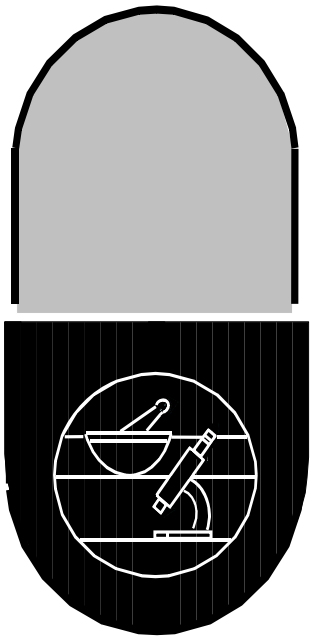
CUMULATIVE SUPPLEMENT 1
January 2012



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

32nd EDITION

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

2012

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

32nd EDITION

Cumulative Supplement 1

January 2012

CONTENTS

PAGE

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

32nd EDITION

CUMULATIVE SUPPLEMENT 1
January 2012

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 30th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 32nd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 33rd Edition. The current Edition Section 2., How To Use The Drug Product Lists, describes the layout and usage of the List.

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

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

- New Drug Application (NDA) approvals (20,000 and 50,000 series) appear in the CS month they were approved.

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

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

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at drugproducts@fda.hhs.gov. Send Changes by FAX: 240-276-8974; mail to:

FDA/CDER Orange Book Staff
Office of Generic Drugs, HFD-610
7620 Standish Place
Rockville, MD 20855-2773

1.3 APPLICANT NAME CHANGES

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

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

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

1.4 LEVOTHYROXINE SODIUM

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

Levothyroxine Sodium (Mylan ANDA 76187) and Levo-T (Alara NDA 21342) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets. Levo-T (Alara NDA 021342), Levothyroxine Sodium (Mylan ANDA 76187), Unithroid (Jerome Stevens NDA 021210), and Levothyroxine Sodium (Merck KGAA ANDA 76752)tablets have been determined to be therapeutically

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

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

Levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levothroid (Lloyd NDA 021116) tablets.

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

Trade Name	Applicant	Potency	TE Code	Appl No	Product No
UNITHROID	STEVENS J	0.025MG	AB1	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB1	76187	001
LEVOXYL	KING PHARMS	0.025MG	AB1	21301	001
SYNTHROID	ABBOTT	0.025MG	AB1	21402	001
LEVO-T	ALARA PHARM	0.025MG	AB1	21342	001
SYNTHROID	ABBOTT	0.025MG	AB2	21402	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB2	76187	001
LEVO-T	ALARA PHARM	0.025MG	AB2	21342	001
UNITHROID	STEVENS J	0.025MG	AB2	21210	001
LEVOTHYROXINE SODIUM	MERCK KGAA	0.025MG	AB2	76752	001
LEVOXYL	KUNG PHARMS	0.025MG	AB3	21301	001
LEVO-T	ALARA PHARM	0.025MG	AB3	21342	001
UNITHROID	STEVENS J	0.025MG	AB3	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB3	76187	001
LEVOTHYROXINE SODIUM	MERCK KGAA	0.025MG	AB3	76752	001
LEVOTHROID	LLOYD	0.025MG	AB4	21116	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB4	76187	001

1.5 AVAILABILITY OF THE EDITION

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

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Publications. The PDF annual and cumulative supplements duplicate previous paper

versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

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

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

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

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

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 2011) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

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

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

CATEGORIES COUNTED	DEC 2011	MAR 2012	JUN 2012	SEPT 2012	DEC 2012
DRUG PRODUCTS LISTED	14480				
SINGLE SOURCE	2451 (16.9%)				
MULTISOURCE	11953 (82.5%)				
THERAPEUTICALLY EQUIVALENT	11792 (81.4%)				
NOT THERAPEUTICALLY EQUIVALENT	161 (1.1%)				
EXCEPTIONS[1]	76 (0.5%)				
NEW MOLECULAR ENTITIES APPROVED	6				
NUMBER OF APPLICANTS	810				

[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.

ACARBOSE

TABLET; ORAL
ACARBOSE

>A>	AB	EMCURE PHARMS LTD	25MG	A202271	001	Feb 07, 2012	Jan	NEWA
>A>	AB		50MG	A202271	002	Feb 07, 2012	Jan	NEWA
>A>	AB		100MG	A202271	003	Feb 07, 2012	Jan	NEWA

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE

>D>	AA	PHARM ASSOC	120MG/5ML;12MG/5ML	A087508	001		Jan	CRLD
>A>	AA	+	120MG/5ML;12MG/5ML	A087508	001		Jan	CRLD

SUSPENSION; ORAL
CAPITAL AND CODEINE

>D>	AA	+ VALEANT	120MG/5ML;12MG/5ML	A086024	001		Jan	CTEC
>A>		+	120MG/5ML;12MG/5ML	A086024	001		Jan	CTEC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>A>	AA	VISTAPHARM	325MG/15ML;7.5MG/15ML	A200343	001	Jan 25, 2012	Jan	NEWA

ADAPALENE

CREAM; TOPICAL
ADAPALENE

>A>	AB	FOUGERA PHARMS	0.1%	A090824	001	Jun 30, 2010	Jan	CAHN
>D>	AB	NYCOMED US	0.1%	A090824	001	Jun 30, 2010	Jan	CAHN

ADENOSINE

INJECTABLE; INJECTION
ADENOSINE

>D>	AP	TEVA PARENTERAL	3MG/ML	A076564	001	Jun 16, 2004	Jan	DISC
>A>		@	3MG/ML	A076564	001	Jun 16, 2004	Jan	DISC

ALCLOMETASONE DIPROPIONATE

CREAM; TOPICAL
ALCLOMETASONE DIPROPIONATE

>D>	AB	ALTANA	0.05%	A076973	001	Jul 12, 2005	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.05%	A076973	001	Jul 12, 2005	Jan	CAHN

OINTMENT; TOPICAL
ALCLOMETASONE DIPROPIONATE

>D>	AB	ALTANA	0.05%	A076884	001	Jul 18, 2005	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.05%	A076884	001	Jul 18, 2005	Jan	CAHN

ALFUZOSIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
ALFUZOSIN HYDROCHLORIDE

>A>	AB	INVAGEN PHARMS	10MG	A090284	001	Jan 17, 2012	Jan	NEWA

ALPRAZOLAM

TABLET, ORALLY DISINTEGRATING; ORAL
NIRAVAM

>D>	AB	SCHWARZ PHARMA	0.25MG	N021726	001	Jan 19, 2005	Jan	CAHN

TABLET, ORALLY DISINTEGRATING; ORAL
NIRAVAM

>D>	AB		SCHWARZ PHARMA	0.5MG	N021726	002	Jan 19, 2005	Jan	CAHN
>D>	AB	+		1MG	N021726	003	Jan 19, 2005	Jan	CAHN
>D>	AB			2MG	N021726	004	Jan 19, 2005	Jan	CAHN
>A>	AB		UCB INC	0.25MG	N021726	001	Jan 19, 2005	Jan	CAHN
>A>	AB			0.5MG	N021726	002	Jan 19, 2005	Jan	CAHN
>A>	AB	+		1MG	N021726	003	Jan 19, 2005	Jan	CAHN
>A>	AB			2MG	N021726	004	Jan 19, 2005	Jan	CAHN

AMCINONIDE

CREAM; TOPICAL
AMCINONIDE

>D>	AB	+	ALTANA	0.1%	A076065	001	May 15, 2003	Jan	CAHN
>A>	AB	+	FOUGERA PHARMS	0.1%	A076065	001	May 15, 2003	Jan	CAHN

LOTION; TOPICAL
AMCINONIDE

>D>		+	ALTANA	0.1%	A076329	001	Nov 06, 2002	Jan	CAHN
>A>		+	FOUGERA PHARMS	0.1%	A076329	001	Nov 06, 2002	Jan	CAHN

OINTMENT; TOPICAL
AMCINONIDE

>D>	AB	+	ALTANA	0.1%	A076096	001	Nov 19, 2002	Jan	CAHN
>A>	AB	+	FOUGERA PHARMS	0.1%	A076096	001	Nov 19, 2002	Jan	CAHN

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION
AMIODARONE HYDROCHLORIDE

>D>	AP	+	TEVA PARENTERAL	50MG/ML	A076163	001	Sep 05, 2003	Jan	DISC
>A>			@	50MG/ML	A076163	001	Sep 05, 2003	Jan	DISC

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL
AMOXICILLIN AND CLAVULANATE POTASSIUM

>A>	AB		AUROBINDO PHARMA LTD	250MG;EQ 125MG BASE	A091569	001	Jan 20, 2012	Jan	NEWA
>A>	AB			500MG;EQ 125MG BASE	A091569	002	Jan 20, 2012	Jan	NEWA
>A>	AB			875MG;EQ 125MG BASE	A091568	001	Jan 20, 2012	Jan	NEWA

ANAGRELIDE HYDROCHLORIDE

CAPSULE; ORAL
AGRYLIN

>D>	AB		SHIRE	EQ 0.5MG BASE	N020333	001	Mar 14, 1997	Jan	CAHN
>A>	AB		SHIRE LLC	EQ 0.5MG BASE	N020333	001	Mar 14, 1997	Jan	CAHN

ARGATROBAN

INJECTABLE; INJECTION
>A> ACOVA

>A>	AP	+	PFIZER	250MG/2.5ML (100MG/ML)	N020883	001	Jun 30, 2000	Jan	CTNA

>A> ARGATROBAN

>A>	AP		HIKMA PHARM CO LTD	250MG/2.5ML (100MG/ML)	N203049	001	Jan 05, 2012	Jan	NEWA
>D>		+	PFIZER	100MG/ML	N020883	001	Jun 30, 2000	Jan	CTNA

ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE

FOR SOLUTION; ORAL

>A>			ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE							
>A>	AA		NOVEL LABS INC	4.7GM;100GM;1.015GM;5.9MG;2.691GM;7.5GM	A090145	001	Jan 25, 2012	Jan	NEWA
			MOVIPREP							
>D>		+	SALIX PHARMS	4.7GM;100GM;1.015GM;5.9GM;2.691GM;7.5GM	N021881	001	Aug 02, 2006	Jan	CFTG
>A>	AA	+		4.7GM;100GM;1.015GM;5.9GM;2.691GM;7.5GM	N021881	001	Aug 02, 2006	Jan	CFTG

>A> AXITINIB

>A> TABLET; ORAL

>A> INLYTA

>A>			PFIZER	1MG	N202324	001	Jan 27, 2012	Jan	NEWA
>A>		+		5MG	N202324	002	Jan 27, 2012	Jan	NEWA

BACLOFEN

TABLET, ORALLY DISINTEGRATING; ORAL

KEMSTRO

>D>			@ SCHWARZ PHARMA	10MG	N021589	001	Oct 30, 2003	Jan	CAHN
>D>			@	20MG	N021589	002	Oct 30, 2003	Jan	CAHN
>A>			@ UCB INC	10MG	N021589	001	Oct 30, 2003	Jan	CAHN
>A>			@	20MG	N021589	002	Oct 30, 2003	Jan	CAHN

BENZOYL PEROXIDE; ERYTHROMYCIN

GEL; TOPICAL

BENZAMYCIN

>D>	AB	+	SANOFI AVENTIS US	5%;3%	N050557	001	Oct 26, 1984	Jan	CAHN
>A>	AB	+	VALEANT INTL	5%;3%	N050557	001	Oct 26, 1984	Jan	CAHN

BENZPHETAMINE HYDROCHLORIDE

TABLET; ORAL

BENZPHETAMINE HYDROCHLORIDE

>A>	AA		EMCURE PHARMS LTD	50MG	A202061	001	Jan 27, 2012	Jan	NEWA

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

>D>	AA	+	LANNETT	0.5MG	A088877	001	Apr 11, 1985	Jan	DISC
>D>	AA	+		1MG	A088894	001	Apr 11, 1985	Jan	DISC
>D>	AA	+		2MG	A088895	001	Apr 11, 1985	Jan	DISC
>A>			@ LANNETT HOLDINGS INC	0.5MG	A088877	001	Apr 11, 1985	Jan	DISC
>A>			@	1MG	A088894	001	Apr 11, 1985	Jan	DISC
>A>			@	2MG	A088895	001	Apr 11, 1985	Jan	DISC
>D>	AA		USL PHARMA	0.5MG	A040103	001	Dec 12, 1996	Jan	CRLD
>A>	AA	+		0.5MG	A040103	001	Dec 12, 1996	Jan	CRLD
>D>	AA			1MG	A040103	002	Dec 12, 1996	Jan	CRLD
>A>	AA	+		1MG	A040103	002	Dec 12, 1996	Jan	CRLD
>D>	AA			2MG	A040103	003	Dec 12, 1996	Jan	CRLD
>A>	AA	+		2MG	A040103	003	Dec 12, 1996	Jan	CRLD

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL
BETAMETHASONE DIPROPIONATE

>D>	AB	+	FOUGERA	EQ 0.05% BASE	N019137	001	Jun 26, 1984	Jan	CAHN
>A>	AB	+	FOUGERA PHARMS	EQ 0.05% BASE	N019137	001	Jun 26, 1984	Jan	CAHN

CREAM, AUGMENTED; TOPICAL
BETAMETHASONE DIPROPIONATE

>D>	AB		ALTANA	EQ 0.05% BASE	A076215	001	Dec 09, 2003	Jan	CAHN
>A>	AB		FOUGERA PHARMS	EQ 0.05% BASE	A076215	001	Dec 09, 2003	Jan	CAHN

GEL, AUGMENTED; TOPICAL
BETAMETHASONE DIPROPIONATE

>D>	AB	+	ALTANA	EQ 0.05% BASE	A075276	001	May 13, 2003	Jan	CAHN
>A>	AB	+	FOUGERA PHARMS	EQ 0.05% BASE	A075276	001	May 13, 2003	Jan	CAHN

LOTION, AUGMENTED; TOPICAL
BETAMETHASONE DIPROPIONATE

>D>	AB		ALTANA	EQ 0.05% BASE	A077111	001	May 21, 2007	Jan	CAHN
>A>	AB		FOUGERA PHARMS	EQ 0.05% BASE	A077111	001	May 21, 2007	Jan	CAHN

OINTMENT, AUGMENTED; TOPICAL
BETAMETHASONE DIPROPIONATE

>D>	AB		ALTANA	EQ 0.05% BASE	A075373	001	Jun 22, 1999	Jan	CAHN
>A>	AB		FOUGERA PHARMS	EQ 0.05% BASE	A075373	001	Jun 22, 1999	Jan	CAHN

BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE

CREAM; TOPICAL
CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE

>D>	AB		ALTANA	EQ 0.05% BASE;1%	A075502	001	Jun 05, 2001	Jan	CAHN
>A>	AB		FOUGERA PHARMS	EQ 0.05% BASE;1%	A075502	001	Jun 05, 2001	Jan	CAHN

LOTION; TOPICAL
CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE

>D>	AB		ALTANA PHARMA	EQ 0.05% BASE;1%	A076516	001	Jun 16, 2005	Jan	CAHN
>A>	AB		FOUGERA PHARMS	EQ 0.05% BASE;1%	A076516	001	Jun 16, 2005	Jan	CAHN

BETAMETHASONE VALERATE

AEROSOL, FOAM; TOPICAL
LUXIQ

>D>		+	CONNECTICS	EQ 0.12% BASE	N020934	001	Feb 28, 1999	Jan	CAHN
>A>		+	STIEFEL	EQ 0.12% BASE	N020934	001	Feb 28, 1999	Jan	CAHN

BISOPROLOL FUMARATE

TABLET; ORAL
ZEBETA

>D>	AB		DURAMED PHARMS BARR	5MG	N019982	002	Jul 31, 1992	Jan	CAHN
>D>	AB	+		10MG	N019982	001	Jul 31, 1992	Jan	CAHN
>A>	AB		TEVA WOMENS	5MG	N019982	002	Jul 31, 1992	Jan	CAHN
>A>	AB	+		10MG	N019982	001	Jul 31, 1992	Jan	CAHN

BORTEZOMIB

>D> INJECTABLE; INTRAVENOUS
>D> VELCADE

>D>		+	MILLENNIUM PHARMS	3.5MG/VIAL	N021602	001	May 13, 2003	Jan	CDFR

>A> INJECTABLE; INTRAVENOUS, SUBCUTANEOUS
>A> VELCADE

>A>		+	MILLENNIUM PHARMS	3.5MG/VIAL	N021602	001	May 13, 2003	Jan	CDFR

BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE

>A>			AEROSOL, METERED; INHALATION						
>A>			SYMBICORT						
>A>		+	ASTRAZENECA	0.08MG/INH;0.0045MG/INH	N021929	001	Jul 21, 2006	Jan	CDFR
>A>		+		0.16MG/INH;0.0045MG/INH	N021929	002	Jul 21, 2006	Jan	CDFR
>D>			SPRAY, METERED; INHALATION						
>D>			SYMBICORT						
>D>		+	ASTRAZENECA	0.08MG/INH;0.0045MG/INH	N021929	001	Jul 21, 2006	Jan	CDFR
>D>		+		0.16MG/INH;0.0045MG/INH	N021929	002	Jul 21, 2006	Jan	CDFR

CAFFEINE CITRATE

			SOLUTION; INTRAVENOUS						
			CAFCIT						
>A>	AP	+	BEDFORD LABS	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	N020793	001	Sep 21, 1999	Jan	CAHN
>D>	AP	+	MEAD JOHNSON	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	N020793	001	Sep 21, 1999	Jan	CAHN
			SOLUTION; ORAL						
			CAFCIT						
>A>	AA	+	BEDFORD LABS	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	N020793	002	Apr 12, 2000	Jan	CAHN
>D>	AA	+	MEAD JOHNSON	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	N020793	002	Apr 12, 2000	Jan	CAHN

CALCIPOTRIENE

			SOLUTION; TOPICAL						
			CALCIPOTRIENE						
>A>	AT		FOUGERA PHARMS	0.005%	A078305	001	May 06, 2008	Jan	CAHN
>D>	AT		NYCOMED US	0.005%	A078305	001	May 06, 2008	Jan	CAHN

CARBIDOPA; LEVODOPA

			TABLET, ORALLY DISINTEGRATING; ORAL						
			PARCOPA						
>D>	AB		SCHWARZ PHARMA	10MG;100MG	A076699	001	Aug 27, 2004	Jan	CAHN
>D>	AB			25MG;100MG	A076699	002	Aug 27, 2004	Jan	CAHN
>D>	AB	+		25MG;250MG	A076699	003	Aug 27, 2004	Jan	CAHN
>A>	AB		UCB INC	10MG;100MG	A076699	001	Aug 27, 2004	Jan	CAHN
>A>	AB			25MG;100MG	A076699	002	Aug 27, 2004	Jan	CAHN
>A>	AB	+		25MG;250MG	A076699	003	Aug 27, 2004	Jan	CAHN

CARBOPLATIN

			INJECTABLE; IV (INFUSION)						
			CARBOPLATIN						
>A>	AP		ACTAVIS TOTOWA	50MG/5ML (10MG/ML)	A078732	001	Feb 06, 2012	Jan	NEWA
>A>	AP			150MG/15ML (10MG/ML)	A078732	002	Feb 06, 2012	Jan	NEWA
>A>	AP			450MG/45ML (10MG/ML)	A078732	003	Feb 06, 2012	Jan	NEWA
>A>	AP			600MG/60ML (10MG/ML)	A078732	004	Feb 06, 2012	Jan	NEWA

CICLESONIDE

			AEROSOL, METERED; NASAL						
>A>			ZETONNA						
>A>		+	NYCOMED GMBH	0.037MG/INH	N202129	001	Jan 20, 2012	Jan	NEWA

CICLOPIROX

CREAM; TOPICAL
CICLOPIROX

>D>	AB	ALTANA	0.77%	A076435	001	Dec 29, 2004	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.77%	A076435	001	Dec 29, 2004	Jan	CAHN

GEL; TOPICAL
CICLOPIROX

>A>	AB	FOUGERA PHARMS	0.77%	A077896	001	Jun 10, 2008	Jan	CAHN
>D>	AB	NYCOMED US	0.77%	A077896	001	Jun 10, 2008	Jan	CAHN

SHAMPOO; TOPICAL
CICLOPIROX

>A>	AT	FOUGERA PHARMS	1%	A090146	001	May 25, 2010	Jan	CAHN
>D>	AT	NYCOMED US	1%	A090146	001	May 25, 2010	Jan	CAHN

SUSPENSION; TOPICAL
CICLOPIROX

>D>	AB	ALTANA	0.77%	A076422	001	Aug 06, 2004	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.77%	A076422	001	Aug 06, 2004	Jan	CAHN

CIPROFLOXACIN

INJECTABLE; INJECTION
CIPROFLOXACIN

>D>	AP	TEVA PARENTERAL	400MG/40ML (10MG/ML)	A077782	002	Aug 28, 2006	Jan	DISC
>A>		@	400MG/40ML (10MG/ML)	A077782	002	Aug 28, 2006	Jan	DISC

CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL
CIPROFLOXACIN HYDROCHLORIDE

>D>	BX	PLIVA	EQ 100MG BASE	A076426	001	Jun 15, 2005	Jan	DISC
>A>		@	EQ 100MG BASE	A076426	001	Jun 15, 2005	Jan	DISC
>D>	BX		EQ 250MG BASE	A076426	002	Jun 15, 2005	Jan	DISC
>A>		@	EQ 250MG BASE	A076426	002	Jun 15, 2005	Jan	DISC
>D>	BX		EQ 500MG BASE	A076426	003	Jun 15, 2005	Jan	DISC
>A>		@	EQ 500MG BASE	A076426	003	Jun 15, 2005	Jan	DISC
>D>	BX		EQ 750MG BASE	A076426	004	Jun 15, 2005	Jan	DISC
>A>		@	EQ 750MG BASE	A076426	004	Jun 15, 2005	Jan	DISC

CISATRACURIUM BESYLATE

INJECTABLE; INJECTION
>A> CISATRACURIUM BESYLATE

>A>	AP	SANDOZ INC	EQ 2MG BASE/ML	A200159	001	Feb 03, 2012	Jan	NEWA

>A> CISATRACURIUM BESYLATE PRESERVATIVE FREE

>A>	AP	SANDOZ INC	EQ 2MG BASE/ML	A200154	001	Feb 03, 2012	Jan	NEWA
>A>	AP		EQ 10MG BASE/ML	A200154	002	Feb 03, 2012	Jan	NEWA

NIMBEX

>D>	+	ABBOTT	EQ 2MG BASE/ML	N020551	001	Dec 15, 1995	Jan	CFTG
>A>	AP +		EQ 2MG BASE/ML	N020551	001	Dec 15, 1995	Jan	CFTG

NIMBEX PRESERVATIVE FREE

>D>	+	ABBOTT	EQ 2MG BASE/ML	N020551	003	Dec 15, 1995	Jan	CFTG
>A>	AP +		EQ 2MG BASE/ML	N020551	003	Dec 15, 1995	Jan	CFTG
>D>	+		EQ 10MG BASE/ML	N020551	002	Dec 15, 1995	Jan	CFTG
>A>	AP +		EQ 10MG BASE/ML	N020551	002	Dec 15, 1995	Jan	CFTG

CLINDAMYCIN PHOSPHATE

CREAM; VAGINAL
CLINDAMYCIN PHOSPHATE

>A>	AB		FOUGERA PHARMS	EQ 2% BASE	A065139	001	Dec 27, 2004	Jan	CAHN
>D>	AB		NYCOMED US	EQ 2% BASE	A065139	001	Dec 27, 2004	Jan	CAHN

GEL; TOPICAL
CLINDAMYCIN PHOSPHATE

>D>	AB		ALTANA	EQ 1% BASE	A064160	001	Jan 28, 2000	Jan	CAHN
>A>	AB		FOUGERA PHARMS	EQ 1% BASE	A064160	001	Jan 28, 2000	Jan	CAHN

LOTION; TOPICAL
CLINDAMYCIN PHOSPHATE

>D>	AB		ALTANA	EQ 1% BASE	A065067	001	Jan 31, 2002	Jan	CAHN
>A>	AB		FOUGERA PHARMS	EQ 1% BASE	A065067	001	Jan 31, 2002	Jan	CAHN

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

>D>	AT		ALTANA	EQ 1% BASE	A065254	001	Feb 14, 2006	Jan	CAHN
>A>	AT		FOUGERA PHARMS	EQ 1% BASE	A065254	001	Feb 14, 2006	Jan	CAHN

CLOBETASOL PROPIONATE

CREAM; TOPICAL
CLOBETASOL PROPIONATE (EMOLLIENT)

>D>	AB2		ALTANA	0.05%	A075430	001	May 26, 1999	Jan	CAHN
>A>	AB2		FOUGERA PHARMS	0.05%	A075430	001	May 26, 1999	Jan	CAHN

TEMOVATE

>A>	AB1	+	FOUGERA PHARMS	0.05%	N019322	001	Dec 27, 1985	Jan	CAHN
>D>	AB1	+	NYCOMED US	0.05%	N019322	001	Dec 27, 1985	Jan	CAHN

GEL; TOPICAL
CLOBETASOL PROPIONATE

>D>	AB		ALTANA	0.05%	A075368	001	Feb 15, 2000	Jan	CAHN
>A>	AB		FOUGERA PHARMS	0.05%	A075368	001	Feb 15, 2000	Jan	CAHN

TEMOVATE

>A>	AB	+	FOUGERA PHARMS	0.05%	N020337	001	Apr 29, 1994	Jan	CAHN
>D>	AB	+	NYCOMED US	0.05%	N020337	001	Apr 29, 1994	Jan	CAHN

OINTMENT; TOPICAL
CLOBETASOL PROPIONATE

>A>	AB		FOUGERA PHARMS	0.05%	A074407	001	Feb 23, 1996	Jan	CAHN
>D>	AB		NYCOMED US	0.05%	A074407	001	Feb 23, 1996	Jan	CAHN

TEMOVATE

>A>	AB	+	FOUGERA PHARMS	0.05%	N019323	001	Dec 27, 1985	Jan	CAHN
>D>	AB	+	NYCOMED US	0.05%	N019323	001	Dec 27, 1985	Jan	CAHN

SOLUTION; TOPICAL
CLOBETASOL PROPIONATE

>A>	AT		FOUGERA PHARMS	0.05%	A075391	001	Feb 08, 1999	Jan	CAHN
>D>	AT		NYCOMED US	0.05%	A075391	001	Feb 08, 1999	Jan	CAHN

TEMOVATE

>A>	AT	+	FOUGERA PHARMS	0.05%	N019966	001	Feb 22, 1990	Jan	CAHN
>D>	AT	+	NYCOMED US	0.05%	N019966	001	Feb 22, 1990	Jan	CAHN

CLOTRIMAZOLE

CREAM; TOPICAL
CLOTRIMAZOLE

>A>	AB		FOUGERA PHARMS	1%	A078338	001	Sep 02, 2008	Jan	CAHN
>D>	AB		NYCOMED US	1%	A078338	001	Sep 02, 2008	Jan	CAHN

CYTARABINE

INJECTABLE; INJECTION

CYTARABINE

>A>	AP	ONCO THERAPIES LTD	100MG/ML	A201784	001	Jan 30, 2012	Jan	NEWA

DESLORATADINE

TABLET; ORAL

DESLORATADINE

>A>	AB	MYLAN PHARMS INC	5MG	A078351	001	Feb 10, 2012	Jan	NEWA

DESONIDE

LOTION; TOPICAL

DESONIDE

>D>	AB	ALTANA	0.05%	A075860	001	Mar 19, 2002	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.05%	A075860	001	Mar 19, 2002	Jan	CAHN

OINTMENT; TOPICAL

DESONIDE

>D>	AB	ALTANA	0.05%	A075751	001	Mar 12, 2001	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.05%	A075751	001	Mar 12, 2001	Jan	CAHN

DESOXIMETASONE

CREAM; TOPICAL

DESOXIMETASONE

>A>	AB	FOUGERA PHARMS	0.25%	A078369	001	Jun 29, 2010	Jan	CAHN
>D>	AB	NYCOMED US	0.25%	A078369	001	Jun 29, 2010	Jan	CAHN

DIFLORASONE DIACETATE

CREAM; TOPICAL

DIFLORASONE DIACETATE

>D>	BX	+	ALTANA	0.05%	A076263	001	Dec 20, 2002	Jan	CAHN
>D>	AB1	+		0.05%	A075187	001	Mar 30, 1998	Jan	CAHN
>A>	AB1	+	FOUGERA PHARMS	0.05%	A075187	001	Mar 30, 1998	Jan	CAHN
>A>	BX	+		0.05%	A076263	001	Dec 20, 2002	Jan	CAHN

OINTMENT; TOPICAL

DIFLORASONE DIACETATE

>D>	AB	ALTANA	0.05%	A075374	001	Apr 27, 1999	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.05%	A075374	001	Apr 27, 1999	Jan	CAHN

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION

DILTIAZEM HYDROCHLORIDE

>D>	AP	TEVA PARENTERAL	5MG/ML	A074894	001	Aug 26, 1997	Jan	DISC
>A>		@	5MG/ML	A074894	001	Aug 26, 1997	Jan	DISC

DIPYRIDAMOLE

INJECTABLE; INJECTION

DIPYRIDAMOLE

>D>	AP	TEVA PARENTERAL	5MG/ML	A074952	001	Nov 26, 1997	Jan	DISC
>A>		@	5MG/ML	A074952	001	Nov 26, 1997	Jan	DISC

DOCETAXEL

INJECTABLE; INJECTION

DOCETAXEL

>D>		ACCORD HLTHCARE	20MG/0.5ML (40MG/ML)	N201195	001	Jun 08, 2011	Jan	CTEC
>A>	AP		20MG/0.5ML (40MG/ML)	N201195	001	Jun 08, 2011	Jan	CTEC

INJECTABLE; INJECTION
DOCETAXEL

>D>		ACCORD HLTHCARE	80MG/2ML (40MG/ML)	N201195	002	Jun 08, 2011	Jan	CTEC
>A>	AP		80MG/2ML (40MG/ML)	N201195	002	Jun 08, 2011	Jan	CTEC
>A>	AP	APOTEX INC	20MG/0.5ML (40MG/ML)	N022312	001	Jan 11, 2012	Jan	NEWA
>A>	AP		80MG/2ML (40MG/ML)	N022312	002	Jan 11, 2012	Jan	NEWA

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL
ZONALON

>A>	+	FOUGERA PHARMS	5%	N020126	001	Apr 01, 1994	Jan	CAHN
>D>	+	NYCOMED US	5%	N020126	001	Apr 01, 1994	Jan	CAHN

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DOXORUBICIN HYDROCHLORIDE

>A>	AP	ONCO THERAPIES LTD	2MG/ML	A200901	001	Feb 14, 2012	Jan	NEWA
>A>	AP	SUN PHARM INDS	2MG/ML	A091418	001	Feb 15, 2012	Jan	NEWA

INJECTABLE, LIPOSOMAL; INJECTION
DOXIL

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

DOXYCYCLINE HYCLATE

TABLET, DELAYED RELEASE; ORAL
DORYX

>D>	+	MAYNE PHARMA	EQ 150MG BASE	N050795	003	Jun 20, 2008	Jan	CTEC
>A>	AB +		EQ 150MG BASE	N050795	003	Jun 20, 2008	Jan	CTEC

DOXYCYCLINE HYCLATE

>A>	AB	MYLAN PHARMS INC	EQ 150MG BASE	A091052	001	Feb 08, 2012	Jan	NEWA

ECONAZOLE NITRATE

CREAM; TOPICAL
ECONAZOLE NITRATE

>D>	AB +	ALTANA	1%	A076075	001	Nov 26, 2002	Jan	CAHN
>A>	AB +	FOUGERA PHARMS	1%	A076075	001	Nov 26, 2002	Jan	CAHN

ENALAPRIL MALEATE

TABLET; ORAL
ENALAPRIL MALEATE

>D>	AB	LEK PHARMS	2.5MG	A075496	001	Aug 22, 2000	Jan	DISC
>D>	AB		5MG	A075496	002	Aug 22, 2000	Jan	DISC
>D>	AB		10MG	A075459	001	Aug 22, 2000	Jan	DISC
>D>	AB		20MG	A075459	002	Aug 22, 2000	Jan	DISC
>A>		@ SANDOZ INC	2.5MG	A075496	001	Aug 22, 2000	Jan	DISC
>A>		@	5MG	A075496	002	Aug 22, 2000	Jan	DISC
>A>		@	10MG	A075459	001	Aug 22, 2000	Jan	DISC
>A>		@	20MG	A075459	002	Aug 22, 2000	Jan	DISC

ERYTHROMYCIN

GEL; TOPICAL
ERYTHROMYCIN

>D>	AT	ALTANA	2%	A064184	001	Sep 30, 1997	Jan	CAHN
>A>	AT	FOUGERA PHARMS	2%	A064184	001	Sep 30, 1997	Jan	CAHN

			SOLUTION; TOPICAL						
			C-SOLVE-2						
>D>			@ BIOGLAN PHARMA	2%	A062468	001	Jul 03, 1985	Jan	CMFD
>A>	AT		FOUGERA PHARMS	2%	A062468	001	Jul 03, 1985	Jan	CMFD
			SWAB; TOPICAL						
			ERYTHROMYCIN						
>D>	AT	+	ALTANA	2%	A065320	001	Jul 25, 2006	Jan	CAHN
>A>	AT	+	FOUGERA PHARMS	2%	A065320	001	Jul 25, 2006	Jan	CAHN
			ETHINYL ESTRADIOL; NORETHINDRONE						
			TABLET; ORAL-28						
>A>			ALYACEN 1/35						
>A>	AB		GLENMARK GENERICS	0.035MG;1MG	A091634	001	Jan 19, 2012	Jan	NEWA
>A>			ALYACEN 7/7/7						
>A>	AB		GLENMARK GENERICS	0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG	A091636	001	Jan 19, 2012	Jan	NEWA
			EXENATIDE SYNTHETIC						
>A>			FOR SUSPENSION, EXTENDED RELEASE; SUBCUTANEOUS						
>A>			BYDUREON						
>A>		+	AMYLIN	2MG/VIAL	N022200	001	Jan 27, 2012	Jan	NEWA
			EZETIMIBE						
			TABLET; ORAL						
			ZETIA						
>D>		+	MSP SINGAPORE	10MG	N021445	001	Oct 25, 2002	Jan	CAHN
>A>		+		10MG	N021445	001	Oct 25, 2002	Jan	CAHN
			EZETIMIBE; SIMVASTATIN						
			TABLET; ORAL						
			VYTORIN						
>D>			MSD INTL	10MG;10MG	N021687	001	Jul 23, 2004	Jan	CAHN
>A>				10MG;10MG	N021687	001	Jul 23, 2004	Jan	CAHN
>D>				10MG;20MG	N021687	002	Jul 23, 2004	Jan	CAHN
>A>				10MG;20MG	N021687	002	Jul 23, 2004	Jan	CAHN
>D>				10MG;40MG	N021687	003	Jul 23, 2004	Jan	CAHN
>A>				10MG;40MG	N021687	003	Jul 23, 2004	Jan	CAHN
>D>		+		10MG;80MG	N021687	004	Jul 23, 2004	Jan	CAHN
>A>		+		10MG;80MG	N021687	004	Jul 23, 2004	Jan	CAHN
			FAMCICLOVIR						
			TABLET; ORAL						
			FAMCICLOVIR						
>A>	AB		MACLEODS PHARMS LTD	125MG	A201022	001	Jan 12, 2012	Jan	NEWA
>A>	AB			250MG	A201022	002	Jan 12, 2012	Jan	NEWA
>A>	AB			500MG	A201022	003	Jan 12, 2012	Jan	NEWA
			FAMOTIDINE						
			TABLET; ORAL						
			PEPCID						
>A>	AB		MARATHON PHARMS	20MG	N019462	001	Oct 15, 1986	Jan	CAHN
>A>	AB	+		40MG	N019462	002	Oct 15, 1986	Jan	CAHN
>D>	AB		MERCK	20MG	N019462	001	Oct 15, 1986	Jan	CAHN
>D>	AB	+		40MG	N019462	002	Oct 15, 1986	Jan	CAHN

TABLET, ORALLY DISINTEGRATING; ORAL
FLUXID

>D>		@ SCHWARZ PHARMA	20MG	N021712	001	Sep 24, 2004	Jan	CAHN
>D>		@	40MG	N021712	002	Sep 24, 2004	Jan	CAHN
>A>		@ UCB INC	20MG	N021712	001	Sep 24, 2004	Jan	CAHN
>A>		@	40MG	N021712	002	Sep 24, 2004	Jan	CAHN

>A> FENTANYL

SPRAY; SUBLINGUAL
SUBSYS

>A>		INSYS THERAP	0.1MCG	N202788	001	Jan 04, 2012	Jan	NEWA
>A>			0.2MCG	N202788	002	Jan 04, 2012	Jan	NEWA
>A>	+		0.4MCG	N202788	003	Jan 04, 2012	Jan	NEWA
>A>			0.6MCG	N202788	004	Jan 04, 2012	Jan	NEWA
>A>			0.8MCG	N202788	005	Jan 04, 2012	Jan	NEWA

FENTANYL CITRATE

SPRAY, METERED; NASAL
LAZANDA

>D>		ARCHIMEDES	100MCG	N022569	001	Jun 30, 2011	Jan	CPOT
>A>			EQ 0.1MG BASE	N022569	001	Jun 30, 2011	Jan	CPOT
>D>	+		400MCG	N022569	002	Jun 30, 2011	Jan	CPOT
>A>	+		EQ 0.4MG BASE	N022569	002	Jun 30, 2011	Jan	CPOT

FLUCONAZOLE

INJECTABLE; INJECTION
FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER

>A>	AP	HIKMA FARMACEUTICA	200MG/100ML (2MG/ML)	A078764	001	Jan 30, 2012	Jan	NEWA
>A>	AP		400MG/200ML (2MG/ML)	A078764	002	Jan 30, 2012	Jan	NEWA

FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

>A>	AP	HIKMA FARMACEUTICA	200MG/100ML (2MG/ML)	A078698	001	Jan 30, 2012	Jan	NEWA
>A>	AP		400MG/200ML (2MG/ML)	A078698	002	Jan 30, 2012	Jan	NEWA

FLUMAZENIL

INJECTABLE; INJECTION
FLUMAZENIL

>D>	AP	TEVA PARENTERAL	0.5MG/5ML (0.1MG/ML)	A076589	002	Oct 12, 2004	Jan	DISC
>A>		@	0.5MG/5ML (0.1MG/ML)	A076589	002	Oct 12, 2004	Jan	DISC
>D>	AP		1MG/10ML (0.1MG/ML)	A076589	001	Oct 12, 2004	Jan	DISC
>A>		@	1MG/10ML (0.1MG/ML)	A076589	001	Oct 12, 2004	Jan	DISC

FLUOCINOLONE ACETONIDE

OIL/DROPS; OTIC
FLUOCINOLONE ACETONIDE

>D>	AT	IDENTI PHARMS INC	0.1%	A091306	001	Oct 17, 2011	Jan	CPOT
>A>	AT		0.01%	A091306	001	Oct 17, 2011	Jan	CPOT

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE EMULSIFIED BASE

>D>	AB2	ALTANA	0.05%	A076586	001	Jun 23, 2004	Jan	CAHN
>A>	AB2	FOUGERA PHARMS	0.05%	A076586	001	Jun 23, 2004	Jan	CAHN

OINTMENT; TOPICAL
FLUOCINONIDE

>D>	AB	ALTANA	0.05%	A074905	001	Aug 26, 1997	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.05%	A074905	001	Aug 26, 1997	Jan	CAHN

FLUOROURACIL

CREAM; TOPICAL

FLUOROPLEX

>D>		+	ALLERGAN HERBERT	1%	N016988	001		Jan	CAHN
>A>		+	AQUA PHARMS	1%	N016988	001		Jan	CAHN

FLUTICASONE PROPIONATE

CREAM; TOPICAL

CUTIVATE

>D>	AB	+	ALTANA	0.05%	N019958	001	Dec 18, 1990	Jan	CAHN
>A>	AB	+	FOUGERA PHARMS	0.05%	N019958	001	Dec 18, 1990	Jan	CAHN

FLUTICASONE PROPIONATE

>D>	AB		ALTANA	0.05%	A076451	001	May 14, 2004	Jan	CAHN
>A>	AB		FOUGERA PHARMS	0.05%	A076451	001	May 14, 2004	Jan	CAHN

OINTMENT; TOPICAL

FLUTICASONE PROPIONATE

>D>	AB		ALTANA	0.005%	A076300	001	May 14, 2004	Jan	CAHN
>A>	AB		FOUGERA PHARMS	0.005%	A076300	001	May 14, 2004	Jan	CAHN

HALOBETASOL PROPIONATE

CREAM; TOPICAL

HALOBETASOL PROPIONATE

>D>	AB		ALTANA	0.05%	A077001	001	Dec 16, 2004	Jan	CAHN
>A>	AB		FOUGERA PHARMS	0.05%	A077001	001	Dec 16, 2004	Jan	CAHN

OINTMENT; TOPICAL

HALOBETASOL PROPIONATE

>D>	AB		ALTANA	0.05%	A076903	001	Dec 16, 2004	Jan	CAHN
>A>	AB		FOUGERA PHARMS	0.05%	A076903	001	Dec 16, 2004	Jan	CAHN

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

>A>	AB		LANNETT HOLDINGS INC	12.5MG	A091662	001	Jan 27, 2012	Jan	NEWA

HYDROCHLOROTHIAZIDE; METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

DUTOPROL

>D>			@ ASTRAZENECA	12.5MG;EQ 25MG TARTRATE	N021956	001	Aug 28, 2006	Jan	CMFD
>A>				12.5MG;EQ 25MG TARTRATE	N021956	001	Aug 28, 2006	Jan	CMFD
>D>			@	12.5MG;EQ 50MG TARTRATE	N021956	002	Aug 28, 2006	Jan	CMFD
>A>				12.5MG;EQ 50MG TARTRATE	N021956	002	Aug 28, 2006	Jan	CMFD
>D>			@	12.5MG;EQ 100MG TARTRATE	N021956	003	Aug 28, 2006	Jan	CMFD
>A>				12.5MG;EQ 100MG TARTRATE	N021956	003	Aug 28, 2006	Jan	CMFD

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET; ORAL

METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE

>D>			MYLAN	50MG;100MG	A076792	003	Aug 20, 2004	Jan	CTEC
>A>	AB			50MG;100MG	A076792	003	Aug 20, 2004	Jan	CTEC
>A>	AB		SUN PHARM INDS	25MG;50MG	A090654	001	Jan 19, 2012	Jan	NEWA
>A>	AB			25MG;100MG	A090654	002	Jan 19, 2012	Jan	NEWA
>A>	AB			50MG;100MG	A090654	003	Jan 19, 2012	Jan	NEWA

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL
MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>D>	AB		PADDOCK LLC	12.5MG;7.5MG	A090096	001	Sep 25, 2008	Jan	DISC
>A>		@		12.5MG;7.5MG	A090096	001	Sep 25, 2008	Jan	DISC
>D>	AB			12.5MG;15MG	A090096	002	Sep 25, 2008	Jan	DISC
>A>		@		12.5MG;15MG	A090096	002	Sep 25, 2008	Jan	DISC
>D>	AB			25MG;15MG	A090096	003	Sep 25, 2008	Jan	DISC
>A>		@		25MG;15MG	A090096	003	Sep 25, 2008	Jan	DISC

HYDROCORTISONE

LOTION; TOPICAL
HYDROCORTISONE

>D>	AT	+	ALTANA	2.5%	A040351	001	Jul 25, 2000	Jan	CAHN
>A>	AT	+	FOUGERA PHARMS	2.5%	A040351	001	Jul 25, 2000	Jan	CAHN

OINTMENT; TOPICAL
HYDROCORTISONE

>D>	AT	+	ALTANA	1%	A080692	001		Jan	CAHN
>A>	AT	+	FOUGERA PHARMS	1%	A080692	001		Jan	CAHN

HYDROCORTISONE ACETATE; UREA

CREAM; TOPICAL
CARMOL HC

>A>	AT		FOUGERA PHARMS	1%;10%	A080505	001		Jan	CAHN
>D>	AT		NYCOMED US	1%;10%	A080505	001		Jan	CAHN

HYDROCORTISONE VALERATE

OINTMENT; TOPICAL
HYDROCORTISONE VALERATE

>D>	AB		ALTANA	0.2%	A075085	001	Jul 31, 2001	Jan	CAHN
>A>	AB		FOUGERA PHARMS	0.2%	A075085	001	Jul 31, 2001	Jan	CAHN

HYDROFLUMETHIAZIDE

TABLET; ORAL
SALURON

>D>	AB	+	SHIRE	50MG	N011949	001		Jan	CAHN
>A>	AB	+	SHIRE LLC	50MG	N011949	001		Jan	CAHN

IMIQUIMOD

CREAM; TOPICAL
IMIQUIMOD

>A>	AB		FOUGERA PHARMS	5%	A078548	001	Feb 25, 2010	Jan	CAHN
>D>	AB		NYCOMED US	5%	A078548	001	Feb 25, 2010	Jan	CAHN

>A> INGENOL MEBUTATE

>A> GEL; TOPICAL
>A> PICATO

>A>			LEO PHARMA AS	0.015%	N202833	001	Jan 23, 2012	Jan	NEWA
>A>		+		0.05%	N202833	002	Jan 23, 2012	Jan	NEWA

IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION
IRINOTECAN HYDROCHLORIDE

>A>	AP		EMCURE PHARMS LTD	40MG/2ML (20MG/ML)	A200771	001	Feb 14, 2012	Jan	NEWA
>A>	AP			100MG/5ML (20MG/ML)	A200771	002	Feb 14, 2012	Jan	NEWA

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL
ISOSORBIDE MONONITRATE

>D>	AB	BRIGHTSTONE	60MG	A075166	001	Oct 07, 1999	Jan	DISC
>A>		@ SKYEPHARMA AG	60MG	A075166	001	Oct 07, 1999	Jan	DISC

ISOTRETINOIN

CAPSULE; ORAL
>A> MYORISAN

>A>	AB	DOUGLAS PHARMS	10MG	A076485	001	Jan 19, 2012	Jan	NEWA
>A>	AB		20MG	A076485	002	Jan 19, 2012	Jan	NEWA
>A>	AB		40MG	A076485	003	Jan 19, 2012	Jan	NEWA

>A> IVACAFTOR

>A> TABLET; ORAL
>A> KALYDECO

>A>	+	VERTEX PHARMS	150MG	N203188	001	Jan 31, 2012	Jan	NEWA

KETOCONAZOLE

CREAM; TOPICAL
KETOCONAZOLE

>D>	AB	ALTANA	2%	A076294	001	Apr 28, 2004	Jan	CAHN
>A>	AB	FOUGERA PHARMS	2%	A076294	001	Apr 28, 2004	Jan	CAHN

LACTULOSE

SOLUTION; ORAL
LACTULOSE

>A>	AA	FRESENIUS KABI	10GM/15ML	A090503	001	Jan 25, 2012	Jan	NEWA

SOLUTION; ORAL, RECTAL
LACTULOSE

>A>	AA	FRESENIUS KABI	10GM/15ML	A090502	001	Jan 25, 2012	Jan	NEWA

LEVETIRACETAM

INJECTABLE; IV (INFUSION)
LEVETIRACETAM

>A>	AP	PHARMAFORCE	500MG/5ML (100MG/ML)	A202143	001	Jan 31, 2012	Jan	NEWA

LEVOFLOXACIN

TABLET; ORAL
LEVOFLOXACIN

>A>	AB	ORCHID HLTHCARE	250MG	A202200	001	Jan 30, 2012	Jan	NEWA
>A>	AB		500MG	A202200	002	Jan 30, 2012	Jan	NEWA
>A>	AB		750MG	A202200	003	Jan 30, 2012	Jan	NEWA

LIDOCAINE; PRILOCAINE

CREAM; TOPICAL
LIDOCAINE AND PRILOCAINE

>A>	AB	FOUGERA PHARMS	2.5%;2.5%	A076453	001	Aug 18, 2003	Jan	CAHN
>D>	AB	NYCOMED US	2.5%;2.5%	A076453	001	Aug 18, 2003	Jan	CAHN

>A> LINAGLIPTIN; METFORMIN HYDROCHLORIDE

>A> TABLET; ORAL
>A> JENTADUETO

>A>		BOEHRINGER INGELHEIM	2.5MG;500MG	N201281	001	Jan 30, 2012	Jan	NEWA
>A>			2.5MG;850MG	N201281	002	Jan 30, 2012	Jan	NEWA

>A>		TABLET; ORAL							
>A>		JENTADUETO							
>A>	+	BOEHRINGER INGELHEIM	2.5MG;1GM		N201281	003	Jan 30, 2012	Jan	NEWA
		LORAZEPAM							
		CONCENTRATE; ORAL							
		LORAZEPAM							
>A>	AA	HI-TECH PHARMA CO	2MG/ML		A200169	001	Jan 30, 2012	Jan	NEWA
		MAGNESIUM SULFATE							
		INJECTABLE; INJECTION							
		MAGNESIUM SULFATE IN PLASTIC CONTAINER							
>A>		HOSPIRA	20GM/500ML (40MG/ML)		N020309	004	Jan 18, 1995	Jan	NEWA
>A>			40GM/1000ML(40MG/ML)		N020309	005	Jan 18, 1995	Jan	NEWA
		MESALAMINE							
		SUPPOSITORY; RECTAL							
		ROWASA							
>D>		@ ALAVEN PHARM	500MG		N019919	001	Dec 18, 1990	Jan	CAHN
>A>		@ MEDA PHARMS	500MG		N019919	001	Dec 18, 1990	Jan	CAHN
		METFORMIN HYDROCHLORIDE							
		TABLET, EXTENDED RELEASE; ORAL							
		METFORMIN HYDROCHLORIDE							
>A>	AB1	INVENTIA HLTHCARE	500MG		A201991	001	Jan 18, 2012	Jan	NEWA
		METHOTREXATE SODIUM							
		INJECTABLE; INJECTION							
		METHOTREXATE PRESERVATIVE FREE							
>D>		@ APP PHARMS	EQ 1GM BASE/VIAL		A040266	001	Feb 26, 1999	Jan	CMFD
>A>	AP	APP PHARMS LLC	EQ 1GM BASE/VIAL		A040266	001	Feb 26, 1999	Jan	CMFD
		METOCLOPRAMIDE HYDROCHLORIDE							
		INJECTABLE; INJECTION							
		METOCLOPRAMIDE HYDROCHLORIDE							
>D>	AP	TEVA PARENTERAL	EQ 5MG BASE/ML		A073135	001	Nov 27, 1991	Jan	DISC
>A>		@	EQ 5MG BASE/ML		A073135	001	Nov 27, 1991	Jan	DISC
		METRONIDAZOLE							
		CREAM; TOPICAL							
		METRONIDAZOLE							
>D>	AB	ALTANA	0.75%		A076408	001	May 28, 2004	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.75%		A076408	001	May 28, 2004	Jan	CAHN
		GEL; TOPICAL							
		METRONIDAZOLE							
>D>	AB	ALTANA	0.75%		A077018	001	Jun 06, 2006	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.75%		A077018	001	Jun 06, 2006	Jan	CAHN
		LOTION; TOPICAL							
		METRONIDAZOLE							
>D>	AB	ALTANA	0.75%		A077197	001	May 24, 2006	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.75%		A077197	001	May 24, 2006	Jan	CAHN
		MIDAZOLAM HYDROCHLORIDE							
		INJECTABLE; INJECTION							
		MIDAZOLAM HYDROCHLORIDE							
>A>	AP	GLAND PHARMA LTD	EQ 5MG BASE/ML		A090850	001	Jan 25, 2012	Jan	NEWA

MIDODRINE HYDROCHLORIDE

TABLET; ORAL
PROAMATINE

>D>	AB		SHIRE	2.5MG	N019815	001	Sep 06, 1996	Jan	CAHN
>D>	AB	+		5MG	N019815	002	Sep 06, 1996	Jan	CAHN
>D>	AB			10MG	N019815	003	Mar 20, 2002	Jan	CAHN
>A>	AB		SHIRE LLC	2.5MG	N019815	001	Sep 06, 1996	Jan	CAHN
>A>	AB	+		5MG	N019815	002	Sep 06, 1996	Jan	CAHN
>A>	AB			10MG	N019815	003	Mar 20, 2002	Jan	CAHN

MOMETASONE FUROATE

CREAM; TOPICAL
MOMETASONE FUROATE

>D>	AB		ALTANA	0.1%	A076171	001	Apr 08, 2005	Jan	CAHN
>A>	AB		FOUGERA PHARMS	0.1%	A076171	001	Apr 08, 2005	Jan	CAHN

LOTION; TOPICAL
MOMETASONE FUROATE

>A>	AB		FOUGERA PHARMS	0.1%	A075919	001	Nov 29, 2007	Jan	CAHN
>D>	AB		NYCOMED US	0.1%	A075919	001	Nov 29, 2007	Jan	CAHN

OINTMENT; TOPICAL
MOMETASONE FUROATE

>D>	AB		ALTANA	0.1%	A077061	001	Mar 28, 2005	Jan	CAHN
>A>	AB		FOUGERA PHARMS	0.1%	A077061	001	Mar 28, 2005	Jan	CAHN

MUPIROCIN

OINTMENT; TOPICAL
MUPIROCIN

>D>	AB		ALTANA	2%	A065192	001	Nov 30, 2005	Jan	CAHN
>A>	AB		FOUGERA PHARMS	2%	A065192	001	Nov 30, 2005	Jan	CAHN

NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL
NAFTIN

>A>		+	MERZ PHARMS	2%	N019599	002	Jan 13, 2012	Jan	NEWA

NITROGLYCERIN

OINTMENT; INTRA-ANAL
RECTIV

>A>		+	APTALIS PHARMA	0.4%	N021359	001	Jun 21, 2011	Jan	CAHN
>D>		+	PROSTRAKAN INC	0.4%	N021359	001	Jun 21, 2011	Jan	CAHN

NYSTATIN

CREAM; TOPICAL
NYSTATIN

>D>	AT		ALTANA	100,000 UNITS/GM	A062129	001		Jan	CAHN
>A>	AT		FOUGERA PHARMS	100,000 UNITS/GM	A062129	001		Jan	CAHN

OINTMENT; TOPICAL
NYSTATIN

>D>	AT	+	ALTANA	100,000 UNITS/GM	A062124	002	Sep 23, 1982	Jan	CAHN
>A>	AT	+	FOUGERA PHARMS	100,000 UNITS/GM	A062124	002	Sep 23, 1982	Jan	CAHN

OLANZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL
OLANZAPINE

>A>	AB		BARR LABS INC	5MG	A077243	001	Jan 30, 2012	Jan	NEWA

TABLET, ORALLY DISINTEGRATING; ORAL
OLANZAPINE

>A>	AB	BARR LABS INC	10MG	A077243	002	Jan 30, 2012	Jan	NEWA
>A>	AB		15MG	A077243	003	Jan 30, 2012	Jan	NEWA
>A>	AB		20MG	A077243	004	Jan 30, 2012	Jan	NEWA

OSELTAMIVIR PHOSPHATE

FOR SUSPENSION; ORAL
TAMIFLU

>D>		ROCHE	EQ 6MG BASE/ML	N021246	002	Mar 21, 2011	Jan	CRLD
>A>	+		EQ 6MG BASE/ML	N021246	002	Mar 21, 2011	Jan	CRLD

OXICONAZOLE NITRATE

CREAM; TOPICAL
OXISTAT

>D>	+	ALTANA	EQ 1% BASE	N019828	001	Dec 30, 1988	Jan	CAHN
>A>	+	FOUGERA PHARMS	EQ 1% BASE	N019828	001	Dec 30, 1988	Jan	CAHN

OXYCODONE HYDROCHLORIDE

SOLUTION; ORAL
OXYCODONE HYDROCHLORIDE

>A>	+	VISTAPHARM	5MG/5ML	N201194	001	Jan 12, 2012	Jan	NEWA

OXYTOCIN

INJECTABLE; INJECTION
OXYTOCIN

>D>	AP	TEVA PARENTERAL	10USP UNITS/ML (10USP UNITS/ML)	A077453	001	Jan 24, 2008	Jan	DISC
>A>	@		10USP UNITS/ML (10USP UNITS/ML)	A077453	001	Jan 24, 2008	Jan	DISC

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL
PANTOPRAZOLE SODIUM

>A>	AB	MACLEODS PHARMS LTD	EQ 20MG BASE	A200821	001	Feb 16, 2012	Jan	NEWA
>A>	AB		EQ 40MG BASE	A200821	002	Feb 16, 2012	Jan	NEWA

PERINDOPRIL ERBUMINE

TABLET; ORAL
ACEON

>D>	AB	ABBOTT PRODS	2MG	N020184	001	Dec 30, 1993	Jan	CAHN
>D>	AB		4MG	N020184	002	Dec 30, 1993	Jan	CAHN
>D>	AB	+	8MG	N020184	003	Dec 30, 1993	Jan	CAHN
>A>	AB	XOMA	2MG	N020184	001	Dec 30, 1993	Jan	CAHN
>A>	AB		4MG	N020184	002	Dec 30, 1993	Jan	CAHN
>A>	AB	+	8MG	N020184	003	Dec 30, 1993	Jan	CAHN

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL
PHENTERMINE RESIN COMPLEX

>D>		LANNETT HOLDINGS INC	EQ 15MG BASE	A040872	001	Jul 28, 2011	Jan	CRLD
>A>	+		EQ 15MG BASE	A040872	001	Jul 28, 2011	Jan	CRLD
>D>			EQ 30MG BASE	A040872	002	Jul 28, 2011	Jan	CRLD
>A>	+		EQ 30MG BASE	A040872	002	Jul 28, 2011	Jan	CRLD

PREDNICARBATE

CREAM; TOPICAL

PREDNICARBATE

>D>	AB		ALTANA	0.1%	A077287	001	Sep 19, 2006	Jan	CAHN
>A>	AB		FOUGERA PHARMS	0.1%	A077287	001	Sep 19, 2006	Jan	CAHN

OINTMENT; TOPICAL

PREDNICARBATE

>D>	AB		ALTANA	0.1%	A077236	001	Mar 09, 2007	Jan	CAHN
>A>	AB		FOUGERA PHARMS	0.1%	A077236	001	Mar 09, 2007	Jan	CAHN

PREGABALIN

CAPSULE; ORAL

LYRICA

>D>			CPPI CV	25MG	N021446	001	Dec 30, 2004	Jan	CAHN
>D>				50MG	N021446	002	Dec 30, 2004	Jan	CAHN
>D>				75MG	N021446	003	Dec 30, 2004	Jan	CAHN
>D>				100MG	N021446	004	Dec 30, 2004	Jan	CAHN
>D>				150MG	N021446	005	Dec 30, 2004	Jan	CAHN
>D>				200MG	N021446	006	Dec 30, 2004	Jan	CAHN
>D>				225MG	N021446	007	Dec 30, 2004	Jan	CAHN
>D>		+		300MG	N021446	008	Dec 30, 2004	Jan	CAHN
>A>			PF PRISM	25MG	N021446	001	Dec 30, 2004	Jan	CAHN
>A>				50MG	N021446	002	Dec 30, 2004	Jan	CAHN
>A>				75MG	N021446	003	Dec 30, 2004	Jan	CAHN
>A>				100MG	N021446	004	Dec 30, 2004	Jan	CAHN
>A>				150MG	N021446	005	Dec 30, 2004	Jan	CAHN
>A>				200MG	N021446	006	Dec 30, 2004	Jan	CAHN
>A>				225MG	N021446	007	Dec 30, 2004	Jan	CAHN
>A>		+		300MG	N021446	008	Dec 30, 2004	Jan	CAHN

SOLUTION; ORAL

LYRICA

>D>		+	CPPI CV	20MG/ML	N022488	001	Jan 04, 2010	Jan	CAHN
>A>		+	PF PRISM	20MG/ML	N022488	001	Jan 04, 2010	Jan	CAHN

RAMIPRIL

TABLET; ORAL

>D>			ALTACE						
>A>			@ KING PFIZER	1.25MG	N022021	001	Feb 27, 2007	Jan	DISC
>A>			@	2.5MG	N022021	002	Feb 27, 2007	Jan	DISC
>A>			@	5MG	N022021	003	Feb 27, 2007	Jan	DISC
>A>			@	10MG	N022021	004	Feb 27, 2007	Jan	DISC
>D>	AB		KING PHARMS	1.25MG	N022021	001	Feb 27, 2007	Jan	DISC
>D>	AB			2.5MG	N022021	002	Feb 27, 2007	Jan	DISC
>D>	AB			5MG	N022021	003	Feb 27, 2007	Jan	DISC
>D>	AB	+		10MG	N022021	004	Feb 27, 2007	Jan	DISC

ROPINIROLE HYDROCHLORIDE

TABLET; ORAL

ROPINIROLE HYDROCHLORIDE

>A>	AB		APOTEX	EQ 0.25MG BASE	A079165	001	Feb 07, 2012	Jan	NEWA
>A>	AB			EQ 0.5MG BASE	A079165	002	Feb 07, 2012	Jan	NEWA
>A>	AB			EQ 1MG BASE	A079165	003	Feb 07, 2012	Jan	NEWA
>A>	AB			EQ 2MG BASE	A079165	004	Feb 07, 2012	Jan	NEWA
>A>	AB			EQ 3MG BASE	A079165	005	Feb 07, 2012	Jan	NEWA
>A>	AB			EQ 4MG BASE	A079165	006	Feb 07, 2012	Jan	NEWA

TABLET; ORAL
ROPINIROLE HYDROCHLORIDE

>A>	AB	APOTEX	EQ 5MG BASE	A079165	007	Feb 07, 2012	Jan	NEWA

SERTACONAZOLE NITRATE

CREAM; TOPICAL
ERTACZO

>D>	+	ORTHO JANSSEN	2%	N021385	001	Dec 10, 2003	Jan	CAHN
>A>	+	VALEANT INTL	2%	N021385	001	Dec 10, 2003	Jan	CAHN

SODIUM BICARBONATE; TARTARIC ACID

GRANULE, EFFERVESCENT; ORAL
BAROS

>A>		@ MALLINCKRODT INC	460MG/GM;420MG/GM	N018509	001	Aug 07, 1985	Jan	CAHN
>D>		@ MALLINCKRODT LLC	460MG/GM;420MG/GM	N018509	001	Aug 07, 1985	Jan	CAHN

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.9%

>A>	AP	HIKMA (MAPLE)	9MG/ML	A201850	001	Jan 20, 2012	Jan	NEWA

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

>A>		MEDEFIL	9MG/ML	N202832	001	Jan 06, 2012	Jan	NEWA

SODIUM IODIDE I-131

CAPSULE; ORAL
SODIUM IODIDE I-131

>D>		DRAXIMAGE	2-200mCi	N021305	004	Nov 18, 2004	Jan	DISC
>A>		@ JUBILANT DRAXIMAGE	2-200mCi	N021305	004	Nov 18, 2004	Jan	DISC

SOLUTION; ORAL
HICON

>A>	+	JUBILANT DRAXIMAGE	250-1000mCi	N021305	007	Dec 05, 2011	Jan	NEWA

SULFACETAMIDE SODIUM

LOTION; TOPICAL
SULFACETAMIDE SODIUM

>D>	AB	ALTANA	10%	A077015	001	Nov 17, 2006	Jan	CAHN
>A>	AB	FOUGERA PHARMS	10%	A077015	001	Nov 17, 2006	Jan	CAHN

TENOFOVIR DISOPROXIL FUMARATE

>A> POWDER; ORAL
>A> VIREAD

>A>	+	GILEAD SCIENCES INC	40MG/SCOOPFUL	N022577	001	Jan 18, 2012	Jan	NEWA

TERBUTALINE SULFATE

INJECTABLE; INJECTION
TERBUTALINE SULFATE

>D>	AP	TEVA PARENTERAL	1MG/ML	A076853	001	Jul 20, 2004	Jan	DISC
>A>		@	1MG/ML	A076853	001	Jul 20, 2004	Jan	DISC

TERCONAZOLE

CREAM; VAGINAL
TERCONAZOLE

>D>	AB	ALTANA	0.4%	A076712	001	Feb 18, 2005	Jan	CAHN
>A>	AB	FOUGERA PHARMS	0.4%	A076712	001	Feb 18, 2005	Jan	CAHN

SUPPOSITORY; VAGINAL
TERCONAZOLE

>D>	AB		ALTANA	80MG	A076850	001	Jul 12, 2006	Jan	CAHN
>A>	AB		FOUGERA PHARMS	80MG	A076850	001	Jul 12, 2006	Jan	CAHN

TETRAHYDROZOLINE HYDROCHLORIDE

SOLUTION; NASAL
TYZINE

>A>		+	FOUGERA PHARMS	0.05%	A086576	002		Jan	CAHN
>A>				0.1%	A086576	001		Jan	CAHN
>D>		+	NYCOMED US	0.05%	A086576	002		Jan	CAHN
>D>				0.1%	A086576	001		Jan	CAHN

SPRAY; NASAL
TYZINE

>A>		+	FOUGERA PHARMS	0.1%	A086576	003		Jan	CAHN
>D>		+	NYCOMED US	0.1%	A086576	003		Jan	CAHN

TIAGABINE HYDROCHLORIDE

TABLET; ORAL
GABITRIL

>D>			CEPHALON	6MG	N020646	006	Nov 29, 2005	Jan	DISC
>A>			@	6MG	N020646	006	Nov 29, 2005	Jan	DISC
>D>				8MG	N020646	007	Nov 29, 2005	Jan	DISC
>A>			@	8MG	N020646	007	Nov 29, 2005	Jan	DISC
>D>				10MG	N020646	008	Nov 29, 2005	Jan	DISC
>A>			@	10MG	N020646	008	Nov 29, 2005	Jan	DISC

TIZANIDINE HYDROCHLORIDE

CAPSULE; ORAL
TIZANIDINE HYDROCHLORIDE

>A>	AB		APOTEX INC	EQ 2MG BASE	A078868	001	Feb 03, 2012	Jan	NEWA
>A>	AB			EQ 4MG BASE	A078868	002	Feb 03, 2012	Jan	NEWA
>A>	AB			EQ 6MG BASE	A078868	003	Feb 03, 2012	Jan	NEWA

ZANAFLEX

>D>			ACORDA	EQ 2MG BASE	N021447	001	Aug 29, 2002	Jan	CFTG
>A>	AB			EQ 2MG BASE	N021447	001	Aug 29, 2002	Jan	CFTG
>D>				EQ 4MG BASE	N021447	002	Aug 29, 2002	Jan	CFTG
>A>	AB			EQ 4MG BASE	N021447	002	Aug 29, 2002	Jan	CFTG
>D>		+		EQ 6MG BASE	N021447	003	Aug 29, 2002	Jan	CFTG
>A>	AB	+		EQ 6MG BASE	N021447	003	Aug 29, 2002	Jan	CFTG

TRANYLCYPROMINE SULFATE

TABLET; ORAL
PARNATE

>A>	AB	+	COVIS PHARMA	EQ 10MG BASE	N012342	003	Aug 16, 1985	Jan	CAHN
>D>	AB	+	GLAXOSMITHKLINE	EQ 10MG BASE	N012342	003	Aug 16, 1985	Jan	CAHN

TRETINOIN

CREAM; TOPICAL
RENOVA

>D>		+	ORTHO JANSSEN	0.02%	N021108	001	Aug 31, 2000	Jan	CAHN
>D>	AB2	+		0.05%	N019963	001	Dec 29, 1995	Jan	CAHN
>A>		+	VALEANT INTL	0.02%	N021108	001	Aug 31, 2000	Jan	CAHN
>A>	AB2	+		0.05%	N019963	001	Dec 29, 1995	Jan	CAHN

RETIN-A

>D>	AB	+	ORTHO JANSSEN	0.025%	N019049	001	Sep 16, 1988	Jan	CAHN

CREAM; TOPICAL
RETIN-A

>D>	AB1	+	ORTHO JANSSEN	0.05%	N017522	001		Jan	CAHN
>D>	AB	+		0.1%	N017340	001		Jan	CAHN
>A>	AB	+	VALEANT INTL	0.025%	N019049	001	Sep 16, 1988	Jan	CAHN
>A>	AB1	+		0.05%	N017522	001		Jan	CAHN
>A>	AB	+		0.1%	N017340	001		Jan	CAHN

GEL; TOPICAL
RETIN-A

>D>	AB	+	ORTHO JANSSEN	0.01%	N017955	001		Jan	CAHN
>D>	AB	+		0.025%	N017579	002		Jan	CAHN
>A>	AB	+	VALEANT INTL	0.01%	N017955	001		Jan	CAHN
>A>	AB	+		0.025%	N017579	002		Jan	CAHN

SOLUTION; TOPICAL
RETIN-A

>D>	AT	+	ORTHO JANSSEN	0.05%	N016921	001		Jan	CAHN
>A>	AT	+	VALEANT INTL	0.05%	N016921	001		Jan	CAHN

SWAB; TOPICAL
RETIN-A

>D>		@	ORTHO JANSSEN	0.05%	N016921	002		Jan	CAHN
>A>		@	VALEANT INTL	0.05%	N016921	002		Jan	CAHN

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE

>D>	AT		ALTANA	0.025%	A085692	001		Jan	CAHN
>D>	AT			0.1%	A085692	003		Jan	CAHN
>D>	AT	+		0.5%	A085692	002		Jan	CAHN
>A>	AT		FOUGERA PHARMS	0.025%	A085692	001		Jan	CAHN
>A>	AT			0.1%	A085692	003		Jan	CAHN
>A>	AT	+		0.5%	A085692	002		Jan	CAHN

LOTION; TOPICAL
TRIAMCINOLONE ACETONIDE

>D>	AT		ALTANA	0.025%	A040467	001	Apr 21, 2003	Jan	CAHN
>D>	AT			0.1%	A040467	002	Apr 21, 2003	Jan	CAHN
>A>	AT		FOUGERA PHARMS	0.025%	A040467	001	Apr 21, 2003	Jan	CAHN
>A>	AT			0.1%	A040467	002	Apr 21, 2003	Jan	CAHN

OINTMENT; TOPICAL
TRIAMCINOLONE ACETONIDE

>A>	AT		FOUGERA PHARMS	0.025%	A085691	001		Jan	CAHN
>A>	AT			0.1%	A085691	003		Jan	CAHN
>A>	AT			0.5%	A085691	002		Jan	CAHN
>D>	AT		NYCOMED US	0.025%	A085691	001		Jan	CAHN
>D>	AT			0.1%	A085691	003		Jan	CAHN
>D>	AT			0.5%	A085691	002		Jan	CAHN

>A> VISMODEGIB

>A> CAPSULE; ORAL
>A> ERIVEDGE

>A>		+	GENENTECH	150MG	N203388	001	Jan 30, 2012	Jan	NEWA

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL

CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY

>A>	SUN PHARM INDS	30MG	A091567	002	Feb 06, 2012	Jan	NEWA
>A>	WOCKHARDT LTD	30MG	A079112	002	Feb 08, 2012	Jan	NEWA

CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES

>A>	SUN PHARM INDS	30MG	A091567	001	Feb 06, 2012	Jan	NEWA
>A>	WOCKHARDT LTD	30MG	A079112	001	Feb 08, 2012	Jan	NEWA

FEXOFENADINE HYDROCHLORIDE ALLERGY

>A>	SUN PHARM INDS	60MG	A091567	004	Feb 06, 2012	Jan	NEWA
>A>		180MG	A091567	006	Feb 06, 2012	Jan	NEWA
>A>	WOCKHARDT LTD	60MG	A079112	004	Feb 08, 2012	Jan	NEWA
>A>		180MG	A079112	006	Feb 08, 2012	Jan	NEWA

FEXOFENADINE HYDROCHLORIDE HIVES

>A>	SUN PHARM INDS	60MG	A091567	003	Feb 06, 2012	Jan	NEWA
>A>		180MG	A091567	005	Feb 06, 2012	Jan	NEWA
>A>	WOCKHARDT LTD	60MG	A079112	003	Feb 08, 2012	Jan	NEWA
>A>		180MG	A079112	005	Feb 08, 2012	Jan	NEWA

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN

>A>	ACCUCAPS INDS	EQ 200MG FREE ACID AND POTASSIUM SALT	A077338	001	Jul 10, 2009	Jan	CAHN
>D>	DR REDDYS LABS LTD	EQ 200MG FREE ACID AND POTASSIUM SALT	A077338	001	Jul 10, 2009	Jan	CAHN

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

CUMULATIVE SUPPLEMENT NUMBER 01 JANUARY 2012

NO JANUARY 2012 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of List of Orphan Designations and Approvals is available at:

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

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

NO JANUARY 2012 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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
AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT						
N022314 001	**>A>** 8101599	May 16, 2023	DP			
AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT						
N022314 002	**>A>** 8101599	May 16, 2023	DP			
AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT						
N022314 003	**>A>** 8101599	May 16, 2023	DP			
AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT						
N022314 004	**>A>** 8101599	May 16, 2023	DP			
AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT						
N022314 005	**>A>** 8101599	May 16, 2023	DP			
ARFORMOTEROL TARTRATE - BROVANA						
N021912 001	**>A>** 8110706	Nov 09, 2021	DP			
ATOVAQUONE; PROGUANIL HYDROCHLORIDE - ATOVAQUONE AND PROGUANIL HYDROCHLORIDE						
A091211 001					**>A>** PC	Mar 13, 2012
AXITINIB - INLYTA						
N202324 001					**>A>** NCE	Jan 27, 2017
AXITINIB - INLYTA						
N202324 002					**>A>** NCE	Jan 27, 2017
AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE - EDARBYCLOR						
N202331 001	**>A>** 5583141	Dec 10, 2013	DS DP U-3			
	>A> 5736555	Jun 25, 2012	DS DP U-3			
	>A> 7157584	May 22, 2025	DS			
	>A> 7572920	Jan 07, 2025	DP U-3			
AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE - EDARBYCLOR						
N202331 002	**>A>** 5583141	Dec 10, 2013	DS DP U-3			
	>A> 5736555	Jun 25, 2012	DS DP U-3			
	>A> 7157584	May 22, 2025	DS			
	>A> 7572920	Jan 07, 2025	DP U-3			
BIMATOPROST - LATISSE						
N022369 001	**>A>** 8101161	May 25, 2024	DP U-1219			
	>A> 8101161	May 25, 2024	DP U-1218			
	>A> 8101161	May 25, 2024	DP U-1217			
BORTEZOMIB - VELCADE						
N021602 001					**>A>** NR	Jan 23, 2015
CICLESONIDE - ZETONNA						
N202129 001	**>A>** 5482934	Oct 24, 2017	DS DP U-1002		**>A>** NP	Jan 20, 2015
	>A> 5605674	Feb 25, 2014	DP			
	>A> 5683677	Nov 04, 2014	DP			
	>A> 5775321	Jul 07, 2015	DP			
	>A> 6006745	Dec 28, 2016	DP			
	>A> 6036942	Apr 30, 2013	DP			
	>A> 6120752	May 13, 2018	DP			
	>A> 6264923	May 13, 2018	DP			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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
COLCHICINE - COLCRYS						
N022352 001	**>A>** 7964648	Oct 06, 2028	U-1161			
	>A> 8097655	Oct 06, 2028	U-1020			
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 001	**>A>** 5843946*PED	Jun 01, 2016				
	>A> 6037157	Jun 26, 2016	U-935			
	>A> 6037157	Jun 26, 2016	U-1209			
	>A> 6037157*PED	Dec 26, 2016				
	>A> 6335460	Aug 25, 2012	DS DP U-935			
	>A> 6335460	Aug 25, 2012	DS DP U-903			
	>A> 6335460	Aug 25, 2012	DS DP U-744			
	>A> 6335460	Aug 25, 2012	DS DP U-1209			
	>A> 6335460*PED	Feb 25, 2013				
	>A> 6703403	Jun 26, 2016	U-935			
	>A> 6703403	Jun 26, 2016	U-1209			
	>A> 6703403*PED	Dec 26, 2016				
	>A> 7470506	Jun 23, 2019	U-935			
	>A> 7470506	Jun 23, 2019	U-1209			
	>A> 7470506*PED	Dec 23, 2019				
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 002	**>A>** 5843946*PED	Jun 01, 2016				
	>A> 6037157	Jun 26, 2016	U-935			
	>A> 6037157	Jun 26, 2016	U-1209			
	>A> 6037157*PED	Dec 26, 2016				
	>A> 6335460	Aug 25, 2012	DS DP U-935			
	>A> 6335460	Aug 25, 2012	DS DP U-903			
	>A> 6335460	Aug 25, 2012	DS DP U-744			
	>A> 6335460	Aug 25, 2012	DS DP U-1209			
	>A> 6335460*PED	Feb 25, 2013				
	>A> 6703403	Jun 26, 2016	U-935			
	>A> 6703403	Jun 26, 2016	U-1209			
	>A> 6703403*PED	Dec 26, 2016				
	>A> 7470506	Jun 23, 2019	U-935			
	>A> 7470506	Jun 23, 2019	U-1209			
	>A> 7470506*PED	Dec 23, 2019				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 003	**>A>** 5843946*PED	Jun 01, 2016				
	>A> 6037157	Jun 26, 2016	U-935			
	>A> 6037157	Jun 26, 2016	U-1209			
	>A> 6037157*PED	Dec 26, 2016				
	>A> 6335460	Aug 25, 2012	DS DP U-935			
	>A> 6335460	Aug 25, 2012	DS DP U-903			
	>A> 6335460	Aug 25, 2012	DS DP U-744			
	>A> 6335460	Aug 25, 2012	DS DP U-1209			
	>A> 6335460*PED	Feb 25, 2013				
	>A> 6703403	Jun 26, 2016	U-935			
	>A> 6703403	Jun 26, 2016	U-1209			
	>A> 6703403*PED	Dec 26, 2016				
	>A> 7470506	Jun 23, 2019	U-935			
	>A> 7470506	Jun 23, 2019	U-1209			
	>A> 7470506*PED	Dec 23, 2019				
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 004	**>A>** 5843946*PED	Jun 01, 2016				
	>A> 6037157	Jun 26, 2016	U-935			
	>A> 6037157	Jun 26, 2016	U-1209			
	>A> 6037157*PED	Dec 26, 2016				
	>A> 6335460	Aug 25, 2012	DS DP U-935			
	>A> 6335460	Aug 25, 2012	DS DP U-903			
	>A> 6335460	Aug 25, 2012	DS DP U-744			
	>A> 6335460	Aug 25, 2012	DS DP U-1209			
	>A> 6335460*PED	Feb 25, 2013				
	>A> 6703403	Jun 26, 2016	U-935			
	>A> 6703403	Jun 26, 2016	U-1209			
	>A> 6703403*PED	Dec 26, 2016				
	>A> 7470506	Jun 23, 2019	U-935			
	>A> 7470506	Jun 23, 2019	U-1209			
	>A> 7470506*PED	Dec 23, 2019				
DARUNAVIR ETHANOLATE - PREZISTA						
N021976 005	**>A>** 5843946*PED	Jun 01, 2016				
	>A> 6037157	Jun 26, 2016	U-935			
	>A> 6037157	Jun 26, 2016	U-1209			
	>A> 6037157*PED	Dec 26, 2016				
	>A> 6335460	Aug 25, 2012	DS DP U-935			
	>A> 6335460	Aug 25, 2012	DS DP U-903			
	>A> 6335460	Aug 25, 2012	DS DP U-744			
	>A> 6335460	Aug 25, 2012	DS DP U-1209			
	>A> 6335460*PED	Feb 25, 2013				
	>A> 6703403	Jun 26, 2016	U-935			
	>A> 6703403	Jun 26, 2016	U-1209			
	>A> 6703403*PED	Dec 26, 2016				
	>A> 7470506	Jun 23, 2019	U-935			
	>A> 7470506	Jun 23, 2019	U-1209			
	>A> 7470506*PED	Dec 23, 2019				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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
DARUNAVIR ETHANOLATE - PREZISTA						
N202895 001	**>A>** 5843946	Dec 01, 2015	DP U-1209			
	>A> 5843946*PED	Jun 01, 2016				
	>A> 6037157	Jun 26, 2016	U-1209			
	>A> 6037157*PED	Dec 26, 2016				
	>A> 6248775	Aug 13, 2014	DS			
	>A> 6248775*PED	Feb 13, 2015				
	>A> 6335460	Aug 25, 2012	DS DP U-1209			
	>A> 6335460*PED	Feb 25, 2013				
	>A> 6703403	Jun 26, 2016	U-1209			
	>A> 6703403*PED	Dec 26, 2016				
	>A> 7470506	Jun 23, 2019	U-1209			
	>A> 7470506*PED	Dec 23, 2019				
	>A> 7700645	Dec 26, 2026	DS DP			
	>A> 7700645*PED	Jun 26, 2027				
	>A> RE42889	Oct 19, 2016	DP			
	>A> RE42889*PED	Apr 19, 2017				
DEXAMETHASONE - OZURDEX						
N022315 001	**>A>** 8088407	Oct 20, 2020	DP U-1205			
DICLOFENAC POTASSIUM - CAMBIA						
N022165 001	**>A>** 8097651	Jun 16, 2026	DS DP U-436			
DICLOFENAC POTASSIUM - ZIPSOR						
N022202 001	**>A>** 8110606	Feb 24, 2029	U-980			
EPROSARTAN MESYLATE - EPROSARTAN MESYLATE						
A202012 001					**>A>** PC	Jun 17, 2012
EPROSARTAN MESYLATE - EPROSARTAN MESYLATE						
A202012 002					**>A>** PC	Jun 17, 2012
ERIBULIN MESYLATE - HALAVEN						
N201532 001	**>A>** 8097648	Jan 22, 2021	U-1096			
ESOMEPRAZOLE MAGNESIUM - NEXIUM						
N021957 001	**>A>** 5877192	May 27, 2014	U-773			
	>A> 5877192	May 27, 2014	U-729			
	>A> 5877192	May 27, 2014	U-1207			
	>A> 5877192*PED	Nov 27, 2014				
ESOMEPRAZOLE MAGNESIUM - NEXIUM						
N021957 002	**>A>** 5877192	May 27, 2014	U-773			
	>A> 5877192	May 27, 2014	U-729			
	>A> 5877192	May 27, 2014	U-1207			
	>A> 5877192*PED	Nov 27, 2014				
EXENATIDE SYNTHETIC - BYDUREON						
N022200 001					**>A>** NP	Jan 27, 2015
EZETIMIBE - ZETIA						
N021445 001					**>A>** M-109	Jan 24, 2015
EZETIMIBE; SIMVASTATIN - VYTORIN						
N021687 001					**>A>** M-109	Jan 24, 2015

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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
EZETIMIBE; SIMVASTATIN - VYTORIN						
N021687 002					**>A>** M-109	Jan 24, 2015
EZETIMIBE; SIMVASTATIN - VYTORIN						
N021687 003					**>A>** M-109	Jan 24, 2015
EZETIMIBE; SIMVASTATIN - VYTORIN						
N021687 004					**>A>** M-109	Jan 24, 2015
FENTANYL - SUBSYS						
N202788 001					**>A>** NP	Jan 04, 2015
FENTANYL - SUBSYS						
N202788 002					**>A>** NP	Jan 04, 2015
FENTANYL - SUBSYS						
N202788 003					**>A>** NP	Jan 04, 2015
FENTANYL - SUBSYS						
N202788 004					**>A>** NP	Jan 04, 2015
FENTANYL - SUBSYS						
N202788 005					**>A>** NP	Jan 04, 2015
FENTANYL CITRATE - FENTORA						
N021947 001	**>A>** 8092832	Dec 30, 2024	DP			
FENTANYL CITRATE - FENTORA						
N021947 002	**>A>** 8092832	Dec 30, 2024	DP			
FENTANYL CITRATE - FENTORA						
N021947 003	**>A>** 8092832	Dec 30, 2024	DP			
FENTANYL CITRATE - FENTORA						
N021947 004	**>A>** 8092832	Dec 30, 2024	DP			
FENTANYL CITRATE - FENTORA						
N021947 005	**>A>** 8092832	Dec 30, 2024	DP			
FESOTERODINE FUMARATE - TOVIAZ						
N022030 001	**>A>** 8088398	Jun 07, 2027	DP U-913			
FESOTERODINE FUMARATE - TOVIAZ						
N022030 002	**>A>** 8088398	Jun 07, 2027	DP U-913			
IMATINIB MESYLATE - GLEEVEC						
N021588 001					**>A>** ODE	Dec 19, 2015
IMATINIB MESYLATE - GLEEVEC						
N021588 002					**>A>** ODE	Dec 19, 2015
INGENOL MEBUTATE - PICATO						
N202833 001					**>A>** NCE	Jan 23, 2017
INGENOL MEBUTATE - PICATO						
N202833 002					**>A>** NCE	Jan 23, 2017
IVACAFTOR - KALYDECO						
N203188 001					**>A>** NCE	Jan 31, 2017
IXABEPILONE - IXEMPRA KIT						
N022065 001	**>A>** RE41911	Sep 28, 2020	DS DP U-961			
	>A> RE41911*PED	Mar 28, 2021				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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
IXABEPILONE - IXEMPRA KIT						
N022065 002	**>A>** RE41911	Sep 28, 2020	DS DP U-961			
	>A> RE41911*PED	Mar 28, 2021				
KETOCONAZOLE - EXTINA						
N021738 001	**>A>** 8026238	Oct 19, 2018	DP U-1213			
LAMIVUDINE; ZIDOVUDINE - LAMIVUDINE AND ZIDOVUDINE						
A079081 001					**>A>** PC	May 15, 2012
LENALIDOMIDE - REVLIMID						
N021880 001	**>A>** 5635517	Oct 04, 2019	DS U-1211			
	>A> 6045501	Aug 28, 2018	U-1210			
	>A> 6281230	Jul 24, 2016	U-1212			
	>A> 6315720	Oct 23, 2020	U-1210			
	>A> 6555554	Jul 24, 2016	DP U-1211			
	>A> 6561976	Aug 28, 2018	U-1210			
	>A> 6561977	Oct 23, 2020	U-1210			
	>A> 6755784	Oct 23, 2020	U-1210			
	>A> 6908432	Aug 28, 2018	U-1210			
	>A> 7189740	Apr 11, 2023	U-1215			
	>A> 7465800	Apr 27, 2027	DS DP			
	>A> 7968569	Oct 07, 2023	U-1216			
LENALIDOMIDE - REVLIMID						
N021880 002	**>A>** 5635517	Oct 04, 2019	DS U-1211			
	>A> 6045501	Aug 28, 2018	U-1210			
	>A> 6281230	Jul 24, 2016	U-1212			
	>A> 6315720	Oct 23, 2020	U-1210			
	>A> 6555554	Jul 24, 2016	DP U-1211			
	>A> 6561976	Aug 28, 2018	U-1210			
	>A> 6561977	Oct 23, 2020	U-1210			
	>A> 6755784	Oct 23, 2020	U-1210			
	>A> 6908432	Aug 28, 2018	U-1210			
	>A> 7189740	Apr 11, 2023	U-1215			
	>A> 7465800	Apr 27, 2027	DS DP			
	>A> 7968569	Oct 07, 2023	U-1216			
LENALIDOMIDE - REVLIMID						
N021880 003	**>A>** 5635517	Oct 04, 2019	DS U-1211			
	>A> 6045501	Aug 28, 2018	U-1210			
	>A> 6281230	Jul 24, 2016	U-1212			
	>A> 6315720	Oct 23, 2020	U-1210			
	>A> 6555554	Jul 24, 2016	DP U-1211			
	>A> 6561976	Aug 28, 2018	U-1210			
	>A> 6561977	Oct 23, 2020	U-1210			
	>A> 6755784	Oct 23, 2020	U-1210			
	>A> 6908432	Aug 28, 2018	U-1210			
	>A> 7189740	Apr 11, 2023	U-1215			
	>A> 7465800	Apr 27, 2027	DS DP			
	>A> 7855217	Nov 24, 2024	DS DP			
	>A> 7968569	Oct 07, 2023	U-1216			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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
LENALIDOMIDE - REVLIMID						
N021880 004	**>A>** 5635517	Oct 04, 2019	DS U-1211			
	>A> 6045501	Aug 28, 2018	U-1210			
	>A> 6281230	Jul 24, 2016	U-1212			
	>A> 6315720	Oct 23, 2020	U-1210			
	>A> 6555554	Jul 24, 2016	DP U-1211			
	>A> 6561976	Aug 28, 2018	U-1210			
	>A> 6561977	Oct 23, 2020	U-1210			
	>A> 6755784	Oct 23, 2020	U-1210			
	>A> 6908432	Aug 28, 2018	U-1210			
	>A> 7189740	Apr 11, 2023	U-1215			
	>A> 7465800	Apr 27, 2027	DS DP			
	>A> 7968569	Oct 07, 2023	U-1216			
LENALIDOMIDE - REVLIMID						
N021880 005	**>A>** 5635517	Oct 04, 2019	DS U-1211			
	>A> 6045501	Aug 28, 2018	U-1210			
	>A> 6281230	Jul 24, 2016	U-1212			
	>A> 6315720	Oct 23, 2020	U-1210			
	>A> 6555554	Jul 24, 2016	DP U-1211			
	>A> 6561976	Aug 28, 2018	U-1210			
	>A> 6561977	Oct 23, 2020	U-1210			
	>A> 6755784	Oct 23, 2020	U-1210			
	>A> 6908432	Aug 28, 2018	U-1210			
	>A> 7119106	Jul 24, 2016	DP			
	>A> 7189740	Apr 11, 2023	U-1215			
	>A> 7465800	Apr 27, 2027	DS DP			
	>A> 7855217	Nov 24, 2024	DS DP			
	>A> 7968569	Oct 07, 2023	U-1216			
LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO						
N201281 001					**>A>** NCE	May 02, 2016
					>A> NC	Jan 30, 2015
LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO						
N201281 002					**>A>** NCE	May 02, 2016
					>A> NC	Jan 30, 2015
LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO						
N201281 003					**>A>** NCE	May 02, 2016
					>A> NC	Jan 30, 2015
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 001	**>A>** 7662788	Feb 24, 2023	U-727		**>A>** I-645	Jan 31, 2015
	>A> 7713936	Feb 24, 2023	U-727			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 002	**>A>** 7662788	Feb 24, 2023	U-727		**>A>** I-645	Jan 31, 2015
	>A> 7713936	Feb 24, 2023	U-727			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 003	**>A>** 7662788	Feb 24, 2023	U-727		**>A>** I-645	Jan 31, 2015
	>A> 7713936	Feb 24, 2023	U-727			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 004	**>A>** 7662788	Feb 24, 2023	U-727		**>A>** I-645	Jan 31, 2015
	>A> 7713936	Feb 24, 2023	U-727			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 005	**>A>** 7662788	Feb 24, 2023	U-727		**>A>** I-645	Jan 31, 2015
	>A> 7713936	Feb 24, 2023	U-727			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 006	**>A>** 7662788	Feb 24, 2023	U-727		**>A>** I-645	Jan 31, 2015
	>A> 7713936	Feb 24, 2023	U-727			
LUBIPROSTONE - AMITIZA						
N021908 001	**>A>** 8097649	Oct 16, 2020	DP			
	>A> 8097653	Nov 14, 2022	U-1214			
	>A> 8114890	Sep 05, 2020	DP			
LUBIPROSTONE - AMITIZA						
N021908 002	**>A>** 8097649	Oct 16, 2020	DP			
	>A> 8114890	Sep 05, 2020	DP			
NAFTIFINE HYDROCHLORIDE - NAFTIN						
N019599 002					**>A>** NS	Jan 13, 2015
OXYCODONE HYDROCHLORIDE - OXYCONTIN						
N022272 001	**>A>** 8114383	Oct 10, 2024	DP			
OXYCODONE HYDROCHLORIDE - OXYCONTIN						
N022272 002	**>A>** 8114383	Oct 10, 2024	DP			
OXYCODONE HYDROCHLORIDE - OXYCONTIN						
N022272 003	**>A>** 8114383	Oct 10, 2024	DP			
OXYCODONE HYDROCHLORIDE - OXYCONTIN						
N022272 004	**>A>** 8114383	Oct 10, 2024	DP			
OXYCODONE HYDROCHLORIDE - OXYCONTIN						
N022272 005	**>A>** 8114383	Oct 10, 2024	DP			
RALTEGRAVIR POTASSIUM - ISENTRESS						
N203045 001	**>A>** 7169780	Oct 03, 2023	DS DP			
	>A> 7217713	Oct 21, 2022	U-257			
	>A> 7435734	Oct 21, 2022	U-257			
	>A> 7754731	Mar 11, 2029	DS DP U-257			
RALTEGRAVIR POTASSIUM - ISENTRESS						
N203045 002	**>A>** 7169780	Oct 03, 2023	DS DP			
	>A> 7217713	Oct 21, 2022	U-257			
	>A> 7435734	Oct 21, 2022	U-257			
	>A> 7754731	Mar 11, 2029	DS DP U-257			
RILPIVIRINE HYDROCHLORIDE - EDURANT						
N202022 001	**>A>** 8080551	Apr 11, 2023	DS DP			
SILDENAFIL CITRATE - REVATIO						
N021845 001	**>A>** 5250534	Mar 27, 2012	DS DP		**>A>** I-598	May 07, 2012
	>A> 5250534*PED	Sep 27, 2012			**>A>** PED	Nov 07, 2012
SILDENAFIL CITRATE - REVATIO						
N022473 001	**>A>** 5250534	Mar 27, 2012	DS DP		**>A>** NDF	Nov 20, 2012
	>A> 5250534*PED	Sep 27, 2012			**>A>** PED	May 20, 2013

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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
SILDENAFIL CITRATE - VIAGRA						
N020895 001	**>A>** 5250534	Mar 27, 2012				
	>A> 5250534*PED	Sep 27, 2012				
	>A> 6469012	Oct 22, 2019	U-155			
	>A> 6469012*PED	Apr 22, 2020				
SILDENAFIL CITRATE - VIAGRA						
N020895 002	**>A>** 5250534	Mar 27, 2012				
	>A> 5250534*PED	Sep 27, 2012				
	>A> 6469012	Oct 22, 2019	U-155			
	>A> 6469012*PED	Apr 22, 2020				
SILDENAFIL CITRATE - VIAGRA						
N020895 003	**>A>** 5250534	Mar 27, 2012				
	>A> 5250534*PED	Sep 27, 2012				
	>A> 6469012	Oct 22, 2019	U-155			
	>A> 6469012*PED	Apr 22, 2020				
TELBIVUDINE - TYZEKA						
N022154 001	**>A>** 7858594	Sep 11, 2023	DS DP U-999			
TENOFOVIR DISOPROXIL FUMARATE - VIREAD						
N021356 001					**>A>** NPP	Jan 18, 2015
					>A> PED	Jul 18, 2015
TENOFOVIR DISOPROXIL FUMARATE - VIREAD						
N022577 001	**>A>** 5922695	Jul 25, 2017	DS U-250		**>A>** NDF	Jan 18, 2015
	>A> 5922695	Jul 25, 2017	DS U-256		**>A>** PED	Jul 18, 2015
	>A> 5922695	Jul 25, 2017	DS U-999			
	>A> 5922695	Jul 25, 2017	DS U-248			
	>A> 5922695*PED	Jan 25, 2018				
	>A> 5935946	Jul 25, 2017	DP U-999	Y		
	>A> 5935946	Jul 25, 2017	DP U-248	Y		
	>A> 5935946	Jul 25, 2017	DP U-250	Y		
	>A> 5935946	Jul 25, 2017	DP U-256	Y		
	>A> 5935946*PED	Jan 25, 2018				
	>A> 5977089	Jul 25, 2017	DS DP U-250			
	>A> 5977089	Jul 25, 2017	DS DP U-256			
	>A> 5977089	Jul 25, 2017	DS DP U-999			
	>A> 5977089	Jul 25, 2017	DS DP U-248			
	>A> 5977089*PED	Jan 25, 2018				
	>A> 6043230	Jul 25, 2017	U-248			
	>A> 6043230	Jul 25, 2017	U-250			
	>A> 6043230	Jul 25, 2017	U-256			
	>A> 6043230	Jul 25, 2017	U-999			
	>A> 6043230*PED	Jan 25, 2018				
TRAMADOL HYDROCHLORIDE - TRAMADOL HYDROCHLORIDE						
A091607 001					**>A>** PC	Jun 27, 2012
TRAMADOL HYDROCHLORIDE - TRAMADOL HYDROCHLORIDE						
A091607 002					**>A>** PC	Jun 27, 2012
TRAMADOL HYDROCHLORIDE - TRAMADOL HYDROCHLORIDE						
A091607 003					**>A>** PC	Jun 27, 2012

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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
VISMODEGIB - ERIVEDGE						
N203388 001					**>A>** NCE	Jan 30, 2017
VORINOSTAT - ZOLINZA						
N021991 001	**>A>** 8093295	May 16, 2026	DP			
	>A> 8101663	Mar 04, 2023	U-892			

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.
3. **** The expiration date for U.S. Patent No. 5,608,075 is March 4, 2009.

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, 31st 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