID

		CAPSULE; ORAL							
		MEFENAMIC ACID							
>A>	AB	CYPRESS PHARM	250MG	A090359	001	Feb 05, 2013	Jan	NEWA	

MEPROBAMATE

		TABLET; ORAL							
		MEPROBAMATE							
>D>	AA	TARO	200MG	A200998	001	May 23, 2011	Jan	DISC	
>A>		@	200MG	A200998	001	May 23, 2011	Jan	DISC	

TABLET; ORAL
MEPROBAMATE

>D>	AA	TARO	400MG	A200998	002	May 23, 2011	Jan	DISC
>A>		@	400MG	A200998	002	May 23, 2011	Jan	DISC

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL
PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE

>A>	AB	AUROBINDO PHARMA LTD	500MG;EQ 15MG BASE	A200823	001	Feb 13, 2013	Jan	NEWA
>A>	AB		850MG;EQ 15MG BASE	A200823	002	Feb 13, 2013	Jan	NEWA
>A>	AB	TORRENT PHARMS LTD	500MG;EQ 15MG BASE	A202001	001	Feb 13, 2013	Jan	NEWA
>A>	AB		850MG;EQ 15MG BASE	A202001	002	Feb 13, 2013	Jan	NEWA

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

>D>	AA	AUSTARPHARMA LLC	500MG	A200958	001	Oct 21, 2011	Jan	DISC
>A>		@	500MG	A200958	001	Oct 21, 2011	Jan	DISC
>D>	AA		750MG	A200958	002	Oct 21, 2011	Jan	DISC
>A>		@	750MG	A200958	002	Oct 21, 2011	Jan	DISC
>D>	AA	SOLCO HLTHCARE	500MG	A086989	001		Jan	DISC
>A>		@	500MG	A086989	001		Jan	DISC

METHYCLOTHIAZIDE

TABLET; ORAL
METHYCLOTHIAZIDE

>D>	AB	+ MYLAN PHARMS INC	5MG	A087672	001	Aug 17, 1982	Jan	CTEC
>A>		+	5MG	A087672	001	Aug 17, 1982	Jan	CTEC
>D>	AB	WATSON LABS	5MG	A088724	001	Sep 06, 1984	Jan	DISC
>A>		@	5MG	A088724	001	Sep 06, 1984	Jan	DISC

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION
MIDAZOLAM HYDROCHLORIDE

>D>	AP	CLARIS LIFESCIENCES	EQ 1MG BASE/ML	A075637	001	Oct 31, 2000	Jan	DISC
>A>		@	EQ 1MG BASE/ML	A075637	001	Oct 31, 2000	Jan	DISC
>D>	AP		EQ 5MG BASE/ML	A075637	002	Oct 31, 2000	Jan	DISC
>A>		@	EQ 5MG BASE/ML	A075637	002	Oct 31, 2000	Jan	DISC

>A> MIPOMERSEN SODIUM

>A> SOLUTION; SUBCUTANEOUS
>A> KYNAMRO

>A>		+ GENZYME CORP	200MG/ML (200MG/ML)	N203568	001	Jan 29, 2013	Jan	NEWA

MUPIROCIN CALCIUM

CREAM; TOPICAL
BACTROBAN

>D>		+ GLAXOSMITHKLINE	EQ 2% BASE	N050746	001	Dec 11, 1997	Jan	CFTG
>A>	AB	+	EQ 2% BASE	N050746	001	Dec 11, 1997	Jan	CFTG

>A> MUPIROCIN

>A>	AB	GLENMARK GENERICS	EQ 2% BASE	A201587	001	Jan 24, 2013	Jan	NEWA

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER

>D>	AP	CLARIS LIFESCIENCES	EQ 0.64MG BASE/ML	A078308	001	Mar 17, 2008	Jan	DISC

INJECTABLE; INJECTION
ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER

>A>			@ CLARIS LIFESCIENCES	EQ 0.64MG BASE/ML	A078308	001	Mar 17, 2008	Jan	DISC
>D>	AP	+	HOSPIRA	EQ 0.64MG BASE/ML	A077348	001	Feb 01, 2007	Jan	DISC
>A>			@	EQ 0.64MG BASE/ML	A077348	001	Feb 01, 2007	Jan	DISC

OXACILLIN SODIUM

INJECTABLE; INJECTION
OXACILLIN SODIUM

>A>	AP		AUROBINDO PHARMA LTD	EQ 1GM BASE/VIAL	A201539	001	Jan 18, 2013	Jan	NEWA
>A>	AP			EQ 2GM BASE/VIAL	A201539	002	Jan 18, 2013	Jan	NEWA
>A>	AP			EQ 10GM BASE/VIAL	A201538	001	Jan 18, 2013	Jan	NEWA

OXAPROZIN

TABLET; ORAL
OXAPROZIN

>D>	AB		CARACO	600MG	A075844	001	Jan 03, 2002	Jan	DISC
>A>			@	600MG	A075844	001	Jan 03, 2002	Jan	DISC

OXYMORPHONE HYDROCHLORIDE

TABLET; ORAL
OXYMORPHONE HYDROCHLORIDE

>A>	AB		AVANTHI INC	5MG	A203601	001	Jan 30, 2013	Jan	NEWA
>A>	AB			10MG	A203601	002	Jan 30, 2013	Jan	NEWA

OXYTOCIN

INJECTABLE; INJECTION
OXYTOCIN

>A>	AP		HIKMA FARMACEUTICA	10USP UNITS/ML (10USP UNITS/ML)	A200219	001	Feb 13, 2013	Jan	NEWA

PACLITAXEL

INJECTABLE; INJECTION
TAXOL

>D>			@ CORDEN PHARMA	6MG/ML	N020262	001	Dec 29, 1992	Jan	CAHN
>A>			@ HQ SPCLT PHARMA	6MG/ML	N020262	001	Dec 29, 1992	Jan	CAHN

PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL
PIOGLITAZONE HYDROCHLORIDE

>A>	AB		ACCORD HLTHCARE	EQ 15MG BASE	A200044	001	Feb 13, 2013	Jan	NEWA
>A>	AB			EQ 30MG BASE	A200044	002	Feb 13, 2013	Jan	NEWA
>A>	AB			EQ 45MG BASE	A200044	003	Feb 13, 2013	Jan	NEWA
>A>	AB		AUROBINDO PHARMA LTD	EQ 15MG BASE	A200268	001	Feb 13, 2013	Jan	NEWA
>A>	AB			EQ 30MG BASE	A200268	002	Feb 13, 2013	Jan	NEWA
>A>	AB			EQ 45MG BASE	A200268	003	Feb 13, 2013	Jan	NEWA
>A>	AB		MACLEODS PHARMS LTD	EQ 15MG BASE	A202467	001	Feb 06, 2013	Jan	NEWA
>A>	AB			EQ 30MG BASE	A202467	002	Feb 06, 2013	Jan	NEWA
>A>	AB			EQ 45MG BASE	A202467	003	Feb 06, 2013	Jan	NEWA
>A>	AB		SANDOZ	EQ 15MG BASE	A078670	001	Feb 13, 2013	Jan	NEWA
>A>	AB			EQ 30MG BASE	A078670	002	Feb 13, 2013	Jan	NEWA
>A>	AB			EQ 45MG BASE	A078670	003	Feb 13, 2013	Jan	NEWA
>A>	AB		SYNTHON PHARMS	EQ 15MG BASE	A078472	001	Feb 13, 2013	Jan	NEWA
>A>	AB			EQ 30MG BASE	A078472	002	Feb 13, 2013	Jan	NEWA
>A>	AB			EQ 45MG BASE	A078472	003	Feb 13, 2013	Jan	NEWA
>A>	AB		TORRENT PHARMS LTD	EQ 15MG BASE	A091298	001	Feb 13, 2013	Jan	NEWA
>A>	AB			EQ 30MG BASE	A091298	002	Feb 13, 2013	Jan	NEWA

TABLET; ORAL
PIOGLITAZONE HYDROCHLORIDE

>A>	AB	TORRENT PHARMS LTD	EQ 45MG BASE	A091298	003	Feb 13, 2013	Jan	NEWA
>A>	AB	ZYDUS PHARMS USA INC	EQ 15MG BASE	A202456	001	Feb 13, 2013	Jan	NEWA
>A>	AB		EQ 30MG BASE	A202456	002	Feb 13, 2013	Jan	NEWA
>A>	AB		EQ 45MG BASE	A202456	003	Feb 13, 2013	Jan	NEWA

PRAMLINTIDE ACETATE

INJECTABLE; SUBCUTANEOUS
SYMLIN

>D>		AMYLIN	EQ 1.5MG BASE/1.5ML (EQ 1MG BASE/ML)	N021332	002	Sep 25, 2007	Jan	CAHN
>D>			EQ 2.7MG BASE/2.7ML (EQ 1MG BASE/ML)	N021332	003	Sep 25, 2007	Jan	CAHN
>D>	+		EQ 3MG BASE/5ML (EQ 600MCG BASE/ML)	N021332	001	Mar 16, 2005	Jan	CAHN
>A>		AMYLIN PHARMS	EQ 1.5MG BASE/1.5ML (EQ 1MG BASE/ML)	N021332	002	Sep 25, 2007	Jan	CAHN
>A>			EQ 2.7MG BASE/2.7ML (EQ 1MG BASE/ML)	N021332	003	Sep 25, 2007	Jan	CAHN
>A>	+		EQ 3MG BASE/5ML (EQ 600MCG BASE/ML)	N021332	001	Mar 16, 2005	Jan	CAHN

QUETIAPINE FUMARATE

TABLET; ORAL
QUETIAPINE FUMARATE

>A>	AB	ALKEM LABS LTD	EQ 25MG BASE	A201504	001	Feb 12, 2013	Jan	NEWA
>A>	AB		EQ 50MG BASE	A201504	002	Feb 12, 2013	Jan	NEWA
>A>	AB		EQ 100MG BASE	A201504	003	Feb 12, 2013	Jan	NEWA
>A>	AB		EQ 150MG BASE	A201504	004	Feb 12, 2013	Jan	NEWA
>A>	AB		EQ 200MG BASE	A201504	005	Feb 12, 2013	Jan	NEWA
>A>	AB		EQ 300MG BASE	A201504	006	Feb 12, 2013	Jan	NEWA
>A>	AB		EQ 400MG BASE	A201504	007	Feb 12, 2013	Jan	NEWA

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE HYDROCHLORIDE

>D>	AB	WATSON LABS	EQ 150MG BASE	A074864	001	Oct 20, 1997	Jan	DISC
>A>		@	EQ 150MG BASE	A074864	001	Oct 20, 1997	Jan	DISC
>D>	AB		EQ 300MG BASE	A074864	002	Oct 20, 1997	Jan	DISC
>A>		@	EQ 300MG BASE	A074864	002	Oct 20, 1997	Jan	DISC

ROCURONIUM BROMIDE

INJECTABLE; INJECTION
ZEMURON

>A>		@ ORGANON USA INC	10MG/ML (10MG/ML)	N020214	002	Mar 17, 1994	Jan	CAHN
>A>	AP	+	50MG/5ML (10MG/ML)	N020214	001	Mar 17, 1994	Jan	CAHN
>A>	AP	+	100MG/10ML (10MG/ML)	N020214	003	Mar 17, 1994	Jan	CAHN
>D>	AP	+ SCHERING	50MG/5ML (10MG/ML)	N020214	001	Mar 17, 1994	Jan	CAHN
>D>		@	10MG/ML (10MG/ML)	N020214	002	Mar 17, 1994	Jan	CAHN
>D>	AP	+	100MG/10ML (10MG/ML)	N020214	003	Mar 17, 1994	Jan	CAHN

ROSIGLITAZONE MALEATE

TABLET; ORAL
AVANDIA

>D>		SB PHARMCO	EQ 2MG BASE	N021071	002	May 25, 1999	Jan	CFTG
>A>	AB		EQ 2MG BASE	N021071	002	May 25, 1999	Jan	CFTG
>D>			EQ 4MG BASE	N021071	003	May 25, 1999	Jan	CFTG

TABLET; ORAL
AVANDIA

>A>	AB		SB PHARMCO	EQ 4MG BASE	N021071	003	May 25, 1999	Jan	CFTG
>D>		+		EQ 8MG BASE	N021071	004	May 25, 1999	Jan	CFTG
>A>	AB	+		EQ 8MG BASE	N021071	004	May 25, 1999	Jan	CFTG

ROSIGLITAZONE MALEATE

>A>	AB		TEVA	EQ 2MG BASE	A076747	001	Jan 25, 2013	Jan	NEWA
>A>	AB			EQ 4MG BASE	A076747	002	Jan 25, 2013	Jan	NEWA
>A>	AB			EQ 8MG BASE	A076747	003	Jan 25, 2013	Jan	NEWA

SELEGILINE HYDROCHLORIDE

TABLET; ORAL
SELEGILINE HYDROCHLORIDE

>D>	AB		DAVA PHARMS INC	5MG	A074641	001	Aug 02, 1996	Jan	DISC
>A>		@		5MG	A074641	001	Aug 02, 1996	Jan	DISC

SODIUM CHLORIDE

SOLUTION; IRRIGATION

>D>			SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER						
>D>	AT		BAXTER HLTHCARE	450MG/100ML	N017864	001		Jan	DISC
>A>		@		450MG/100ML	N017864	001		Jan	DISC

SUMATRIPTAN SUCCINATE

SYSTEM; IONTOPHORESIS

>A>			ZECUITY						
>A>		+	NUPATHE	EQ 6.5MG BASE/4HR	N202278	001	Jan 17, 2013	Jan	NEWA

TESTOSTERONE

GEL; TRANSDERMAL

>A>			TESTOSTERONE						
>A>			PERRIGO ISRAEL	25MG/2.5GM PACKET	N203098	002	Jan 31, 2013	Jan	NEWA
>A>				50MG/5GM PACKET	N203098	003	Jan 31, 2013	Jan	NEWA

GEL, METERED; TRANSDERMAL

>A>			TESTOSTERONE						
>A>			PERRIGO ISRAEL	12.5MG/1.25GM ACTUATION	N203098	001	Jan 31, 2013	Jan	NEWA

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
DELATESTRYL

>D>	AO	+	ENDO PHARM	200MG/ML	N009165	003		Jan	CAHN
>D>		@		200MG/ML	N009165	001		Jan	CAHN
>A>	AO	+	ENDO PHARMS	200MG/ML	N009165	003		Jan	CAHN
>A>		@		200MG/ML	N009165	001		Jan	CAHN

TIMOLOL MALEATE

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC
TIMOPTIC-XE

>D>	AB	+	ATON	EQ 0.25% BASE	N020330	001	Nov 04, 1993	Jan	CAHN
>D>	AB	+		EQ 0.5% BASE	N020330	002	Nov 04, 1993	Jan	CAHN
>A>	AB	+	VALEANT PHARMS LLC	EQ 0.25% BASE	N020330	001	Nov 04, 1993	Jan	CAHN
>A>	AB	+		EQ 0.5% BASE	N020330	002	Nov 04, 1993	Jan	CAHN

TRAMADOL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
RYZOLT

>D>	AB2	+	PURDUE PHARMA	100MG	N021745	001	Dec 30, 2008	Jan	DISC

TABLET, EXTENDED RELEASE; ORAL
RYZOLT

>A>		@ PURDUE PHARMA	100MG	N021745	001	Dec 30, 2008	Jan		DISC
>D>	AB2		200MG	N021745	002	Dec 30, 2008	Jan		DISC
>A>		@	200MG	N021745	002	Dec 30, 2008	Jan		DISC
>D>	AB2		300MG	N021745	003	Dec 30, 2008	Jan		DISC
>A>		@	300MG	N021745	003	Dec 30, 2008	Jan		DISC

VERTEPORFIN

INJECTABLE; INJECTION
VISUDYNE

>D>		+ QLT	15MG/VIAL	N021119	001	Apr 12, 2000	Jan		CAHN
>A>		+ VALEANT PHARMS INC	15MG/VIAL	N021119	001	Apr 12, 2000	Jan		CAHN

ZIDOVUDINE

TABLET; ORAL
ZIDOVUDINE

>D>	AB	HEC PHARM USA INC	300MG	A202058	001	Oct 07, 2011	Jan		DISC
>A>		@	300MG	A202058	001	Oct 07, 2011	Jan		DISC

ASPIRIN

>A> CAPSULE; ORAL
>A> ASPIRIN
>A> + PLX PHARMA 325MG N203697 001 Jan 14, 2013 Jan NEWA

FEXOFENADINE HYDROCHLORIDE

TABLET, ORALLY DISINTEGRATING; ORAL
>A> CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY
>A> DR REDDYS LABS LTD 30MG A202978 001 Jan 18, 2013 Jan NEWA
>A> CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES
>A> DR REDDYS LABS LTD 30MG A202978 002 Jan 18, 2013 Jan NEWA

LEVONORGESTREL

TABLET; ORAL
LEVONORGESTREL
>A> LUPIN LTD 0.75MG A091328 001 Jan 23, 2013 Jan NEWA

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE NITRATE
>A> APHENA PHARMA MD 2% A074366 001 Feb 22, 1996 Jan CAHN
>D> G AND W LABS 2% A074366 001 Feb 22, 1996 Jan CAHN

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE
>A> AKORN INC 0.025%;0.3% A202795 001 Jan 24, 2013 Jan NEWA

>A> OXYBUTYNIN

>A> FILM, EXTENDED RELEASE; TRANSDERMAL
>A> OXYTROL FOR WOMEN
>A> + MSD CONSUMER 3.9MG/24HR N202211 001 Jan 25, 2013 Jan NEWA

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL
POLYETHYLENE GLYCOL 3350
>A> PAR PHARM 17GM/SCOOPFUL A079214 001 Jan 31, 2013 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 2013

NO JANUARY 2013 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of 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 2013 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2013

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
ADAPALENE; BENZOYL PEROXIDE - EPIDUO						
N022320 001					**>A>** NPP	Feb 01, 2016
ALOGLIPTIN BENZOATE - NESINA						
N022271 001					**>A>** NCE	Jan 25, 2018
ALOGLIPTIN BENZOATE - NESINA						
N022271 002					**>A>** NCE	Jan 25, 2018
ALOGLIPTIN BENZOATE - NESINA						
N022271 003					**>A>** NCE	Jan 25, 2018
ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE - KAZANO						
N203414 001					**>A>** NCE	Jan 25, 2018
					>A> NC	Jan 25, 2016
ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE - KAZANO						
N203414 002					**>A>** NCE	Jan 25, 2018
					>A> NC	Jan 25, 2016
ALOGLIPTIN BENZOATE; PIOGLITAZONE - OSENI						
N022426 001					**>A>** NCE	Jan 25, 2018
					>A> NC	Jan 25, 2016
ALOGLIPTIN BENZOATE; PIOGLITAZONE - OSENI						
N022426 002					**>A>** NCE	Jan 25, 2018
					>A> NC	Jan 25, 2016
ALOGLIPTIN BENZOATE; PIOGLITAZONE - OSENI						
N022426 003					**>A>** NCE	Jan 25, 2018
					>A> NC	Jan 25, 2016
ALOGLIPTIN BENZOATE; PIOGLITAZONE - OSENI						
N022426 004					**>A>** NCE	Jan 25, 2018
					>A> NC	Jan 25, 2016
ALOGLIPTIN BENZOATE; PIOGLITAZONE - OSENI						
N022426 005					**>A>** NCE	Jan 25, 2018
					>A> NC	Jan 25, 2016
ALOGLIPTIN BENZOATE; PIOGLITAZONE - OSENI						
N022426 006					**>A>** NCE	Jan 25, 2018
					>A> NC	Jan 25, 2016
AMOXICILLIN - MOXATAG						
N050813 001	**>A>** 8357394	Dec 08, 2026	DP			
APIXABAN - ELIQUIS						
N202155 002	**>A>** 6413980	Dec 22, 2019	DS DP U-1200			
	>A> 6967208	Feb 03, 2023	DS DP U-1323			
	>A> 6967208	Feb 03, 2023	DS DP U-1200			
BEDAQUILINE FUMARATE - SIRTURO						
N204384 001	**>A>** 7498343	Oct 02, 2024	DS DP U-1321		**>A>** ODE	Dec 28, 2019
BUDESONIDE - UCERIS						
N203634 001	**>A>** 7410651	Jun 09, 2020	DP U-1325		**>A>** NDF	Jan 14, 2016
	>A> 7431943	Jun 09, 2020	DP			
	>A> 8293273	Jun 09, 2020	DP			
	>A> RE43799	Jun 09, 2020	DP U-1325			
CABOZANTINIB S-MALATE - COMETRIQ						
N203756 001					**>A>** ODE	Nov 29, 2019

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2013

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CABOZANTINIB S-MALATE - COMETRIQ						
N203756 002					**>A>** ODE	Nov 29, 2019
CICLESONIDE - ALVESCO						
N021658 002					**>A>** M-125	Dec 17, 2015
CICLESONIDE - ALVESCO						
N021658 003					**>A>** M-125	Dec 17, 2015
CLOBETASOL PROPIONATE - CLOBETASOL PROPIONATE						
A201402 001					**>A>** PC	Jul 31, 2013
DEFERASIROX - EXJADE						
N021882 001					**>A>** I-665	Jan 23, 2016
DEFERASIROX - EXJADE						
N021882 002					**>A>** I-665	Jan 23, 2016
DEFERASIROX - EXJADE						
N021882 003					**>A>** I-665	Jan 23, 2016
DROSPIRENONE; ETHINYL ESTRADIOL - YAZ						
N021676 001	**>A>** RE43916	Jun 30, 2014	U-1326			
DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - BEYAZ						
N022532 001	**>A>** RE43916	Jun 30, 2014	U-1326			
DULOXETINE HYDROCHLORIDE - CYMBALTA						
N021427 001					**>A>** M-61	Oct 18, 2015
					>A> PED	Apr 18, 2016
DULOXETINE HYDROCHLORIDE - CYMBALTA						
N021427 002					**>A>** M-61	Oct 18, 2015
					>A> PED	Apr 18, 2016
DULOXETINE HYDROCHLORIDE - CYMBALTA						
N021427 004					**>A>** M-61	Oct 18, 2015
					>A> PED	Apr 18, 2016
EFAVIRENZ - SUSTIVA						
N020972 001	**>A>** 5519021	May 21, 2013	DS DP			
	>A> 5519021*PED	Nov 21, 2013				
	>A> 5663169	Sep 02, 2014	U-257			
	>A> 5663169*PED	Mar 02, 2015				
	>A> 6238695	Apr 06, 2019	DP			
	>A> 6238695*PED	Oct 06, 2019				
	>A> 6555133	Apr 06, 2019	U-248			
	>A> 6555133*PED	Oct 06, 2019				
	>A> 6639071	Feb 14, 2018	DS			
	>A> 6639071*PED	Aug 14, 2018				
	>A> 6939964	Jan 20, 2018	DS			
	>A> 6939964*PED	Jul 20, 2018				

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EFAVIRENZ - SUSTIVA						
N020972 002	**>A>** 5519021	May 21, 2013	DS DP			
	>A> 5519021*PED	Nov 21, 2013				
	>A> 5663169	Sep 02, 2014	U-257			
	>A> 5663169*PED	Mar 02, 2015				
	>A> 6238695	Apr 06, 2019	DP			
	>A> 6238695*PED	Oct 06, 2019				
	>A> 6555133	Apr 06, 2019	U-248			
	>A> 6555133*PED	Oct 06, 2019				
	>A> 6639071	Feb 14, 2018	DS			
	>A> 6639071*PED	Aug 14, 2018				
	>A> 6939964	Jan 20, 2018	DS			
	>A> 6939964*PED	Jul 20, 2018				
EFAVIRENZ - SUSTIVA						
N020972 003	**>A>** 5519021	May 21, 2013	DS DP			
	>A> 5519021*PED	Nov 21, 2013				
	>A> 5663169	Sep 02, 2014	U-257			
	>A> 5663169*PED	Mar 02, 2015				
	>A> 6238695	Apr 06, 2019	DP			
	>A> 6238695*PED	Oct 06, 2019				
	>A> 6555133	Apr 06, 2019	U-248			
	>A> 6555133*PED	Oct 06, 2019				
	>A> 6639071	Feb 14, 2018	DS			
	>A> 6639071*PED	Aug 14, 2018				
	>A> 6939964	Jan 20, 2018	DS			
	>A> 6939964*PED	Jul 20, 2018				
EFAVIRENZ - SUSTIVA						
N021360 001	**>A>** 5519021	May 21, 2013				
	>A> 5519021*PED	Nov 21, 2013				
	>A> 5663169	Sep 02, 2014				
	>A> 5663169*PED	Mar 02, 2015				
	>A> 6639071	Feb 14, 2018	DS			
	>A> 6639071*PED	Aug 14, 2018				
	>A> 6939964	Jan 20, 2018	DS			
	>A> 6939964*PED	Jul 20, 2018				
EFAVIRENZ - SUSTIVA						
N021360 002	**>A>** 5519021	May 21, 2013	DS DP			
	>A> 5519021*PED	Nov 21, 2013				
	>A> 5663169	Sep 02, 2014	U-248			
	>A> 5663169*PED	Mar 02, 2015				
	>A> 6639071	Feb 14, 2018	DS			
	>A> 6639071*PED	Aug 14, 2018				
	>A> 6939964	Jan 20, 2018	DS			
	>A> 6939964*PED	Jul 20, 2018				

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EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - ATRIPLA						
N021937 001	**>A>** 5519021	May 21, 2013	DS DP			
	>A> 5519021*PED	Nov 21, 2013				
	>A> 5663169	Sep 02, 2014	U-750			
	>A> 5663169	Sep 02, 2014	U-1170			
	>A> 5663169*PED	Mar 02, 2015				
	>A> 6639071	Feb 14, 2018	DS			
	>A> 6639071*PED	Aug 14, 2018				
	>A> 6939964	Jan 20, 2018	DS			
	>A> 6939964*PED	Jul 20, 2018				
EPOPROSTENOL SODIUM - VELETRI						
N022260 001	**>A>** 8318802	Mar 15, 2027	DP			
EPOPROSTENOL SODIUM - VELETRI						
N022260 002	**>A>** 8318802	Mar 15, 2027	DP			
ESZOPICLONE - LUNESTA						
N021476 001					**>A>** M-61	Oct 10, 2015
					>A> PED	Apr 10, 2016
ESZOPICLONE - LUNESTA						
N021476 002					**>A>** M-61	Oct 10, 2015
					>A> PED	Apr 10, 2016
ESZOPICLONE - LUNESTA						
N021476 003					**>A>** M-61	Oct 10, 2015
					>A> PED	Apr 10, 2016
FESOTERODINE FUMARATE - TOVIAZ						
N022030 001	**>A>** 8338478	May 11, 2019	DS DP U-913			
FESOTERODINE FUMARATE - TOVIAZ						
N022030 002	**>A>** 8338478	May 11, 2019	DS DP U-913			
FLUTICASONE FUROATE - VERAMYST						
N022051 001	**>A>** 8347879	Apr 01, 2027	DP			
GABAPENTIN - GRALISE						
N022544 001	**>A>** 8333992	Oct 25, 2022	DP U-1114			
GABAPENTIN - GRALISE						
N022544 002	**>A>** 8333992	Oct 25, 2022	DP U-1114			
ICOSAPENT ETHYL - VASCEPA						
N202057 001	**>A>** 8357677	Feb 09, 2030	U-1287			
	>A> 8367652	Feb 09, 2030	U-1287			
IMATINIB MESYLATE - GLEEVEC						
N021588 001	**>A>** 7544799	Jan 16, 2019	DS DP	Y	**>A>** I-666	Jan 25, 2016
	>A> RE43932	Jan 16, 2019	DS DP			
	>A> RE43932*PED	Jul 16, 2019				
IMATINIB MESYLATE - GLEEVEC						
N021588 002	**>A>** 7544799	Jan 16, 2019	DS DP	Y	**>A>** I-666	Jan 25, 2016
	>A> RE43932	Jan 16, 2019	DS DP			
	>A> RE43932*PED	Jul 16, 2019				

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LEVOLEUCOVORIN CALCIUM - FUSILEV						
N020140 001	**>A>** 6500829	Mar 07, 2022	DS DP			
LEVOLEUCOVORIN CALCIUM - FUSILEV						
N020140 002	**>A>** 6500829	Mar 07, 2022	DS DP			
LEVOLEUCOVORIN CALCIUM - FUSILEV						
N020140 003	**>A>** 6500829	Mar 07, 2022	DS DP			
LEVONORGESTREL - SKYLA						
N203159 001	**>A>** 5785053	Dec 05, 2015	DP		**>A>** NP	Jan 09, 2016
	>A> 7252839	Nov 13, 2023	DP			
LOMITAPIDE MESYLATE - JUXTAPID						
N203858 001					**>A>** ODE	Dec 21, 2019
LOMITAPIDE MESYLATE - JUXTAPID						
N203858 002					**>A>** ODE	Dec 21, 2019
LOMITAPIDE MESYLATE - JUXTAPID						
N203858 003					**>A>** ODE	Dec 21, 2019
MAGNESIUM SULFATE; POTASSIUM SULFATE; SODIUM SULFATE - SUCLEAR						
N203595 001					**>A>** NC	Jan 18, 2016
MIPOMERSEN SODIUM - KYNAMRO						
N203568 001					**>A>** NCE	Jan 29, 2018
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021087 001					**>A>** NPP	Dec 21, 2015
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021087 002					**>A>** NPP	Dec 21, 2015
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021087 003					**>A>** NPP	Dec 21, 2015
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021246 001					**>A>** NPP	Dec 21, 2015
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021246 002					**>A>** NPP	Dec 21, 2015
OXYBUTYNIN - OXYTROL FOR WOMEN						
N202211 001					**>A>** NP	Jan 25, 2016
PLERIXAFOR - MOZOBIL						
N022311 001	**>A>** RE42152	Dec 10, 2018	DP			
PONATINIB HYDROCHLORIDE - ICLUSIG						
N203469 001					**>A>** ODE	Dec 14, 2019
PONATINIB HYDROCHLORIDE - ICLUSIG						
N203469 002					**>A>** ODE	Dec 14, 2019
PRALATREXATE - FOLOTYN						
N022468 001	**>A>** 6028071	Jul 16, 2022	DS DP U-1004			
PRALATREXATE - FOLOTYN						
N022468 002	**>A>** 6028071	Jul 16, 2022	DS DP U-1004			
SAPROPTERIN DIHYDROCHLORIDE - KUVAN						
N022181 001	**>A>** 8318745	Nov 17, 2024	DP			

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SAQUINAVIR MESYLATE - INVIRASE						
N020628 001					**>A>** M-61	Nov 30, 2015
					>A> PED	May 30, 2016
SAQUINAVIR MESYLATE - INVIRASE						
N021785 001					**>A>** M-61	Nov 30, 2015
					>A> PED	May 30, 2016
SUMATRIPTAN SUCCINATE - SUMAVEL DOSEPRO						
N022239 001	**>A>** 8343130	Oct 18, 2022	DP			
SUMATRIPTAN SUCCINATE - ZECUITY						
N202278 001					**>A>** NDF	Jan 17, 2016
TAPENTADOL HYDROCHLORIDE - NUCYNTA ER						
N200533 001	**>A>** 8114383	Oct 10, 2024	DP	Y		
TAPENTADOL HYDROCHLORIDE - NUCYNTA ER						
N200533 002	**>A>** 8114383	Oct 10, 2024	DP	Y		
TAPENTADOL HYDROCHLORIDE - NUCYNTA ER						
N200533 003	**>A>** 8114383	Oct 10, 2024	DP	Y		
TAPENTADOL HYDROCHLORIDE - NUCYNTA ER						
N200533 004	**>A>** 8114383	Oct 10, 2024	DP	Y		
TAPENTADOL HYDROCHLORIDE - NUCYNTA ER						
N200533 005	**>A>** 8114383	Oct 10, 2024	DP	Y		
TEDUGLUTIDE - GATTEX KIT						
N203441 001	**>A>** 5789379	Apr 14, 2015	DS DP U-1320		**>A>** ODE	Dec 21, 2019
	>A> 7056886	Sep 18, 2022	DP U-1320			
	>A> 7847061	Nov 01, 2025	U-1320			
TELBIVUDINE - TYZEKA						
N022011 001					**>A>** M-124	Jan 28, 2016
TELBIVUDINE - TYZEKA						
N022154 001					**>A>** M-124	Jan 28, 2016
TESTOSTERONE - TESTOSTERONE						
N203098 001					**>A>** NP	Jan 31, 2016
TESTOSTERONE - TESTOSTERONE						
N203098 002					**>A>** NP	Jan 31, 2016
TESTOSTERONE - TESTOSTERONE						
N203098 003					**>A>** NP	Jan 31, 2016
TOBRAMYCIN - BETHKIS						
N201820 001	**>A>** 6987094	Sep 22, 2022	DP			
	>A> 7696178	Mar 17, 2023	DP			
	>A> 7939502	Jun 14, 2022	U-1324			
UNOPROSTONE ISOPROPYL - RESCULA						
N021214 001	**>A>** 6770675	Nov 24, 2018	DP U-1322			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2013

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

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, 33rd 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/docs/pattermsall.cfm

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