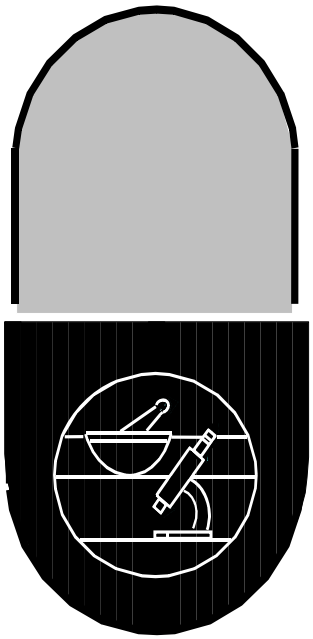
CUMULATIVE SUPPLEMENT 2
FEBRUARY 2013



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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Cumulative Supplement 2

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CONTENTS

PAGE

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CUMULATIVE SUPPLEMENT 2
February 2013

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 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.

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

>D>	AA		MIRROR PHARMS	500MG;50MG;40MG	A040883	001	Dec 23, 2008	Feb	DISC
>A>		@	MIRROR PHARMS LLC	500MG;50MG;40MG	A040883	001	Dec 23, 2008	Feb	DISC

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL
ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

>D>	AA	+	MIKART	356.4MG;30MG;16MG	A040109	001	Aug 26, 1997	Feb	DISC
>A>		@		356.4MG;30MG;16MG	A040109	001	Aug 26, 1997	Feb	DISC

TABLET; ORAL
ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

>D>	AA	+	MIKART	712.8MG;60MG;32MG	A040316	001	Apr 28, 1999	Feb	DISC
>A>		@		712.8MG;60MG;32MG	A040316	001	Apr 28, 1999	Feb	DISC

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE

>D>		+	MIKART	650MG;30MG	A089231	001	Mar 03, 1986	Feb	DISC
>A>		@		650MG;30MG	A089231	001	Mar 03, 1986	Feb	DISC
>D>		+		650MG;60MG	A089363	001	Sep 09, 1991	Feb	DISC
>A>		@		650MG;60MG	A089363	001	Sep 09, 1991	Feb	DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D>	AA		MIKART	500MG;5MG	A081067	001	Nov 30, 1989	Feb	DISC
>A>		@		500MG;5MG	A081067	001	Nov 30, 1989	Feb	DISC

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D>	AA	+	MIKART	500MG;2.5MG	A089698	001	Aug 25, 1989	Feb	DISC
>A>		@		500MG;2.5MG	A089698	001	Aug 25, 1989	Feb	DISC
>D>				650MG;5MG	A040849	001	Jun 09, 2010	Feb	DISC
>A>		@		650MG;5MG	A040849	001	Jun 09, 2010	Feb	DISC

ACETAZOLAMIDE

TABLET; ORAL
ACETAZOLAMIDE

		@	WATSON LABS	250MG	A088882	001	Oct 22, 1985	Jan	DISC

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION
ACETAZOLAMIDE SODIUM

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

ALBENDAZOLE

TABLET; ORAL
ALBENZA

>A>		+	AMEDRA PHARMS	200MG	N020666	001	Jun 11, 1996	Feb	CAHN
>D>		+	COREPHARMA	200MG	N020666	001	Jun 11, 1996	Feb	CAHN

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

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

ALENDRONATE SODIUM

SOLUTION; ORAL

ALENDRONATE SODIUM

>A> AA		ROXANE	EQ 70MG BASE/75ML	A090520	001	Feb 25, 2013	Feb	NEWA

FOSAMAX

>D>	+	MERCK	EQ 70MG BASE/75ML	N021575	001	Sep 17, 2003	Feb	CFTG
>A> AA	+		EQ 70MG BASE/75ML	N021575	001	Sep 17, 2003	Feb	CFTG

ALOGLIPTIN BENZOATE

TABLET; ORAL

NESINA

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

ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

KAZANO

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

>D> ALOGLIPTIN BENZOATE; PIOGLITAZONE

>D> TABLET; ORAL

>D> OSENI

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

>A> ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE

>A> TABLET; ORAL

>A> OSENI

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

AMMONIA N-13

INJECTABLE; INTRAVENOUS

>A>			AMMONIA N 13							
>A>	AP		CARDINAL HEALTH 414	30MCI-300MCI/8ML (3.75-37.5MCI/ML)	A203700	001	Feb 25, 2013	Feb	NEWA
>A>	AP	+	FEINSTEIN	30MCI-300MCI/8ML (3.75-37.5MCI/ML)	N022119	001	Aug 23, 2007	Feb	CFTG
>A>	AP		MCPRF	30MCI-300MCI/8ML (3.75-37.5MCI/ML)	A203321	001	Feb 25, 2013	Feb	NEWA

AMMONIA, N-13

INJECTABLE; INTRAVENOUS

			AMMONIA N 13							
>D>		+	FEINSTEIN	30MCI-300MCI/8ML (3.75-37.5MCI/ML)	N022119	001	Aug 23, 2007	Feb	CFTG

AMOXICILLIN

FOR SUSPENSION; ORAL

			AMOXICILLIN							
>D>	AB		RANBAXY	200MG/5ML	A065113	001	Nov 29, 2002	Feb	DISC
>A>			@	200MG/5ML	A065113	001	Nov 29, 2002	Feb	DISC
>D>	AB			400MG/5ML	A065113	002	Nov 29, 2002	Feb	DISC
>A>			@	400MG/5ML	A065113	002	Nov 29, 2002	Feb	DISC

TABLET, CHEWABLE; ORAL

			AMOXICILLIN							
>D>			RANBAXY	200MG	A065060	001	Nov 29, 2000	Feb	DISC
>A>			@	200MG	A065060	001	Nov 29, 2000	Feb	DISC
>D>				400MG	A065060	002	Nov 29, 2000	Feb	DISC
>A>			@	400MG	A065060	002	Nov 29, 2000	Feb	DISC
			AMOXIL							
>D>	AB		DR REDDYS LABS INC	200MG	N050761	001	Apr 15, 1999	Feb	DISC
>A>			@	200MG	N050761	001	Apr 15, 1999	Feb	DISC
>D>	AB			400MG	N050761	002	Apr 15, 1999	Feb	DISC
>A>			@	400MG	N050761	002	Apr 15, 1999	Feb	DISC

TABLET, FOR SUSPENSION; ORAL

			AMOXICILLIN							
			@ AUROBINDO PHARMA LTD	200MG	A065324	001	Jan 17, 2007	Jan	DISC
			@	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							
	AB		BARR LABS INC	1.25MG;1.25MG;1.25MG;1.25MG	A076536	001	Feb 12, 2013	Jan	NEWA
	AB			2.5MG;2.5MG;2.5MG;2.5MG	A076536	002	Feb 12, 2013	Jan	NEWA
	AB			3.75MG;3.75MG;3.75MG;3.75MG	A076536	003	Feb 12, 2013	Jan	NEWA
	AB			5MG;5MG;5MG;5MG	A076536	004	Feb 12, 2013	Jan	NEWA
	AB			6.25MG;6.25MG;6.25MG;6.25MG	A076536	005	Feb 12, 2013	Jan	NEWA
	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							
			@ TEVA PHARMS	1.25MG;1.25MG;1.25MG;1.25MG	A040472	001	Sep 30, 2003	Jan	DISC
			@	2.5MG;2.5MG;2.5MG;2.5MG	A040472	002	Sep 30, 2003	Jan	DISC
			@	5MG;5MG;5MG;5MG	A040472	003	Sep 30, 2003	Jan	DISC
			@	7.5MG;7.5MG;7.5MG;7.5MG	A040472	004	Sep 30, 2003	Jan	DISC

ANASTROZOLE

TABLET; ORAL
ANASTROZOLE

>D>	AB	KUDCO IRELAND	1MG	A091331	001	Jan 05, 2011	Feb	DISC
>A>		@	1MG	A091331	001	Jan 05, 2011	Feb	DISC

>A> ARIPIPRAZOLE

>A> FOR SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR
>A> ABILIFY MAINTENA KIT

>A>		OTSUKA PHARM CO LTD	300MG/VIAL	N202971	001	Feb 28, 2013	Feb	NEWA
>A>	+		400MG/VIAL	N202971	002	Feb 28, 2013	Feb	NEWA

BENZPHETAMINE HYDROCHLORIDE

TABLET; ORAL
BENZPHETAMINE HYDROCHLORIDE

>D>	AA	COREPHARMA	50MG	A040714	001	Oct 29, 2007	Feb	DISC
>A>		@	50MG	A040714	001	Oct 29, 2007	Feb	DISC

BENZTROPINE MESYLATE

INJECTABLE; INJECTION
BENZTROPINE MESYLATE

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

BEXAROTENE

GEL; TOPICAL
TARGRETIN

>D>	+	EISAI INC	1%	N021056	001	Jun 28, 2000	Feb	CAHN
>A>	+	VALEANT PHARMS INC	1%	N021056	001	Jun 28, 2000	Feb	CAHN

BLEOMYCIN SULFATE

INJECTABLE; INJECTION
BLEOMYCIN SULFATE

>D>	AP	PHARMACHEMIE BV	EQ 15 UNITS BASE/VIAL	A065201	001	Dec 13, 2007	Feb	DISC
>A>		@	EQ 15 UNITS BASE/VIAL	A065201	001	Dec 13, 2007	Feb	DISC

BROMFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
BROMFENAC SODIUM

>A>	AT	LUITPOLD	0.09%	A202030	001	Jan 09, 2013	Feb	CAHN
>D>	AT	PHARMAFORCE	0.09%	A202030	001	Jan 09, 2013	Feb	CAHN

BUDESONIDE

TABLET, EXTENDED RELEASE; ORAL
UCERIS

	+	SANTARUS	9MG	N203634	001	Jan 14, 2013	Jan	NEWA

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE

TABLET; SUBLINGUAL
>A> BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE DIHYDRATE

>A>	AB	ACTAVIS ELIZABETH	EQ 2MG BASE;EQ 0.5MG BASE	A091422	001	Feb 22, 2013	Feb	NEWA
>A>	AB		EQ 8MG BASE;EQ 2MG BASE	A091422	002	Feb 22, 2013	Feb	NEWA
>A>	AB	AMNEAL PHARMS	EQ 2MG BASE;EQ 0.5MG BASE	A203136	001	Feb 22, 2013	Feb	NEWA
>A>	AB		EQ 8MG BASE;EQ 2MG BASE	A203136	002	Feb 22, 2013	Feb	NEWA

SUBOXONE

>D>		RECKITT BENCKISER	EQ 2MG BASE;EQ 0.5MG BASE	N020733	001	Oct 08, 2002	Feb	CFTG

TABLET; SUBLINGUAL
SUBOXONE

>A>	AB	RECKITT BENCKISER	EQ 2MG BASE;EQ 0.5MG BASE	N020733	001	Oct 08, 2002	Feb	CFTG
>D>	+		EQ 8MG BASE;EQ 2MG BASE	N020733	002	Oct 08, 2002	Feb	CFTG
>A>	AB	+	EQ 8MG BASE;EQ 2MG BASE	N020733	002	Oct 08, 2002	Feb	CFTG

BUPROPION HYDROCHLORIDE

TABLET; ORAL
BUPROPION HYDROCHLORIDE

>D>	AB	TEVA	75MG	A075310	001	Nov 29, 1999	Feb	CDFR
>A>		@	75MG	A075310	001	Nov 29, 1999	Feb	CDFR
>D>	AB		100MG	A075310	002	Nov 29, 1999	Feb	DISC
>A>		@	100MG	A075310	002	Nov 29, 1999	Feb	DISC

CABERGOLINE

TABLET; ORAL
CABERGOLINE

>A>	AB	APOTEX CORP	0.5MG	A201503	001	Mar 08, 2013	Feb	NEWA

CAFFEINE; ERGOTAMINE TARTRATE

TABLET; ORAL
ERGOTAMINE TARTRATE AND CAFFEINE

		@ MIKART	100MG;1MG	A040590	001	Sep 16, 2005	Jan	DISC

CALCIUM ACETATE

CAPSULE; ORAL
CALCIUM ACETATE

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

TABLET; ORAL
CALCIUM ACETATE

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

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL
INPERSOL-LC/LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

>D>	AT	FRESENIUS	18.4MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374	001	Jun 13, 1994	Feb	DISC
>A>		@	18.4MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374	001	Jun 13, 1994	Feb	DISC

INPERSOL-LC/LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

>D>	AT	FRESENIUS	18.4MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374	002	Jun 13, 1994	Feb	DISC
>A>		@	18.4MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374	002	Jun 13, 1994	Feb	DISC

INPERSOL-LC/LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

>D>		FRESENIUS	18.4MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374	003	Jun 13, 1994	Feb	DISC
>A>		@	18.4MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374	003	Jun 13, 1994	Feb	DISC

INPERSOL-LC/LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

>D>	AT	FRESENIUS	18.4MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374	004	Jun 13, 1994	Feb	DISC
>A>		@	18.4MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML	N020374	004	Jun 13, 1994	Feb	DISC

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL
CARBIDOPA AND LEVODOPA

	AB	ACCORD HLTHCARE	25MG;100MG	A202323	001	Feb 08, 2013	Jan	NEWA

TABLET, EXTENDED RELEASE; ORAL
CARBIDOPA AND LEVODOPA

	AB	ACCORD HLTHCARE	50MG;200MG	A202323	002	Feb 08, 2013	Jan	NEWA

CARBOPLATIN

INJECTABLE; INJECTION
CARBOPLATIN

>D>	AP	PLIVA	50MG/VIAL	A076602	001	Nov 16, 2004	Feb	DISC
>A>		@	50MG/VIAL	A076602	001	Nov 16, 2004	Feb	DISC
>D>	AP		150MG/VIAL	A076602	002	Nov 16, 2004	Feb	DISC
>A>		@	150MG/VIAL	A076602	002	Nov 16, 2004	Feb	DISC
>D>	AP		450MG/VIAL	A076602	003	Nov 16, 2004	Feb	DISC
>A>		@	450MG/VIAL	A076602	003	Nov 16, 2004	Feb	DISC

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

>D>	AA	COREPHARMA	350MG	A040397	001	Sep 21, 2000	Feb	DISC
>A>		@	350MG	A040397	001	Sep 21, 2000	Feb	DISC

CARMUSTINE

INJECTABLE; INJECTION
BICNU

	+	EMCURE PHARMS LTD	100MG/VIAL	N017422	001		Jan	CAHN

CARVEDILOL

TABLET; ORAL
CARVEDILOL

>D>	AB	WOCKHARDT	3.125MG	A078786	001	Dec 22, 2009	Feb	DISC
>D>	AB		6.25MG	A078786	002	Dec 22, 2009	Feb	DISC
>D>	AB		12.5MG	A078786	003	Dec 22, 2009	Feb	DISC
>D>	AB		25MG	A078786	004	Dec 22, 2009	Feb	DISC
>A>		@ WOCKHARDT LTD	3.125MG	A078786	001	Dec 22, 2009	Feb	DISC
>A>		@	6.25MG	A078786	002	Dec 22, 2009	Feb	DISC
>A>		@	12.5MG	A078786	003	Dec 22, 2009	Feb	DISC
>A>		@	25MG	A078786	004	Dec 22, 2009	Feb	DISC

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

>D>	AP	HOSPIRA INC	EQ 500MG BASE/VIAL	A065226	001	Apr 21, 2005	Feb	CRLD
>A>	AP	+	EQ 500MG BASE/VIAL	A065226	001	Apr 21, 2005	Feb	CRLD
>D>	AP		EQ 1GM BASE/VIAL	A065226	002	Apr 21, 2005	Feb	CRLD
>D>	AP		EQ 1GM BASE/VIAL	A065244	001	Aug 12, 2005	Feb	CRLD
>A>	AP	+	EQ 1GM BASE/VIAL	A065244	001	Aug 12, 2005	Feb	CRLD
>A>	AP	+	EQ 1GM BASE/VIAL	A065226	002	Apr 21, 2005	Feb	CRLD
>D>	AP		EQ 10GM BASE/VIAL	A065247	001	Aug 12, 2005	Feb	CRLD
>A>	AP	+	EQ 10GM BASE/VIAL	A065247	001	Aug 12, 2005	Feb	CRLD

CEFIXIME

FOR SUSPENSION; ORAL
SUPRAX

>A>	+	LUPIN LTD	500MG/5ML	N202091	001	Feb 20, 2013	Feb	CDFR
>A>		LUPIN PHARMS	100MG/5ML	A065129	001	Feb 23, 2004	Feb	CDFR
>A>			200MG/5ML	A065355	001	Apr 10, 2007	Feb	CDFR

>D>		SUSPENSION; ORAL							
>D>		SUPRAX							
>D>		LUPIN PHARMS	100MG/5ML	A065129	001	Feb 23, 2004	Feb	CDFR	
>D>		+	200MG/5ML	A065355	001	Apr 10, 2007	Feb	CDFR	
		CETIRIZINE HYDROCHLORIDE							
		SYRUP; ORAL							
		CETIRIZINE HYDROCHLORIDE							
>D>	AA	AUROBINDO PHARMA	5MG/5ML	A090751	001	Dec 16, 2009	Feb	DISC	
>A>		@ AUROBINDO PHARMA LTD	5MG/5ML	A090751	001	Dec 16, 2009	Feb	DISC	
		CHLOROTHIAZIDE							
		TABLET; ORAL							
		DIURIL							
		@ OAK PHARMS AKORN	250MG	N011145	004		Jan	CAHN	
		@	500MG	N011145	002		Jan	CAHN	
		CHLOROTHIAZIDE SODIUM							
		INJECTABLE; INJECTION							
		DIURIL							
	AP	+ OAK PHARMS AKORN	EQ 500MG BASE/VIAL	N011145	005		Jan	CAHN	
>A>		CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE							
>A>		SOLUTION; ORAL							
>A>		VITUZ							
>A>		+ CYPRESS PHARM	4MG/5ML;5MG/5ML	N204307	001	Feb 20, 2013	Feb	NEWA	
		CHLORPROPAMIDE							
		TABLET; ORAL							
		CHLORPROPAMIDE							
		@ WATSON LABS INC	100MG	A088852	001	Sep 26, 1984	Jan	DISC	
		@	250MG	A088826	001	Sep 26, 1984	Jan	DISC	
		CICLOPIROX							
		SOLUTION; TOPICAL							
		CICLOPIROX							
		@ TEVA PHARMS	8%	A078079	001	Sep 18, 2007	Jan	DISC	
		PENLAC							
>D>	AT	+ SANOFI AVENTIS US	8%	N021022	001	Dec 17, 1999	Feb	CAHN	
>A>	AT	+ VALEANT INTL	8%	N021022	001	Dec 17, 1999	Feb	CAHN	
		CISPLATIN							
		INJECTABLE; INJECTION							
		PLATINOL							
		@ HQ SPCLT PHARMA	10MG/VIAL	N018057	001		Jan	CAHN	
		@	50MG/VIAL	N018057	002		Jan	CAHN	
		PLATINOL-AQ							
		@ HQ SPCLT PHARMA	0.5MG/ML	N018057	003	Jul 18, 1984	Jan	CAHN	
		@	1MG/ML	N018057	004	Nov 08, 1988	Jan	CAHN	
		CITALOPRAM HYDROBROMIDE							
		TABLET; ORAL							
		CITALOPRAM HYDROBROMIDE							
>D>	AB	COREPHARMA	EQ 10MG BASE	A077036	001	Oct 28, 2004	Feb	DISC	
>A>		@	EQ 10MG BASE	A077036	001	Oct 28, 2004	Feb	DISC	
>D>	AB		EQ 20MG BASE	A077036	002	Oct 28, 2004	Feb	DISC	

TABLET; ORAL
CITALOPRAM HYDROBROMIDE

>A>		@ COREPHARMA	EQ 20MG BASE	A077036	002	Oct 28, 2004	Feb	DISC
>D>	AB		EQ 40MG BASE	A077036	003	Oct 28, 2004	Feb	DISC
>A>		@	EQ 40MG BASE	A077036	003	Oct 28, 2004	Feb	DISC

>A> CLEVIDIPINE

>A> EMULSION; INTRAVENOUS
>A> CLEVIPREX

>A>	+	MEDICINES CO	25MG/50ML (0.5MG/ML)	N022156	001	Aug 01, 2008	Feb	CAIN
>A>	+		50MG/100ML (0.5MG/ML)	N022156	002	Aug 01, 2008	Feb	CAIN

>D> CLEVIDIPINE BUTYRATE

>D> EMULSION; INTRAVENOUS
>D> CLEVIPREX

>D>	+	MEDICINES CO	25MG/50ML (0.5MG/ML)	N022156	001	Aug 01, 2008	Feb	CAIN
>D>	+		50MG/100ML (0.5MG/ML)	N022156	002	Aug 01, 2008	Feb	CAIN

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

>D>	AT	PERRIGO NEW YORK	EQ 1% BASE	A064050	001	Nov 30, 1995	Feb	DISC
>A>		@	EQ 1% BASE	A064050	001	Nov 30, 1995	Feb	DISC

CLONAZEPAM

TABLET; ORAL
CLONAZEPAM

>D>	AB	APOTEX	0.5MG	A075468	001	Oct 06, 2000	Feb	DISC
>D>	AB		1MG	A075468	002	Oct 06, 2000	Feb	DISC
>D>	AB		2MG	A075468	003	Oct 06, 2000	Feb	DISC
>A>		@ APOTEX INC	0.5MG	A075468	001	Oct 06, 2000	Feb	DISC
>A>		@	1MG	A075468	002	Oct 06, 2000	Feb	DISC
>A>		@	2MG	A075468	003	Oct 06, 2000	Feb	DISC

CLOZAPINE

>A> SUSPENSION; ORAL
>A> VERSACLOZ

>A>	+	DOUGLAS PHARMS	50MG/ML	N203479	001	Feb 06, 2013	Feb	NEWA

COSYNTROPIN

INJECTABLE; INJECTION
COSYNTROPIN

>D>	AP	BIONICHE PHARMA	0.25MG/VIAL	A090574	001	Dec 17, 2009	Feb	CAHN
>A>	AP	MYLAN LLC	0.25MG/VIAL	A090574	001	Dec 17, 2009	Feb	CAHN

CYCLOBENZAPRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
AMRIX

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

CYCLOBENZAPRINE HYDROCHLORIDE

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

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION
CYTOXAN (LYOPHILIZED)

		@ BAXTER HLTHCARE	500MG/VIAL	N012142	008	Jan 04, 1984	Jan	CTNA
		@	1GM/VIAL	N012142	010	Sep 24, 1985	Jan	CTNA
		@	2GM/VIAL	N012142	009	Dec 10, 1985	Jan	CTNA

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION
DESMOPRESSIN ACETATE

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

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28
ENSKYCE

>A>	AB	LUPIN LTD	0.15MG;0.03MG	A201887	001	Mar 07, 2013	Feb	NEWA

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

		@ 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
POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% IN PLASTIC CONTAINER

		@ B BRAUN	5GM/100ML;220MG/100ML	N018744	003	Nov 09, 1982	Jan	DISC

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
DILTIAZEM HYDROCHLORIDE

>D>	AB4	ACTAVIS ELIZABETH	120MG	A091022	001	Sep 28, 2012	Feb	CAHN
>D>	AB4		180MG	A091022	002	Sep 28, 2012	Feb	CAHN
>D>	AB4		240MG	A091022	003	Sep 28, 2012	Feb	CAHN
>D>	AB4		300MG	A091022	004	Sep 28, 2012	Feb	CAHN
>D>	AB4		360MG	A091022	005	Sep 28, 2012	Feb	CAHN
>D>	AB4		420MG	A091022	006	Sep 28, 2012	Feb	CAHN
	AB3	PAR PHARM	120MG	A074984	001	Dec 20, 1999	Jan	CAHN
	AB3		180MG	A074984	002	Dec 20, 1999	Jan	CAHN
	AB3		240MG	A074984	003	Dec 20, 1999	Jan	CAHN
	AB3		300MG	A074984	004	Dec 20, 1999	Jan	CAHN
>A>	AB4	SANDOZ	120MG	A091022	001	Sep 28, 2012	Feb	CAHN
>A>	AB4		180MG	A091022	002	Sep 28, 2012	Feb	CAHN
>A>	AB4		240MG	A091022	003	Sep 28, 2012	Feb	CAHN
>A>	AB4		300MG	A091022	004	Sep 28, 2012	Feb	CAHN
>A>	AB4		360MG	A091022	005	Sep 28, 2012	Feb	CAHN
>A>	AB4		420MG	A091022	006	Sep 28, 2012	Feb	CAHN

TABLET; ORAL
DILTIAZEM HYDROCHLORIDE

		@ DAVA PHARMS INC	30MG	A074093	001	Nov 05, 1992	Jan	DISC
		@	60MG	A074093	002	Nov 05, 1992	Jan	DISC
		@	90MG	A074093	003	Nov 05, 1992	Jan	DISC
		@	120MG	A074093	004	Nov 05, 1992	Jan	DISC

DONEPEZIL HYDROCHLORIDE

TABLET; ORAL

DONEPEZIL HYDROCHLORIDE

		@	ACCORD HLTHCARE	5MG	A201335	001	Aug 29, 2011	Jan	DISC
		@		10MG	A201335	002	Aug 29, 2011	Jan	DISC
>A>	AB		ALEMBIC PHARMS LTD	5MG	A201724	001	Feb 25, 2013	Feb	NEWA
>A>	AB			10MG	A201724	002	Feb 25, 2013	Feb	NEWA

DOXAZOSIN MESYLATE

TABLET; ORAL

DOXAZOSIN MESYLATE

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

DOXORUBICIN HYDROCHLORIDE

INJECTABLE, LIPOSOMAL; INJECTION

DOXIL

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

DOXORUBICIN HYDROCHLORIDE

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

EPIRUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

EPIRUBICIN HYDROCHLORIDE

>D>	AP		BIONICHE PHARMA USA	50MG/25ML (2MG/ML)	A065371	001	Nov 28, 2007	Feb	DISC
>D>	AP			200MG/100ML (2MG/ML)	A065371	002	Nov 28, 2007	Feb	DISC
>A>		@	MYLAN LLC	50MG/25ML (2MG/ML)	A065371	001	Nov 28, 2007	Feb	DISC
>A>		@		200MG/100ML (2MG/ML)	A065371	002	Nov 28, 2007	Feb	DISC

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-28

LEVONORGESTREL AND ETHINYL ESTRADIOL

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

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

FEMHRT

		@	WARNER CHILCOTT LLC	0.005MG;1MG	N021065	002	Oct 15, 1999	Jan	DISC

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL

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

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28

ESTARYLLA

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

TRI-ESTARYLLA

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

FENOFIBRIC ACID

TABLET; ORAL
FIBRICOR

>D>		AR HOLDING CO INC	35MG	N022418	001	Aug 14, 2009	Feb	CAHN
>D>	+		105MG	N022418	002	Aug 14, 2009	Feb	CAHN
>A>		MUTUAL PHARM CO INC	35MG	N022418	001	Aug 14, 2009	Feb	CAHN
>A>	+		105MG	N022418	002	Aug 14, 2009	Feb	CAHN

FENTANYL CITRATE

TABLET; BUCCAL
FENTORA

>D>	AB	CEPHALON	EQ 0.1MG BASE	N021947	001	Sep 25, 2006	Feb	CDFR
>D>	AB		EQ 0.2MG BASE	N021947	002	Sep 25, 2006	Feb	CDFR
>D>		@	EQ 0.3MG BASE	N021947	006	Mar 02, 2007	Feb	CDFR
>D>	AB +		EQ 0.4MG BASE	N021947	003	Sep 25, 2006	Feb	CDFR
>D>	AB		EQ 0.6MG BASE	N021947	004	Sep 25, 2006	Feb	CDFR
>D>	AB		EQ 0.8MG BASE	N021947	005	Sep 25, 2006	Feb	CDFR

TABLET; BUCCAL, SUBLINGUAL
FENTORA

>A>	AB	CEPHALON	EQ 0.1MG BASE	N021947	001	Sep 25, 2006	Feb	CDFR
>A>	AB		EQ 0.2MG BASE	N021947	002	Sep 25, 2006	Feb	CDFR
>A>		@	EQ 0.3MG BASE	N021947	006	Mar 02, 2007	Feb	CDFR
>A>	AB +		EQ 0.4MG BASE	N021947	003	Sep 25, 2006	Feb	CDFR
>A>	AB		EQ 0.6MG BASE	N021947	004	Sep 25, 2006	Feb	CDFR
>A>	AB		EQ 0.8MG BASE	N021947	005	Sep 25, 2006	Feb	CDFR

FERUMOXSIL

SUSPENSION; ORAL
GASTROMARK

>D>	+	AMAG PHARMS INC	EQ 0.175MG IRON/ML	N020410	001	Dec 06, 1996	Feb	DISC
>A>		@	EQ 0.175MG IRON/ML	N020410	001	Dec 06, 1996	Feb	DISC

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION
FLUDARABINE PHOSPHATE

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

FLUDEOXYGLUCOSE F-18

INJECTABLE; INTRAVENOUS
FLUDEOXYGLUCOSE F18

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

FLUOCINONIDE

CREAM; TOPICAL
LIDEX

		@ CNTY LINE PHARMS	0.05%	N016908	002		Jan	CAHN

LIDEX-E

		@ CNTY LINE PHARMS	0.05%	N016908	003		Jan	CAHN

GEL; TOPICAL
FLUOCINONIDE

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

LIDEX

		@ CNTY LINE PHARMS	0.05%	N017373	001		Jan	CAHN

OINTMENT; TOPICAL
FLUOCINONIDE

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

LIDEX

		@	CNTY LINE PHARMS	0.05%	N016909	002		Jan	CAHN

SOLUTION; TOPICAL
FLUOCINONIDE

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

LIDEX

		@	MEDICIS	0.05%	N018849	001	Apr 06, 1984	Jan	DISC

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

>D>	AP	+	BIONICHE PHARMA	500MG/10ML (50MG/ML)	A040743	002	Apr 26, 2007	Feb	CAHN
>D>	AP	+		1GM/20ML (50MG/ML)	A040743	001	Apr 26, 2007	Feb	CAHN
>A>	AP	+	MYLAN LLC	500MG/10ML (50MG/ML)	A040743	002	Apr 26, 2007	Feb	CAHN
>A>	AP	+		1GM/20ML (50MG/ML)	A040743	001	Apr 26, 2007	Feb	CAHN

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
FLUOXETINE HYDROCHLORIDE

>D>	AB1		WOCKHARDT	EQ 10MG BASE	A078143	001	Jan 16, 2008	Feb	DISC
>D>	AB1			EQ 20MG BASE	A078143	002	Jan 16, 2008	Feb	DISC
>D>	AB			EQ 40MG BASE	A078143	003	Jan 16, 2008	Feb	DISC
>A>		@	WOCKHARDT LTD	EQ 10MG BASE	A078143	001	Jan 16, 2008	Feb	DISC
>A>		@		EQ 20MG BASE	A078143	002	Jan 16, 2008	Feb	DISC
>A>		@		EQ 40MG BASE	A078143	003	Jan 16, 2008	Feb	DISC

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

		@	INTL MEDICATION	10MG/ML	N018025	001		Jan	DISC

TABLET; ORAL
FUROSEMIDE

>D>	AB		DAVA PHARMS INC	20MG	N018415	001	Jul 27, 1982	Feb	DISC
>A>		@		20MG	N018415	001	Jul 27, 1982	Feb	DISC
>D>	AB			40MG	N018415	002	Jul 27, 1982	Feb	DISC
>A>		@		40MG	N018415	002	Jul 27, 1982	Feb	DISC
>D>	AB			80MG	N018415	003	Nov 26, 1984	Feb	DISC
>A>		@		80MG	N018415	003	Nov 26, 1984	Feb	DISC

GADOXETATE DISODIUM

SOLUTION; INTRAVENOUS
EOVIST

>A>			BAYER HLTHCARE	2.72145GM/15ML (181.43MG/ML)	N022090	002	Feb 04, 2013	Feb	NEWA

GLIMEPIRIDE

TABLET; ORAL
GLIMEPIRIDE

>D>	AB		COREPHARMA	1MG	A077274	001	Oct 06, 2005	Feb	DISC
>A>		@		1MG	A077274	001	Oct 06, 2005	Feb	DISC
>D>	AB			2MG	A077274	002	Oct 06, 2005	Feb	DISC
>A>		@		2MG	A077274	002	Oct 06, 2005	Feb	DISC
>D>	AB			4MG	A077274	003	Oct 06, 2005	Feb	DISC
>A>		@		4MG	A077274	003	Oct 06, 2005	Feb	DISC

>A>		GLYCEROL PHENYLBUTYRATE							
>A>		LIQUID; ORAL							
>A>		RAVICTI							
>A>		+ HYPERION THERAP INC	1.1GM/ML	N203284	001	Feb 01, 2013	Feb	NEWA	
		GRANISETRON HYDROCHLORIDE							
		INJECTABLE; INJECTION							
		GRANISETRON HYDROCHLORIDE							
>D>	AP	EBEWE PHARMA	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A078808	001	Apr 29, 2008	Feb	DISC	
>A>		@	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A078808	001	Apr 29, 2008	Feb	DISC	
		HYDRALAZINE HYDROCHLORIDE							
		TABLET; ORAL							
		HYDRALAZINE HYDROCHLORIDE							
>A>	AA	ACTAVIS PHARMA	10MG	A091679	001	Mar 04, 2013	Feb	NEWA	
>A>	AA		25MG	A091679	002	Mar 04, 2013	Feb	NEWA	
>A>	AA		50MG	A091679	003	Mar 04, 2013	Feb	NEWA	
>A>	AA		100MG	A091679	004	Mar 04, 2013	Feb	NEWA	
		HYDROCHLOROTHIAZIDE; IRBESARTAN							
		TABLET; ORAL							
		IRBESARTAN AND HYDROCHLOROTHIAZIDE							
>A>	AB	AUROBINDO PHARMA LTD	12.5MG;150MG	A203630	001	Feb 22, 2013	Feb	NEWA	
>A>	AB		12.5MG;300MG	A203630	002	Feb 22, 2013	Feb	NEWA	
>A>	AB	LUPIN LTD	12.5MG;150MG	A201524	001	Feb 27, 2013	Feb	NEWA	
>A>	AB		12.5MG;300MG	A201524	002	Feb 27, 2013	Feb	NEWA	
		HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM							
		TABLET; ORAL							
		LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE							
>A>	AB	IPCA LABS LTD	12.5MG;50MG	A201682	001	Mar 01, 2013	Feb	NEWA	
>A>	AB		12.5MG;100MG	A201682	002	Mar 01, 2013	Feb	NEWA	
>A>	AB		25MG;100MG	A201682	003	Mar 01, 2013	Feb	NEWA	
		HYDROCHLOROTHIAZIDE; TRIAMTERENE							
		TABLET; ORAL							
		TRIAMTERENE AND HYDROCHLOROTHIAZIDE							
		@ WATSON LABS	50MG;75MG	A071969	001	Apr 17, 1988	Jan	DISC	
		HYDROCORTISONE							
		LOTION; TOPICAL							
		STIE-CORT							
>D>	AT	PERRIGO	1%	A089066	001	Nov 25, 1985	Feb	DISC	
>A>		@ PERRIGO CO	1%	A089066	001	Nov 25, 1985	Feb	DISC	
		HYDROCORTISONE VALERATE							
		OINTMENT; TOPICAL							
		HYDROCORTISONE VALERATE							
>D>	AB	FOUGERA PHARMS	0.2%	A075085	001	Jul 31, 2001	Feb	DISC	
>A>		@	0.2%	A075085	001	Jul 31, 2001	Feb	DISC	
>D>	AB	TARO	0.2%	A075043	001	Aug 25, 1998	Feb	CRLD	
>A>		+	0.2%	A075043	001	Aug 25, 1998	Feb	CRLD	

			OINTMENT; TOPICAL							
>D>			WESTCORT							
>D>	AB	+	RANBAXY	0.2%	N018726	001	Aug 08, 1983	Feb	DISC	
>A>			@	0.2%	N018726	001	Aug 08, 1983	Feb	DISC	
			HYDROMORPHONE HYDROCHLORIDE							
			TABLET, EXTENDED RELEASE; ORAL							
			EXALGO							
			MALLINCKRODT INC	16MG	N021217	003	Mar 01, 2010	Jan	CRLD	
		+		32MG	N021217	004	Aug 24, 2012	Jan	CRLD	
			ISOSORBIDE DINITRATE							
			TABLET; ORAL							
			ISOSORBIDE DINITRATE							
>D>	AB		PAR PHARM	5MG	A086923	001	Mar 12, 1987	Feb	DISC	
>A>			@	5MG	A086923	001	Mar 12, 1987	Feb	DISC	
			ISOTRETINOIN							
			CAPSULE; ORAL							
			ABSORICA							
>D>	BX		CIPHER	10MG	N021951	001	May 25, 2012	Feb	CAHN	
>D>	BX			20MG	N021951	002	May 25, 2012	Feb	CAHN	
>D>	BX			30MG	N021951	003	May 25, 2012	Feb	CAHN	
>D>	BX			40MG	N021951	004	May 25, 2012	Feb	CAHN	
>A>	BX		RANBAXY	10MG	N021951	001	May 25, 2012	Feb	CAHN	
>A>	BX			20MG	N021951	002	May 25, 2012	Feb	CAHN	
>A>	BX			30MG	N021951	003	May 25, 2012	Feb	CAHN	
>A>	BX			40MG	N021951	004	May 25, 2012	Feb	CAHN	
			LABETALOL HYDROCHLORIDE							
			TABLET; ORAL							
			LABETALOL HYDROCHLORIDE							
	AB	+	SANDOZ	200MG	A075113	002	Aug 04, 1998	Jan	CRLD	
			TRANDATE							
			@ PROMETHEUS LABS	100MG	N018716	001	May 24, 1985	Jan	DISC	
			@	200MG	N018716	002	Aug 01, 1984	Jan	DISC	
			LAMOTRIGINE							
			TABLET, EXTENDED RELEASE; ORAL							
			LAMOTRIGINE							
	AB		PAR PHARM	25MG	A201791	001	Jan 18, 2013	Jan	NEWA	
	AB			50MG	A201791	002	Jan 18, 2013	Jan	NEWA	
	AB			100MG	A201791	003	Jan 18, 2013	Jan	NEWA	
	AB			200MG	A201791	004	Jan 18, 2013	Jan	NEWA	
	AB			250MG	A201791	005	Jan 18, 2013	Jan	NEWA	
	AB			300MG	A201791	006	Jan 18, 2013	Jan	NEWA	
			LATANOPROST							
			SOLUTION/DROPS; OPHTHALMIC							
			LATANOPROST							
	AT		DR REDDYS LABS LTD	0.005%	A202077	001	Feb 11, 2013	Jan	NEWA	
			LEVETIRACETAM							
			SOLUTION; ORAL							
			LEVETIRACETAM							
>A>	AA		HETERO DRUGS LTD	100MG/ML	A203052	001	Feb 28, 2013	Feb	NEWA	

TABLET, EXTENDED RELEASE; ORAL
LEVETIRACETAM

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

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET; ORAL
LEVOCETIRIZINE DIHYDROCHLORIDE

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

LEVOFLOXACIN

INJECTABLE; INJECTION
LEVOFLOXACIN

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

LEVONORGESTREL

INTRAUTERINE DEVICE; INTRAUTERINE
SKYLA

+	BAYER HLTHCARE	13.5MG	N203159	001	Jan 09, 2013	Jan	NEWA

TABLET; ORAL
LEVONORGESTREL

AB	LUPIN LTD	0.75MG	A091328	001	Jan 23, 2013	Jan	NEWA
>A> AB	NOVEL LABS INC	1.5MG	A202508	001	Feb 22, 2013	Feb	NEWA

LISINOPRIL

TABLET; ORAL
LISINOPRIL

@	SANDOZ	2.5MG	A075999	001	Jul 01, 2002	Jan	CAHN
@		5MG	A075999	002	Jul 01, 2002	Jan	CAHN
@		10MG	A075999	003	Jul 01, 2002	Jan	CAHN
@		20MG	A075999	004	Jul 01, 2002	Jan	CAHN
@		30MG	A075999	005	Jul 01, 2002	Jan	CAHN
@		40MG	A075999	006	Jul 01, 2002	Jan	CAHN

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE

>D> AB	APOTEX INC	300MG	A076795	001	Nov 22, 2004	Feb	DISC
>A>	@	300MG	A076795	001	Nov 22, 2004	Feb	DISC

LORAZEPAM

CONCENTRATE; ORAL
LORAZEPAM

>A> AA	LUPIN LTD	2MG/ML	A091407	001	Feb 19, 2013	Feb	NEWA

LOVASTATIN

TABLET; ORAL
LOVASTATIN

>D> AB	CARLSBAD	40MG	A075991	003	Jun 05, 2002	Feb	CRLD
>A> AB	+	40MG	A075991	003	Jun 05, 2002	Feb	CRLD
>D>	MEVACOR						
>D> AB	MERCK	20MG	N019643	003	Aug 31, 1987	Feb	DISC
>A>	@	20MG	N019643	003	Aug 31, 1987	Feb	DISC

			TABLET; ORAL							
>D>			MEVACOR							
>D>	AB	+	MERCK	40MG	N019643	004	Dec 14, 1988	Feb		DISC
>A>			@	40MG	N019643	004	Dec 14, 1988	Feb		DISC
			MAFENIDE ACETATE							
			FOR SOLUTION; TOPICAL							
			MAFENIDE ACETATE							
	AB		PAR FORM	5%	A201511	001	Feb 12, 2013	Jan		NEWA
			SULFAMYLON							
	AB	+	MYLAN LLC	5%	N019832	003	Jun 05, 1998	Jan		CFTG
			MAGNESIUM SULFATE, POTASSIUM SULFATE, SODIUM SULFATE; POLYETHYLENE GLYCOL 3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE							
			SOLUTION, FOR SOLUTION;ORAL, ORAL							
			SUCLEAR							
		+	BRAINTREE LABS	1.6GM/BOT,3.13GM/BOT,17.5GM/BOT,N/A,N/A,N/A,N/A;N/A,N/A,N/A,210GM,0.74GM,2.86GM,5.6GM	N203595	001	Jan 18, 2013	Jan		NEWA
			MANNITOL							
			INJECTABLE; INJECTION							
			MANNITOL 20%							
			@ B BRAUN	20GM/100ML	N014738	001		Jan		DISC
			MEFENAMIC ACID							
			CAPSULE; ORAL							
			MEFENAMIC ACID							
	AB		CYPRESS PHARM	250MG	A090359	001	Feb 05, 2013	Jan		NEWA
			MELOXICAM							
			TABLET; ORAL							
			MELOXICAM							
>D>	AB		COREPHARMA	7.5MG	A077930	001	Jul 19, 2006	Feb		DISC
>A>			@	7.5MG	A077930	001	Jul 19, 2006	Feb		DISC
>D>	AB			15MG	A077930	002	Jul 19, 2006	Feb		DISC
>A>			@	15MG	A077930	002	Jul 19, 2006	Feb		DISC
			MEPROBAMATE							
			TABLET; ORAL							
			MEPROBAMATE							
			@ TARO	200MG	A200998	001	May 23, 2011	Jan		DISC
			@	400MG	A200998	002	May 23, 2011	Jan		DISC
			MESALAMINE							
>A>			CAPSULE, DELAYED RELEASE; ORAL							
>A>			DELZICOL							
>A>		+	WARNER CHILCOTT LLC	400MG	N204412	001	Feb 01, 2013	Feb		NEWA
			SUPPOSITORY; RECTAL							
			CANASA							
>D>			APTALIS PHARMA US	1GM	N021252	002	Nov 05, 2004	Feb		CRLD
>A>		+		1GM	N021252	002	Nov 05, 2004	Feb		CRLD
			METAPROTERENOL SULFATE							
			SYRUP; ORAL							
			METAPROTERENOL SULFATE							
>D>	AA		NOVEX	10MG/5ML	A075235	001	Jan 27, 2000	Feb		DISC

SYRUP; ORAL
METAPROTERENOL SULFATE

>A>		@	NOVEX	10MG/5ML	A075235	001	Jan 27, 2000	Feb	DISC
>D>	AA	+	SILARX	10MG/5ML	A073632	001	Jul 22, 1992	Feb	CTEC
>A>		+		10MG/5ML	A073632	001	Jul 22, 1992	Feb	CTEC

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL
PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE

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

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

		@	AUSTARPHARMA LLC	500MG	A200958	001	Oct 21, 2011	Jan	DISC
		@		750MG	A200958	002	Oct 21, 2011	Jan	DISC
>A>	AA		PRINSTON INC	500MG	A086989	001		Feb	CMFD
>A>	AA			750MG	A086988	001		Feb	CAHN
>D>		@	SOLCO HLTHCARE	500MG	A086989	001		Feb	CMFD
		@		500MG	A086989	001		Jan	DISC
>D>	AA			750MG	A086988	001		Feb	CAHN

METHYCLOTHIAZIDE

TABLET; ORAL
METHYCLOTHIAZIDE

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

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
METHYLIN ER

>D>	AB		MALLINCKRODT	10MG	A075629	001	May 09, 2000	Feb	CTEC
>A>			MALLINCKRODT INC	10MG	A075629	001	May 09, 2000	Feb	CTEC

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HYDROCHLORIDE

>D>	AP		TEVA PARENTERAL	EQ 5MG BASE/ML	A073135	001	Nov 27, 1991	Feb	DISC
>A>		@		EQ 5MG BASE/ML	A073135	001	Nov 27, 1991	Feb	DISC

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL
METOPROLOL SUCCINATE

>D>	AB		NESHER PHARMS	EQ 25MG TARTRATE	A077779	001	Mar 20, 2008	Feb	DISC
>A>		@		EQ 25MG TARTRATE	A077779	001	Mar 20, 2008	Feb	DISC

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION
MIDAZOLAM HYDROCHLORIDE

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

MIPOMERSEN SODIUM

SOLUTION; SUBCUTANEOUS
KYNAMRO

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

MUPIROCIN CALCIUM

CREAM; TOPICAL
BACTROBAN

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

MUPIROCIN

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

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
MACRODANTIN

>D>	AB		ALMATICA	25MG	N016620	003		Feb	CAHN
>D>	AB			50MG	N016620	001		Feb	CAHN
>D>	AB	+		100MG	N016620	002		Feb	CAHN
>A>	AB		ALVOGEN INC	25MG	N016620	003		Feb	CAHN
>A>	AB			50MG	N016620	001		Feb	CAHN
>A>	AB	+		100MG	N016620	002		Feb	CAHN

NIZATIDINE

CAPSULE; ORAL
NIZATIDINE

>D>	AB		APOTEX	150MG	A076383	001	Jan 23, 2003	Feb	DISC
>D>	AB			300MG	A076383	002	Jan 23, 2003	Feb	DISC
>A>			@ APOTEX INC	150MG	A076383	001	Jan 23, 2003	Feb	DISC
>A>			@	300MG	A076383	002	Jan 23, 2003	Feb	DISC

NYSTATIN

SUSPENSION; ORAL
NILSTAT

>D>	AA	+	GLENMARK GENERICS	100,000 UNITS/ML	N050299	001		Feb	DISC
>A>			@	100,000 UNITS/ML	N050299	001		Feb	DISC

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ONDANSETRON HYDROCHLORIDE

>A>	AP		CLARIS LIFESCIENCES	2MG/ML	A078288	001	Feb 22, 2013	Feb	NEWA
>D>	AP		PLIVA HRVATSKA DOO	EQ 2MG BASE/ML	A077544	001	Dec 26, 2006	Feb	DISC
>A>			@	EQ 2MG BASE/ML	A077544	001	Dec 26, 2006	Feb	DISC

ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER

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

ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE

>A>	AP		CLARIS LIFESCIENCES	2MG/ML	A078287	001	Feb 22, 2013	Feb	NEWA

>A> OSPEMIFENE

>A> TABLET; ORAL
>A> OSPHENA

>A>		+	SHIONOGI INC	60MG	N203505	001	Feb 26, 2013	Feb	NEWA

OXACILLIN SODIUM

INJECTABLE; INJECTION
OXACILLIN SODIUM

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

OXAPROZIN

TABLET; ORAL
OXAPROZIN

	@ CARACO	600MG	A075844	001	Jan 03, 2002	Jan	DISC

OXYMORPHONE HYDROCHLORIDE

TABLET; ORAL
OXYMORPHONE HYDROCHLORIDE

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

OXYTOCIN

INJECTABLE; INJECTION
OXYTOCIN

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

PACLITAXEL

INJECTABLE; INJECTION
TAXOL

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

PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL
PIOGLITAZONE HYDROCHLORIDE

AB	ACCORD HLTHCARE	EQ 15MG BASE	A200044	001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A200044	002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A200044	003	Feb 13, 2013	Jan	NEWA
AB	AUROBINDO PHARMA LTD	EQ 15MG BASE	A200268	001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A200268	002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A200268	003	Feb 13, 2013	Jan	NEWA
AB	MACLEODS PHARMS LTD	EQ 15MG BASE	A202467	001	Feb 06, 2013	Jan	NEWA
AB		EQ 30MG BASE	A202467	002	Feb 06, 2013	Jan	NEWA
AB		EQ 45MG BASE	A202467	003	Feb 06, 2013	Jan	NEWA
AB	SANDOZ	EQ 15MG BASE	A078670	001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A078670	002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A078670	003	Feb 13, 2013	Jan	NEWA
AB	SYNTHON PHARMS	EQ 15MG BASE	A078472	001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A078472	002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A078472	003	Feb 13, 2013	Jan	NEWA
AB	TORRENT PHARMS LTD	EQ 15MG BASE	A091298	001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A091298	002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A091298	003	Feb 13, 2013	Jan	NEWA
AB	ZYDUS PHARMS USA INC	EQ 15MG BASE	A202456	001	Feb 13, 2013	Jan	NEWA
AB		EQ 30MG BASE	A202456	002	Feb 13, 2013	Jan	NEWA
AB		EQ 45MG BASE	A202456	003	Feb 13, 2013	Jan	NEWA

>A>		POMALIDOMIDE							
>A>		CAPSULE; ORAL							
>A>		POMALYST							
>A>		CELGENE	1MG	N204026	001	Feb 08, 2013	Feb	NEWA	
>A>			2MG	N204026	002	Feb 08, 2013	Feb	NEWA	
>A>			3MG	N204026	003	Feb 08, 2013	Feb	NEWA	
>A>		+	4MG	N204026	004	Feb 08, 2013	Feb	NEWA	
		POTASSIUM CHLORIDE							
		CAPSULE, EXTENDED RELEASE; ORAL							
		POTASSIUM CHLORIDE							
>A>	AB	AMNEAL PHARMS	10MEQ	A202128	001	Feb 22, 2013	Feb	NEWA	
		PRAMLINTIDE ACETATE							
		INJECTABLE; SUBCUTANEOUS							
		SYMLIN							
		AMYLIN PHARMS	EQ 1.5MG BASE/1.5ML (EQ 1MG BASE/ML)	N021332	002	Sep 25, 2007	Jan	CAHN	
			EQ 2.7MG BASE/2.7ML (EQ 1MG BASE/ML)	N021332	003	Sep 25, 2007	Jan	CAHN	
		+	EQ 3MG BASE/5ML (EQ 600MCG BASE/ML)	N021332	001	Mar 16, 2005	Jan	CAHN	
		PROPRANOLOL HYDROCHLORIDE							
		CAPSULE, EXTENDED RELEASE; ORAL							
		PROPRANOLOL HYDROCHLORIDE							
>A>	AB	GLATT AIR	60MG	A078065	001	Jan 26, 2007	Feb	CAHN	
>A>	AB		80MG	A078065	002	Jan 26, 2007	Feb	CAHN	
>A>	AB		120MG	A078065	003	Jan 26, 2007	Feb	CAHN	
>A>	AB		160MG	A078065	004	Jan 26, 2007	Feb	CAHN	
>D>	AB	PAR PHARM	60MG	A078065	001	Jan 26, 2007	Feb	CAHN	
>D>	AB		80MG	A078065	002	Jan 26, 2007	Feb	CAHN	
>D>	AB		120MG	A078065	003	Jan 26, 2007	Feb	CAHN	
>D>	AB		160MG	A078065	004	Jan 26, 2007	Feb	CAHN	
		QUETIAPINE FUMARATE							
		TABLET; ORAL							
		QUETIAPINE FUMARATE							
>A>	AB	ACTAVIS PHARMA	EQ 25MG BASE	A201762	001	Feb 27, 2013	Feb	NEWA	
>A>	AB		EQ 50MG BASE	A201762	002	Feb 27, 2013	Feb	NEWA	
>A>	AB		EQ 100MG BASE	A201762	003	Feb 27, 2013	Feb	NEWA	
>A>	AB		EQ 150MG BASE	A201762	004	Feb 27, 2013	Feb	NEWA	
>A>	AB		EQ 200MG BASE	A201762	005	Feb 27, 2013	Feb	NEWA	
>A>	AB		EQ 300MG BASE	A201762	006	Feb 27, 2013	Feb	NEWA	
>A>	AB		EQ 400MG BASE	A201762	007	Feb 27, 2013	Feb	NEWA	
	AB	ALKEM LABS LTD	EQ 25MG BASE	A201504	001	Feb 12, 2013	Jan	NEWA	
	AB		EQ 50MG BASE	A201504	002	Feb 12, 2013	Jan	NEWA	
	AB		EQ 100MG BASE	A201504	003	Feb 12, 2013	Jan	NEWA	
	AB		EQ 150MG BASE	A201504	004	Feb 12, 2013	Jan	NEWA	
	AB		EQ 200MG BASE	A201504	005	Feb 12, 2013	Jan	NEWA	
	AB		EQ 300MG BASE	A201504	006	Feb 12, 2013	Jan	NEWA	
	AB		EQ 400MG BASE	A201504	007	Feb 12, 2013	Jan	NEWA	

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
RANITIDINE HYDROCHLORIDE

>A>	AP	ZYDUS PHARMS USA INC	25MG/ML	A091534	001	Feb 22, 2013	Feb	NEWA

TABLET; ORAL
RANITIDINE HYDROCHLORIDE

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

RIMANTADINE HYDROCHLORIDE

TABLET; ORAL
RIMANTADINE HYDROCHLORIDE

>D>	AB	COREPHARMA	100MG	A075916	001	Nov 02, 2001	Feb	DISC
>A>		@	100MG	A075916	001	Nov 02, 2001	Feb	DISC

RISPERIDONE

TABLET, ORALLY DISINTEGRATING; ORAL
RISPERIDONE

>A>	AB	MYLAN PHARMS INC	0.25MG	A091537	006	Feb 12, 2013	Feb	NEWA
>D>		PAR PHARM	0.25MG	A077494	001	Apr 30, 2009	Feb	CTEC
>A>	AB		0.25MG	A077494	001	Apr 30, 2009	Feb	CTEC

ROCURONIUM BROMIDE

INJECTABLE; INJECTION
ZEMURON

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

ROSIGLITAZONE MALEATE

TABLET; ORAL
AVANDIA

	AB	SB PHARMCO	EQ 2MG BASE	N021071	002	May 25, 1999	Jan	CFTG
	AB		EQ 4MG BASE	N021071	003	May 25, 1999	Jan	CFTG
	AB	+	EQ 8MG BASE	N021071	004	May 25, 1999	Jan	CFTG

ROSIGLITAZONE MALEATE

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

SAQUINAVIR MESYLATE

TABLET; ORAL
INVIRASE

>A>		+ HOFFMAN LA ROCHE	EQ 500MG BASE	N021785	001	Dec 17, 2004	Feb	CAHN
>D>		+ ROCHE	EQ 500MG BASE	N021785	001	Dec 17, 2004	Feb	CAHN

SELEGILINE HYDROCHLORIDE

TABLET; ORAL
SELEGILINE HYDROCHLORIDE

		@ DAVA PHARMS INC	5MG	A074641	001	Aug 02, 1996	Jan	DISC

SILDENAFIL CITRATE

TABLET; ORAL
SILDENAFIL CITRATE

>A>	AB	ACTAVIS PHARMA	EQ 20MG BASE	A200149	001	Feb 25, 2013	Feb	NEWA

TABLET; ORAL
SILDENAFIL CITRATE

>A>	AB		AMNEAL PHARMS	EQ 20MG BASE	A202025	001	Feb 28, 2013	Feb	NEWA

SODIUM CHLORIDE

SOLUTION; IRRIGATION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

		@	BAXTER HLTHCARE	450MG/100ML	N017864	001		Jan	DISC

SULFACETAMIDE SODIUM

LOTION; TOPICAL
KLARON

>D>	AB	+	SANOFI AVENTIS US	10%	N019931	001	Dec 23, 1996	Feb	CAHN
>A>	AB	+	VALEANT BERMUDA	10%	N019931	001	Dec 23, 1996	Feb	CAHN

SUMATRIPTAN SUCCINATE

INJECTABLE; SUBCUTANEOUS
SUMATRIPTAN SUCCINATE

>A>	AP		SAGENT AGILA	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A090641	001	Jul 28, 2010	Feb	CAHN
>D>	AP		SAGENT STRIDES	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A090641	001	Jul 28, 2010	Feb	CAHN

SYSTEM; IONTOPHORESIS
ZECUITY

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

TESTOSTERONE

GEL; TRANSDERMAL
TESTOSTERONE

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

GEL, METERED; TRANSDERMAL
TESTOSTERONE

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

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
DELATESTRYL

	AO	+	ENDO PHARMS	200MG/ML	N009165	003		Jan	CAHN
		@		200MG/ML	N009165	001		Jan	CAHN

TIMOLOL MALEATE

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC
TIMOPTIC-XE

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

TIZANIDINE HYDROCHLORIDE

TABLET; ORAL
TIZANIDINE HYDROCHLORIDE

>D>	AB		MYLAN PHARMS INC	EQ 2MG BASE	A076282	001	Dec 16, 2003	Feb	DISC
>A>			@	EQ 2MG BASE	A076282	001	Dec 16, 2003	Feb	DISC
>D>	AB			EQ 4MG BASE	A076282	002	Dec 16, 2003	Feb	DISC
>A>			@	EQ 4MG BASE	A076282	002	Dec 16, 2003	Feb	DISC

TOPIRAMATE

TABLET; ORAL
TOPIRAMATE

>A>	AB		ACTIVIS TOTOWA LLC	25MG	A078637	001	Feb 27, 2013	Feb	NEWA
>A>	AB			50MG	A078637	002	Feb 27, 2013	Feb	NEWA
>A>	AB			100MG	A078637	003	Feb 27, 2013	Feb	NEWA
>A>	AB			200MG	A078637	004	Feb 27, 2013	Feb	NEWA
>A>	AB		UNICHEM LABS LTD	200MG	A090162	004	Feb 19, 2013	Feb	NEWA

TRAMADOL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
RYZOLT

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

TRAMADOL HYDROCHLORIDE

>D>	AB1		PAR PHARM	100MG	A078783	001	Nov 13, 2009	Feb	CRLD
>A>	AB1		PAR PHARM INC	100MG	A078783	001	Nov 13, 2009	Feb	CRLD
>D>	AB2		SUN PHARMA GLOBAL	100MG	A091607	001	Dec 30, 2011	Feb	CRLD
>A>	AB2	+		100MG	A091607	001	Dec 30, 2011	Feb	CRLD

TRAVOPROST

SOLUTION/DROPS; OPHTHALMIC
>A> TRAVOPROST

>A>			PAR PHARM	0.004%	A091340	001	Mar 01, 2013	Feb	NEWA

URSODIOL

TABLET; ORAL
URSODIOL

>A>	AB		PAR PHARM	250MG	A202540	001	Feb 14, 2013	Feb	NEWA
>A>	AB			500MG	A202540	002	Feb 14, 2013	Feb	NEWA

VALPROIC ACID

CAPSULE; ORAL
VALPROIC ACID

>A>	AB		SUN PHARM INDS LTD	250MG	A091037	001	Feb 22, 2013	Feb	NEWA

VERTEPORFIN

INJECTABLE; INJECTION
VISUDYNE

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

WARFARIN SODIUM

TABLET; ORAL
WARFARIN SODIUM

>A>	AB		AMNEAL PHARMS	1MG	A202202	001	Mar 04, 2013	Feb	NEWA
>A>	AB			2MG	A202202	002	Mar 04, 2013	Feb	NEWA
>A>	AB			2.5MG	A202202	003	Mar 04, 2013	Feb	NEWA
>A>	AB			3MG	A202202	004	Mar 04, 2013	Feb	NEWA
>A>	AB			4MG	A202202	005	Mar 04, 2013	Feb	NEWA
>A>	AB			5MG	A202202	006	Mar 04, 2013	Feb	NEWA
>A>	AB			6MG	A202202	007	Mar 04, 2013	Feb	NEWA
>A>	AB			7.5MG	A202202	008	Mar 04, 2013	Feb	NEWA
>A>	AB			10MG	A202202	009	Mar 04, 2013	Feb	NEWA

ZIDOVUDINE

TABLET; ORAL

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

ZOLEDRONIC ACID

INJECTABLE; IV (INFUSION)

>A>		ZOLEDRONIC ACID							
>A>	AP	ACTAVIS INC	EQ 4MG BASE/5ML	A202472	001	Mar 04, 2013	Feb	NEWA
>A>	AP	AGILA SPECLTS	EQ 4MG BASE/5ML	A202650	001	Mar 04, 2013	Feb	NEWA
>A>	AP	DR REDDYS LABS LTD	EQ 4MG BASE/5ML	A091186	001	Mar 04, 2013	Feb	NEWA
>A>	AP	PHARMACEUTICS	EQ 4MG BASE/5ML	A091170	001	Mar 04, 2013	Feb	NEWA
>A>	AP	SUN PHARMA GLOBAL	EQ 4MG BASE/5ML	A202746	001	Mar 04, 2013	Feb	NEWA
>A>		+	EQ 4MG BASE/VIAL	A090018	001	Mar 04, 2013	Feb	NEWA
		ZOMETA							
>D>		+ NOVARTIS	EQ 4MG BASE/5ML	N021223	002	Mar 07, 2003	Feb	CFTG
>A>	AP	+	EQ 4MG BASE/5ML	N021223	002	Mar 07, 2003	Feb	CFTG

ZONISAMIDE

CAPSULE; ORAL

		ZONISAMIDE							
>D>	AB	COREPHARMA	25MG	A077876	001	Feb 21, 2007	Feb	DISC
>A>		@	25MG	A077876	001	Feb 21, 2007	Feb	DISC
>D>	AB		50MG	A077876	002	Feb 21, 2007	Feb	DISC
>A>		@	50MG	A077876	002	Feb 21, 2007	Feb	DISC
>D>	AB		100MG	A077876	003	Feb 21, 2007	Feb	DISC
>A>		@	100MG	A077876	003	Feb 21, 2007	Feb	DISC

ASPIRIN

CAPSULE; ORAL

ASPIRIN

+	PLX PHARMA	325MG	N203697	001	Jan 14, 2013	Jan	NEWA	

CETIRIZINE HYDROCHLORIDE

TABLET, CHEWABLE; ORAL

CHILDREN'S ZYRTEC ALLERGY

>D>	MCNEIL CONS	5MG	N021621	003	Nov 16, 2007	Feb	CRLD	
>A>	+	5MG	N021621	003	Nov 16, 2007	Feb	CRLD	
>D>	+	10MG	N021621	004	Nov 16, 2007	Feb	DISC	
>A>	@	10MG	N021621	004	Nov 16, 2007	Feb	DISC	

CHILDREN'S ZYRTEC HIVES RELIEF

>D>	MCNEIL CONS	5MG	N021621	005	Nov 16, 2007	Feb	CRLD	
>A>	+	5MG	N021621	005	Nov 16, 2007	Feb	CRLD	
>D>	+	10MG	N021621	006	Nov 16, 2007	Feb	DISC	
>A>	@	10MG	N021621	006	Nov 16, 2007	Feb	DISC	

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

DEXBROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE

>A>	AVANTHI INC	6MG;120MG	A078648	001	Feb 27, 2013	Feb	NEWA	

FEXOFENADINE HYDROCHLORIDE

TABLET, ORALLY DISINTEGRATING; ORAL

CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY

	DR REDDYS LABS LTD	30MG	A202978	001	Jan 18, 2013	Jan	NEWA	

CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES

	DR REDDYS LABS LTD	30MG	A202978	002	Jan 18, 2013	Jan	NEWA	

LEVONORGESTREL

TABLET; ORAL

LEVONORGESTREL

		LUPIN LTD	0.75MG	A091328	001	Jan 23, 2013	Jan	NEWA	
>A>	AB	NOVEL LABS INC	1.5MG	A202508	001	Feb 22, 2013	Feb	NEWA	

LORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

LORATADINE AND PSEUDOEPHEDRINE SULFATE

>D>	WATSON LABS FLORIDA	5MG;120MG	A076208	001	Jan 28, 2004	Feb	DISC	
>A>	@ WATSON LABS INC FL	5MG;120MG	A076208	001	Jan 28, 2004	Feb	DISC	

MICONAZOLE NITRATE

CREAM; VAGINAL

MICONAZOLE NITRATE

	APHENA PHARMA MD	2%	A074366	001	Feb 22, 1996	Jan	CAHN	

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE

	AKORN INC	0.025%;0.3%	A202795	001	Jan 24, 2013	Jan	NEWA	

OXYBUTYNIN

FILM, EXTENDED RELEASE; TRANSDERMAL

OXYTROL FOR WOMEN							
+ MSD CONSUMER	3.9MG/24HR		N202211	001	Jan 25, 2013	Jan	NEWA

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL

POLYETHYLENE GLYCOL 3350							
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 02 FEBRUARY 2013

NO FEBRUARY 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 FEBRUARY 2013 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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					NPP	Feb 01, 2016
ALOGLIPTIN BENZOATE - NESINA						
N022271 001	**>A>** 6150383	Jun 19, 2016	U-1330		NCE	Jan 25, 2018
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			
ALOGLIPTIN BENZOATE - NESINA						
N022271 002	**>A>** 6150383	Jun 19, 2016	U-1330		NCE	Jan 25, 2018
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			
ALOGLIPTIN BENZOATE - NESINA						
N022271 003	**>A>** 6150383	Jun 19, 2016	U-1330		NCE	Jan 25, 2018
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE - KAZANO						
N203414 001	**>A>** 5965584	Jun 19, 2016	U-1339		NCE	Jan 25, 2018
	>A> 6150383	Jun 19, 2016	U-1330		NC	Jan 25, 2016
	>A> 6150384	Jun 19, 2016	U-1340			
	>A> 6166042	Jun 19, 2016	U-1341			
	>A> 6166043	Jun 19, 2016	U-1342			
	>A> 6172090	Jun 19, 2016	U-1343			
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			
ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE - KAZANO						
N203414 002	**>A>** 5965584	Jun 19, 2016	U-1339		NCE	Jan 25, 2018
	>A> 6150383	Jun 19, 2016	U-1330		NC	Jan 25, 2016
	>A> 6150384	Jun 19, 2016	U-1340			
	>A> 6166042	Jun 19, 2016	U-1341			
	>A> 6166043	Jun 19, 2016	U-1342			
	>A> 6172090	Jun 19, 2016	U-1343			
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI						
N022426 001	**>A>** 5965584	Jun 19, 2016	DP U-1339		NCE	Jan 25, 2018
	>A> 6150383	Jun 19, 2016	U-1330		NC	Jan 25, 2016
	>A> 6150384	Jun 19, 2016	U-1340			
	>A> 6166042	Jun 19, 2016	U-1341			
	>A> 6166043	Jun 19, 2016	U-1342			
	>A> 6172090	Jun 19, 2016	U-1343			
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6271243	Jun 19, 2016	U-1344			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			
ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI						
N022426 002	**>A>** 5965584	Jun 19, 2016	DP U-1339		NCE	Jan 25, 2018
	>A> 6150383	Jun 19, 2016	U-1330		NC	Jan 25, 2016
	>A> 6150384	Jun 19, 2016	U-1340			
	>A> 6166042	Jun 19, 2016	U-1341			
	>A> 6166043	Jun 19, 2016	U-1342			
	>A> 6172090	Jun 19, 2016	U-1343			
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6271243	Jun 19, 2016	U-1344			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI						
N022426 003	**>A>** 5965584	Jun 19, 2016	DP U-1339		NCE	Jan 25, 2018
	>A> 6150383	Jun 19, 2016	U-1330		NC	Jan 25, 2016
	>A> 6150384	Jun 19, 2016	U-1340			
	>A> 6166042	Jun 19, 2016	U-1341			
	>A> 6166043	Jun 19, 2016	U-1342			
	>A> 6172090	Jun 19, 2016	U-1343			
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6271243	Jun 19, 2016	U-1344			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			
ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI						
N022426 004	**>A>** 5965584	Jun 19, 2016	DP U-1339		NCE	Jan 25, 2018
	>A> 6150383	Jun 19, 2016	U-1330		NC	Jan 25, 2016
	>A> 6150384	Jun 19, 2016	U-1340			
	>A> 6166042	Jun 19, 2016	U-1341			
	>A> 6166043	Jun 19, 2016	U-1342			
	>A> 6172090	Jun 19, 2016	U-1343			
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6271243	Jun 19, 2016	U-1344			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI						
N022426 005	**>A>** 5965584	Jun 19, 2016	DP U-1339		NCE	Jan 25, 2018
	>A> 6150383	Jun 19, 2016	U-1330		NC	Jan 25, 2016
	>A> 6150384	Jun 19, 2016	U-1340			
	>A> 6166042	Jun 19, 2016	U-1341			
	>A> 6166043	Jun 19, 2016	U-1342			
	>A> 6172090	Jun 19, 2016	U-1343			
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6271243	Jun 19, 2016	U-1344			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			
ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE - OSENI						
N022426 006	**>A>** 5965584	Jun 19, 2016	DP U-1339		NCE	Jan 25, 2018
	>A> 6150383	Jun 19, 2016	U-1330		NC	Jan 25, 2016
	>A> 6150384	Jun 19, 2016	U-1340			
	>A> 6166042	Jun 19, 2016	U-1341			
	>A> 6166043	Jun 19, 2016	U-1342			
	>A> 6172090	Jun 19, 2016	U-1343			
	>A> 6211205	Jun 19, 2016	U-1331			
	>A> 6271243	Jun 19, 2016	U-1344			
	>A> 6303640	Aug 09, 2016	U-1332			
	>A> 6303661	Apr 24, 2017	U-1333			
	>A> 6329404	Jun 19, 2016	DP U-1334			
	>A> 6890898	Feb 02, 2019	U-1335			
	>A> 7078381	Feb 02, 2019	U-1335			
	>A> 7459428	Feb 02, 2019	U-1336			
	>A> 7807689	Jun 27, 2028	DS DP U-1337			
	>A> 8173663	Mar 15, 2025	U-1338			
	>A> 8288539	Mar 15, 2025	DS			
AMOXICILLIN - MOXATAG						
N050813 001	8357394	Dec 08, 2026	DP			
APIXABAN - ELIQUIS						
N202155 001	**>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			
APIXABAN - ELIQUIS						
N202155 002	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			
ARIPIPRAZOLE - ABILIFY MAINTENA KIT						
N202971 001					**>A>** NDF	Feb 28, 2016

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
ARIPIPRAZOLE - ABILIFY MAINTENA KIT						
N202971 002					**>A>** NDF	Feb 28, 2016
BEDAQUILINE FUMARATE - SIRTURO						
N204384 001	7498343	Oct 02, 2024	DS DP U-1321		ODE	Dec 28, 2019
BOCEPREVIR - VICTRELIS						
N202258 001					**>A>** M-126	Feb 27, 2016
					>A> NPP	Feb 13, 2016
BUDESONIDE - UCERIS						
N203634 001	7410651	Jun 09, 2020	DP U-1325		NDF	Jan 14, 2016
	7431943	Jun 09, 2020	DP			
	8293273	Jun 09, 2020	DP			
	RE43799	Jun 09, 2020	DP U-1325			
CABOZANTINIB S-MALATE - COMETRIQ						
N203756 001					ODE	Nov 29, 2019
CABOZANTINIB S-MALATE - COMETRIQ						
N203756 002					ODE	Nov 29, 2019
CELECOXIB - CELEBREX						
N020998 001	**>A>** RE44048	Jun 02, 2015	U-247			
	>A> RE44048	Jun 02, 2015	U-1352			
	>A> RE44048	Jun 02, 2015	U-1351			
	>A> RE44048	Jun 02, 2015	U-1350			
	>A> RE44048	Jun 02, 2015	U-1349			
	>A> RE44048	Jun 02, 2015	U-1348			
	>A> RE44048*PED	Dec 02, 2015				
CELECOXIB - CELEBREX						
N020998 002	**>A>** RE44048	Jun 02, 2015	U-247			
	>A> RE44048	Jun 02, 2015	U-1352			
	>A> RE44048	Jun 02, 2015	U-1351			
	>A> RE44048	Jun 02, 2015	U-1350			
	>A> RE44048	Jun 02, 2015	U-1349			
	>A> RE44048	Jun 02, 2015	U-1348			
	>A> RE44048*PED	Dec 02, 2015				
CELECOXIB - CELEBREX						
N020998 003	**>A>** RE44048	Jun 02, 2015	U-247			
	>A> RE44048	Jun 02, 2015	U-1352			
	>A> RE44048	Jun 02, 2015	U-1351			
	>A> RE44048	Jun 02, 2015	U-1350			
	>A> RE44048	Jun 02, 2015	U-1349			
	>A> RE44048	Jun 02, 2015	U-1348			
	>A> RE44048*PED	Dec 02, 2015				
CELECOXIB - CELEBREX						
N020998 004	**>A>** RE44048	Jun 02, 2015	U-247			
	>A> RE44048	Jun 02, 2015	U-1352			
	>A> RE44048	Jun 02, 2015	U-1351			
	>A> RE44048	Jun 02, 2015	U-1350			
	>A> RE44048	Jun 02, 2015	U-1349			
	>A> RE44048	Jun 02, 2015	U-1348			
	>A> RE44048*PED	Dec 02, 2015				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
CICLESONIDE - ALVESCO						
N021658 002	**>A>** 8371292	Aug 25, 2027	U-1355		M-125	Dec 17, 2015
CICLESONIDE - ALVESCO						
N021658 003	**>A>** 8371292	Aug 25, 2027	U-1355		M-125	Dec 17, 2015
CICLESONIDE - OMNARIS						
N022004 001	**>A>** 8371292	Aug 25, 2027	U-1356			
CICLESONIDE - ZETONNA						
N202129 001	**>A>** 8371292	Aug 25, 2027	U-1357			
CLOBAZAM - ONFI						
N203993 001					**>A>** ODE	Oct 21, 2018
CLOBETASOL PROPIONATE - CLOBETASOL PROPIONATE						
A201402 001					PC	Jul 31, 2013
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 001					**>A>** D-135	Feb 01, 2016
					>A> PED	Aug 01, 2016
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 002					**>A>** D-135	Feb 01, 2016
					>A> PED	Aug 01, 2016
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 003					**>A>** D-135	Feb 01, 2016
					>A> PED	Aug 01, 2016
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 004					**>A>** D-135	Feb 01, 2016
					>A> PED	Aug 01, 2016
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 005					**>A>** D-135	Feb 01, 2016
					>A> PED	Aug 01, 2016
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 006					**>A>** D-135	Feb 01, 2016
					>A> PED	Aug 01, 2016
DARUNAVIR ETHANOLATE - PREZISTA						
N202895 001					**>A>** D-135	Feb 01, 2016
					>A> PED	Aug 01, 2016
DEFERASIROX - EXJADE						
N021882 001					I-665	Jan 23, 2016
DEFERASIROX - EXJADE						
N021882 002					I-665	Jan 23, 2016
DEFERASIROX - EXJADE						
N021882 003					I-665	Jan 23, 2016
DROSPIRENONE; ETHINYL ESTRADIOL - YAZ						
N021676 001	RE43916	Jun 30, 2014	U-1326			
DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - BEYAZ						
N022532 001	RE43916	Jun 30, 2014	U-1326			
DULOXETINE HYDROCHLORIDE - CYMBALTA						
N021427 001					M-61	Oct 18, 2015
					PED	Apr 18, 2016

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
DULOXETINE HYDROCHLORIDE - CYMBALTA						
N021427 002					M-61	Oct 18, 2015
					PED	Apr 18, 2016
DULOXETINE HYDROCHLORIDE - CYMBALTA						
N021427 004					M-61	Oct 18, 2015
					PED	Apr 18, 2016
EFAVIRENZ - SUSTIVA						
N020972 001	5519021	May 21, 2013	DS DP			
	5519021*PED	Nov 21, 2013				
	5663169	Sep 02, 2014	U-257			
	5663169*PED	Mar 02, 2015				
	6238695	Apr 06, 2019	DP			
	6238695*PED	Oct 06, 2019				
	6555133	Apr 06, 2019	U-248			
	6555133*PED	Oct 06, 2019				
	6639071	Feb 14, 2018	DS			
	6639071*PED	Aug 14, 2018				
	6939964	Jan 20, 2018	DS			
	6939964*PED	Jul 20, 2018				
EFAVIRENZ - SUSTIVA						
N020972 002	5519021	May 21, 2013	DS DP			
	5519021*PED	Nov 21, 2013				
	5663169	Sep 02, 2014	U-257			
	5663169*PED	Mar 02, 2015				
	6238695	Apr 06, 2019	DP			
	6238695*PED	Oct 06, 2019				
	6555133	Apr 06, 2019	U-248			
	6555133*PED	Oct 06, 2019				
	6639071	Feb 14, 2018	DS			
	6639071*PED	Aug 14, 2018				
	6939964	Jan 20, 2018	DS			
	6939964*PED	Jul 20, 2018				
EFAVIRENZ - SUSTIVA						
N020972 003	5519021	May 21, 2013	DS DP			
	5519021*PED	Nov 21, 2013				
	5663169	Sep 02, 2014	U-257			
	5663169*PED	Mar 02, 2015				
	6238695	Apr 06, 2019	DP			
	6238695*PED	Oct 06, 2019				
	6555133	Apr 06, 2019	U-248			
	6555133*PED	Oct 06, 2019				
	6639071	Feb 14, 2018	DS			
	6639071*PED	Aug 14, 2018				
	6939964	Jan 20, 2018	DS			
	6939964*PED	Jul 20, 2018				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
EFAVIRENZ - SUSTIVA							
N021360 001		5519021	May 21, 2013				
		5519021*PED	Nov 21, 2013				
		5663169	Sep 02, 2014				
		5663169*PED	Mar 02, 2015				
		6639071	Feb 14, 2018	DS			
		6639071*PED	Aug 14, 2018				
		6939964	Jan 20, 2018	DS			
		6939964*PED	Jul 20, 2018				
EFAVIRENZ - SUSTIVA							
N021360 002		5519021	May 21, 2013	DS DP			
		5519021*PED	Nov 21, 2013				
		5663169	Sep 02, 2014			U-248	
		5663169*PED	Mar 02, 2015				
		6639071	Feb 14, 2018	DS			
		6639071*PED	Aug 14, 2018				
		6939964	Jan 20, 2018	DS			
		6939964*PED	Jul 20, 2018				
EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - ATRIPLA							
N021937 001		5519021	May 21, 2013	DS DP			
		5519021*PED	Nov 21, 2013				
		5663169	Sep 02, 2014			U-750	
		5663169	Sep 02, 2014			U-1170	
		5663169*PED	Mar 02, 2015				
		6639071	Feb 14, 2018	DS			
		6639071*PED	Aug 14, 2018				
		6939964	Jan 20, 2018	DS			
		6939964*PED	Jul 20, 2018				
EPINEPHRINE - AUVI-Q							
N201739 001	**>A>**	7731686	Jun 01, 2026	DP			
	>A>	7731690	Jan 15, 2025	DP			
	>A>	7749194	Oct 30, 2028	DP			
	>A>	7918823	Nov 23, 2024	DP			
	>A>	7947017	Mar 12, 2028	DP			
	>A>	8016788	Mar 21, 2025	DP			
	>A>	8361029	Nov 23, 2024	DP			
EPINEPHRINE - AUVI-Q							
N201739 002	**>A>**	7731686	Jun 01, 2026	DP			
	>A>	7731690	Jan 15, 2025	DP			
	>A>	7749194	Oct 30, 2028	DP			
	>A>	7918823	Nov 23, 2024	DP			
	>A>	7947017	Mar 12, 2028	DP			
	>A>	8016788	Mar 21, 2025	DP			
	>A>	8361029	Nov 23, 2024	DP			
EPOPROSTENOL SODIUM - VELETRI							
N022260 001		8318802	Mar 15, 2027	DP			
EPOPROSTENOL SODIUM - VELETRI							
N022260 002		8318802	Mar 15, 2027	DP			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
ESZOPICLONE - LUNESTA						
N021476 001					M-61	Oct 10, 2015
					PED	Apr 10, 2016
ESZOPICLONE - LUNESTA						
N021476 002					M-61	Oct 10, 2015
					PED	Apr 10, 2016
ESZOPICLONE - LUNESTA						
N021476 003					M-61	Oct 10, 2015
					PED	Apr 10, 2016
EVEROLIMUS - ZORTRESS						
N021560 001					**>A>** I-668	Feb 15, 2016
EVEROLIMUS - ZORTRESS						
N021560 002					**>A>** I-668	Feb 15, 2016
EVEROLIMUS - ZORTRESS						
N021560 003					**>A>** I-668	Feb 15, 2016
FEBUXOSTAT - ULORIC						
N021856 001	**>A>** 8372872	Sep 08, 2031	U-1346			
FEBUXOSTAT - ULORIC						
N021856 002	**>A>** 8372872	Sep 08, 2031	U-1346			
FESOTERODINE FUMARATE - TOVIAZ						
N022030 001	8338478	May 11, 2019	DS DP U-913			
FESOTERODINE FUMARATE - TOVIAZ						
N022030 002	8338478	May 11, 2019	DS DP U-913			
FLUTICASONE FUROATE - VERAMYST						
N022051 001	8347879	Apr 01, 2027	DP			
GABAPENTIN - GRALISE						
N022544 001	8333992	Oct 25, 2022	DP U-1114			
GABAPENTIN - GRALISE						
N022544 002	8333992	Oct 25, 2022	DP U-1114			
GADOXETATE DISODIUM - EOVIST						
N022090 002					**>A>** NCE	Jul 03, 2013
GANIRELIX ACETATE - GANIRELIX ACETATE INJECTION						
N021057 001	**>A>** 6653286	Jun 16, 2018	U-1354			
GLYCEROL PHENYLBUTYRATE - RAVICTI						
N203284 001					**>A>** NE	Feb 01, 2016
ICOSAPENT ETHYL - VASCEPA						
N202057 001	8357677	Feb 09, 2030	U-1287			
	8367652	Feb 09, 2030	U-1287			
	>A> 8377920	Feb 09, 2030	U-1287			
IMATINIB MESYLATE - GLEEVEC						
N021588 001	7544799	Jan 16, 2019	DS DP	Y	I-666	Jan 25, 2016
	RE43932	Jan 16, 2019	DS DP			
	RE43932*PED	Jul 16, 2019				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
IMATINIB MESYLATE - GLEEVEC						
N021588 002	7544799	Jan 16, 2019	DS DP	Y	I-666	Jan 25, 2016
	RE43932	Jan 16, 2019	DS DP			
	RE43932*PED	Jul 16, 2019				
INGENOL MEBUTATE - PICATO						
N202833 001	**>A>** 8372827	Dec 18, 2026	DS DP			
	>A> 8372828	Dec 18, 2026	DS DP			
	>A> 8377919	Dec 18, 2026	DS DP			
INGENOL MEBUTATE - PICATO						
N202833 002	**>A>** 8372827	Dec 18, 2026	DS DP			
	>A> 8372828	Dec 18, 2026	DS DP			
	>A> 8377919	Dec 18, 2026	DS DP			
ISOTRETINOIN - ABSORICA						
N021951 001	**>A>** 8367102	Sep 21, 2021	U-1347			
ISOTRETINOIN - ABSORICA						
N021951 002	**>A>** 8367102	Sep 21, 2021	U-1347			
ISOTRETINOIN - ABSORICA						
N021951 003	**>A>** 8367102	Sep 21, 2021	U-1347			
ISOTRETINOIN - ABSORICA						
N021951 004	**>A>** 8367102	Sep 21, 2021	U-1347			
LEVALBUTEROL HYDROCHLORIDE - LEVALBUTEROL HYDROCHLORIDE						
A077756 001					**>A>** PC	Feb 16, 2013
LEVALBUTEROL HYDROCHLORIDE - LEVALBUTEROL HYDROCHLORIDE						
A077756 002					**>A>** PC	Feb 16, 2013
LEVALBUTEROL HYDROCHLORIDE - LEVALBUTEROL HYDROCHLORIDE						
A077756 003					**>A>** PC	Feb 16, 2013
LEVOLEUCOVORIN CALCIUM - FUSILEV						
N020140 001	6500829	Mar 07, 2022	DS DP			
LEVOLEUCOVORIN CALCIUM - FUSILEV						
N020140 002	6500829	Mar 07, 2022	DS DP			
LEVOLEUCOVORIN CALCIUM - FUSILEV						
N020140 003	6500829	Mar 07, 2022	DS DP			
LEVONORGESTREL - SKYLA						
N203159 001	5785053	Dec 05, 2015	DP		NP	Jan 09, 2016
	7252839	Nov 13, 2023	DP			
LOMITAPIDE MESYLATE - JUXTAPID						
N203858 001	**>A>** 5712279	Feb 21, 2015	DS U-1317		ODE	Dec 21, 2019
	>A> 7932268	Aug 19, 2027	U-1316			
LOMITAPIDE MESYLATE - JUXTAPID						
N203858 002	**>A>** 5712279	Feb 21, 2015	DS U-1317		ODE	Dec 21, 2019
	>A> 7932268	Aug 19, 2027	U-1316			
LOMITAPIDE MESYLATE - JUXTAPID						
N203858 003	**>A>** 5712279	Feb 21, 2015	DS U-1317		ODE	Dec 21, 2019
	>A> 7932268	Aug 19, 2027	U-1316			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
LOPINAVIR; RITONAVIR - KALETRA						
N021906 001	**>A>** 8025899	Dec 14, 2027	DP			
	>A> 8025899*PED	Jun 14, 2028				
LOPINAVIR; RITONAVIR - KALETRA						
N021906 002	**>A>** 8025899	Dec 14, 2027	DP			
	>A> 8025899*PED	Jun 14, 2028				
LOTEPREDNOL ETABONATE - LOTEMAX						
N202872 001	**>A>** 5800807	Jan 29, 2017	DP			
LUBIPROSTONE - AMITIZA						
N021908 001	**>A>** 8389542	Nov 14, 2022	DP U-1345			
MAGNESIUM SULFATE; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; POTASSIUM SULFATE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE - SUCLEAR						
N203595 001					NC	Jan 18, 2016
MIPOMERSEN SODIUM - KYNAMRO						
N203568 001	**>A>** 5914396	Jun 22, 2016	DS		NCE	Jan 29, 2018
	>A> 6166197	Dec 26, 2017	DS		**>A>** ODE	Jan 29, 2020
	>A> 6222025	Mar 06, 2015	DS			
	>A> 6451991	Feb 11, 2017	DS			
	>A> 7015315	Mar 21, 2023	DS			
	>A> 7101993	Sep 05, 2023	DS			
	>A> 7407943	Aug 01, 2021	U-1353			
	>A> 7511131	Dec 13, 2025	DS			
MUPIROCIN CALCIUM - BACTROBAN						
N050703 001	**>A>** 5569672	Oct 29, 2013	U-1357			
MUPIROCIN CALCIUM - BACTROBAN						
N050746 001	**>A>** 5569672	Oct 29, 2013	U-1358			
NEPAFENAC - NEPAFENAC						
N203491 001	**>A>** 5475034	Jun 06, 2014	U-100			
	>A> 6403609	Jul 17, 2018	DP			
	>A> 7947295	Jun 08, 2024	DP			
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021087 001					NPP	Dec 21, 2015
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021087 002					NPP	Dec 21, 2015
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021087 003					NPP	Dec 21, 2015
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021246 001					NPP	Dec 21, 2015
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021246 002					NPP	Dec 21, 2015
OSPEMIFENE - OSPHENA						
N203505 001					**>A>** NCE	Feb 26, 2018

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
OXYBUTYNIN - OXYTROL FOR WOMEN						
N202211 001	**>A>** 5601839	Apr 26, 2015	DP U-1329		NP	Jan 25, 2016
	>A> 5834010	Apr 26, 2015	DP U-1329			
	>A> 6743441	Apr 26, 2020	DP U-1329			
	>A> 7081249	Apr 26, 2020	DP U-1329			
	>A> 7081250	Apr 26, 2020	DP U-1329			
	>A> 7081251	Apr 26, 2020	DP U-1329			
	>A> 7081252	Apr 26, 2020	DP U-1329			
	>A> 7179483	Apr 26, 2020	U-1329			
PLERIXAFOR - MOZOBIL						
N022311 001	RE42152	Dec 10, 2018	DP			
POMALIDOMIDE - POMALYST						
N204026 001					**>A>** NCE	Feb 08, 2018
					>A> ODE	Feb 08, 2020
POMALIDOMIDE - POMALYST						
N204026 002					**>A>** NCE	Feb 08, 2018
					>A> ODE	Feb 08, 2020
POMALIDOMIDE - POMALYST						
N204026 003					**>A>** NCE	Feb 08, 2018
					>A> ODE	Feb 08, 2020
POMALIDOMIDE - POMALYST						
N204026 004					**>A>** NCE	Feb 08, 2018
					>A> ODE	Feb 08, 2020
PONATINIB HYDROCHLORIDE - ICLUSIG						
N203469 001					ODE	Dec 14, 2019
PONATINIB HYDROCHLORIDE - ICLUSIG						
N203469 002					ODE	Dec 14, 2019
PRALATREXATE - FOLOTYN						
N022468 001	6028071	Jul 16, 2022	DS DP U-1004			
PRALATREXATE - FOLOTYN						
N022468 002	6028071	Jul 16, 2022	DS DP U-1004			
PREGABALIN - LYRICA						
N022488 001					**>A>** I-651	Jun 20, 2015
REGORAFENIB - STIVARGA						
N203085 001					**>A>** I-667	Feb 25, 2016
SAPROPTERIN DIHYDROCHLORIDE - KUVAN						
N022181 001	8318745	Nov 17, 2024	DP			
SAQUINAVIR MESYLATE - INVIRASE						
N020628 001					M-61	Nov 30, 2015
					PED	May 30, 2016
SAQUINAVIR MESYLATE - INVIRASE						
N021785 001					M-61	Nov 30, 2015
					PED	May 30, 2016
SUMATRIPTAN SUCCINATE - SUMAVEL DOSEPRO						
N022239 001	8343130	Oct 18, 2022	DP			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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
SUMATRIPTAN SUCCINATE - ZECUITY						
N202278 001	**>A>** 6745071	Feb 21, 2023	DP		NDF	Jan 17, 2016
	>A> 7973058	Apr 12, 2027	U-1328			
	>A> 8155737	Apr 12, 2027	U-1328			
	>A> 8366600	Apr 21, 2029	U-1327			
TAPENTADOL HYDROCHLORIDE - NUCYNTA ER						
N200533 001	8114383	Oct 10, 2024	DP	Y		
TAPENTADOL HYDROCHLORIDE - NUCYNTA ER						
N200533 002	8114383	Oct 10, 2024	DP	Y		
TAPENTADOL HYDROCHLORIDE - NUCYNTA ER						
N200533 003	8114383	Oct 10, 2024	DP	Y		
TAPENTADOL HYDROCHLORIDE - NUCYNTA ER						
N200533 004	8114383	Oct 10, 2024	DP	Y		
TAPENTADOL HYDROCHLORIDE - NUCYNTA ER						
N200533 005	8114383	Oct 10, 2024	DP	Y		
TEDUGLUTIDE - GATTEX KIT						
N203441 001	5789379	Apr 14, 2015	DS DP U-1320		ODE	Dec 21, 2019
	7056886	Sep 18, 2022	DP U-1320			
	7847061	Nov 01, 2025	U-1320			
TELBIVUDINE - TYZEKA						
N022011 001					M-124	Jan 28, 2016
TELBIVUDINE - TYZEKA						
N022154 001					M-124	Jan 28, 2016
TESTOSTERONE - TESTOSTERONE						
N203098 001					NP	Jan 31, 2016
TESTOSTERONE - TESTOSTERONE						
N203098 002					NP	Jan 31, 2016
TESTOSTERONE - TESTOSTERONE						
N203098 003					NP	Jan 31, 2016
TIGECYCLINE - TYGACIL						
N021821 001	**>A>** 8372995	Oct 08, 2030	DP			
TOBRAMYCIN - BETHKIS						
N201820 001	6987094	Sep 22, 2022	DP			
	7696178	Mar 17, 2023	DP			
	7939502	Jun 14, 2022	U-1324			
TRAVOPROST - TRAVATAN Z						
N021994 001	**>A>** 8388941	Sep 20, 2027	DP			
TROSPIUM CHLORIDE - TROSPIUM CHLORIDE						
A091289 001					**>A>** PC	Apr 10, 2013
UNOPROSTONE ISOPROPYL - RESCULA						
N021214 001	6770675	Nov 24, 2018	DP U-1322			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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