

APPROVED DRUG PRODUCTS

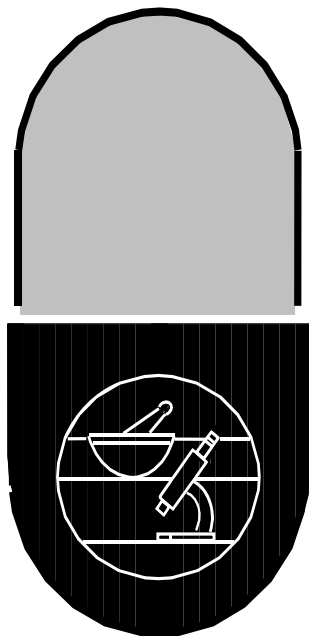
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**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**

31st EDITION

Cumulative Supplement 1

January 2012

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**APPROVED DRUG PRODUCTS
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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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 30th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 31st 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

<u>CATEGORIES COUNTED</u>	<u>DEC 2011</u>	<u>MAR 2012</u>	<u>JUN 2012</u>	<u>SEPT 2012</u>	<u>DEC 2012</u>
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				

¹Amino 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 preceded 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.

PRESCRIPTION DRUG PRODUCT LIST - 32ND EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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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
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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
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ALPRAZOLAM

TABLET, ORALLY DISINTEGRATING; ORAL

NIRAVAM

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

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;5.9GM;2.691GM A090145 001 Jan 25, 2012 Jan NEWA
;7.5GM

MOVIPREP

>D> + SALIX PHARMS 4.7GM;100GM;1.015GM;5.9GM;2.691GM N021881 001 Aug 02, 2006 Jan CFTG
;7.5GM

>A> AA + 4.7GM;100GM;1.015GM;5.9GM;2.691GM N021881 001 Aug 02, 2006 Jan CFTG
;7.5GM

>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						
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>D>			VELCADE						
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>D>		+	MILLENNIUM PHARMS	3.5MG/VIAL	N021602	001	May 13, 2003	Jan	CDFR
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>A>			INJECTABLE; INTRAVENOUS, SUBCUTANEOUS						
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>A>			VELCADE						
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>A>		+	MILLENNIUM PHARMS	3.5MG/VIAL	N021602	001	May 13, 2003	Jan	CDFR
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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

ZETONNA

>A>									
>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

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
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DESLOTRADINE

TABLET; ORAL

DESLOTRADINE

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

LOTION; TOPICAL

DESONIDE

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

DESONIDE

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

CREAM; TOPICAL

DESOXIMETASONE

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

CREAM; TOPICAL

DIFLORASONE DIACETATE

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

DIFLORASONE DIACETATE

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

INJECTABLE; INJECTION

DILTIAZEM HYDROCHLORIDE

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

INJECTABLE; INJECTION

DIPYRIDAMOLE

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

INJECTABLE; INJECTION

DOCETAXEL

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

>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 HYDROCHLORIDECREAM; TOPICALZONALON

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

DOXORUBICIN HYDROCHLORIDEINJECTABLE; INJECTIONDOXORUBICIN 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; INJECTIONDOXIL

>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 HYCLATETABLET, DELAYED RELEASE; ORALDORYX

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

ECONAZOLE NITRATECREAM; TOPICALECONAZOLE 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 MALEATETABLET; ORALENALAPRIL 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

ERYTHROMYCINGEL; TOPICALERYTHROMYCIN

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

SOLUTION; TOPICALC-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; TOPICALERYTHROMYCIN

>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; NORETHINDRONETABLET; 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 SYNTHETICFOR SUSPENSION, EXTENDED RELEASE; SUBCUTANEOUSBYDUREON

>A>								
>A>								
>A>		+	AMYLIN	2MG/VIAL	N022200 001	Jan 27, 2012	Jan	NEWA

EZETIMIBETABLET; ORALZETIA

>D>		+	MSP SINGAPORE	10MG	N021445 001	Oct 25, 2002	Jan	CAHN
>A>		+		10MG	N021445 001	Oct 25, 2002	Jan	CAHN

EZETIMIBE; SIMVASTATINTABLET; ORALVYTORIN

>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

FAMCICLOVIRTABLET; ORALFAMCICLOVIR

>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

FAMOTIDINETABLET; ORALPEPCID

>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

>A> SPRAY; SUBLINGUAL

>A> 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
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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
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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
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SOLUTION; ORAL, RECTAL

LACTULOSE

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

INJECTABLE; IV (INFUSION)

LEVETIRACETAM

>A>	AP	PHARMAFORCE	500MG/5ML (100MG/ML)	A202143 001	Jan 31, 2012	Jan	NEWA
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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
<u>LORAZEPAM</u>									
		CONCENTRATE; ORAL							
		LORAZEPAM							
>A>	AA	HI-TECH PHARMA CO	2MG/ML		A200169	001	Jan 30, 2012	Jan	NEWA
<u>MAGNESIUM SULFATE</u>									
		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
<u>MESALAMINE</u>									
		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
<u>METFORMIN HYDROCHLORIDE</u>									
		TABLET, EXTENDED RELEASE; ORAL							
		METFORMIN HYDROCHLORIDE							
>A>	AB1	INVENTIA HLTHCARE	500MG		A201991	001	Jan 18, 2012	Jan	NEWA
<u>METHOTREXATE SODIUM</u>									
		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
<u>METOCLOPRAMIDE HYDROCHLORIDE</u>									
		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
<u>METRONIDAZOLE</u>									
		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
<u>MIDAZOLAM HYDROCHLORIDE</u>									
		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

MUPIROCI

OINTMENT; TOPICAL

MUPIROCI

>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
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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
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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

>A>		SOLUTION; ORAL					
>A>		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

ALTACE

>D>							
>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
		<u>SERTACONAZOLE NITRATE</u>			
		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
		<u>SODIUM BICARBONATE; TARTARIC ACID</u>			
		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
		<u>SODIUM CHLORIDE</u>			
		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
		<u>SODIUM IODIDE I-131</u>			
		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
		<u>SULFACETAMIDE SODIUM</u>			
		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
		<u>TENOFOVIR DISOPROXIL FUMARATE</u>			
>A>		POWDER; ORAL			
>A>		VIREAD			
>A>	+	GILEAD SCIENCES INC	40MG/SC00PFUL	N022577 001	Jan 18, 2012 Jan NEWA
		<u>TERBUTALINE SULFATE</u>			
		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
		<u>TERCONAZOLE</u>			
		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

TRANLYCYPROMINE 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
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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
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OTC DRUG PRODUCT LIST - 32ND EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2012

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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

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST - 32ND EDITION

A - 1

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
<u>AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u>						
N022314 001	>A> 8101599	May 16, 2023	DP			
<u>AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u>						
N022314 002	>A> 8101599	May 16, 2023	DP			
<u>AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u>						
N022314 003	>A> 8101599	May 16, 2023	DP			
<u>AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u>						
N022314 004	>A> 8101599	May 16, 2023	DP			
<u>AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u>						
N022314 005	>A> 8101599	May 16, 2023	DP			
<u>ARFORMOTEROL TARTRATE - BROVANA</u>						
N021912 001	>A> 8110706	Nov 09, 2021	DP			
<u>ATOVAQUONE; PROGUANIL HYDROCHLORIDE - ATOVAQUONE AND PROGUANIL HYDROCHLORIDE</u>						
A091211 001					>A> PC	Mar 13, 2012
<u>AXITINIB - INLYTA</u>						
N202324 001					>A> NCE	Jan 27, 2017
<u>AXITINIB - INLYTA</u>						
N202324 002					>A> NCE	Jan 27, 2017
<u>AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE - EDARBYCLOR</u>						
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			
<u>AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE - EDARBYCLOR</u>						
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			
<u>BIMATOPROST - LATISSE</u>						
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			
<u>BORTEZOMIB - VELCADE</u>						
N021602 001					>A> NR	Jan 23, 2015
<u>CICLESONIDE - ZETONNA</u>						
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

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<u>COLCHICINE - COLCRYS</u>						
N022352 001	>A> 7964648	Oct 06, 2028	U-1161			
	>A> 8097655	Oct 06, 2028	U-1020			
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
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				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
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

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<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
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				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
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				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
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

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
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				
<u>DEXAMETHASONE - OZURDEX</u>						
N022315 001	>A> 8088407	Oct 20, 2020	DP U-1205			
<u>DICLOFENAC POTASSIUM - CAMBIA</u>						
N022165 001	>A> 8097651	Jun 16, 2026	DS DP U-436			
<u>DICLOFENAC POTASSIUM - ZIPSOR</u>						
N022202 001	>A> 8110606	Feb 24, 2029	U-980			
<u>EPROSARTAN MESYLATE - EPROSARTAN MESYLATE</u>						
A202012 001					>A> PC	Jun 17, 2012
<u>EPROSARTAN MESYLATE - EPROSARTAN MESYLATE</u>						
A202012 002					>A> PC	Jun 17, 2012
<u>ERIBULIN MESYLATE - HALAVEN</u>						
N201532 001	>A> 8097648	Jan 22, 2021	U-1096			
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>						
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				
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>						
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				
<u>EXENATIDE SYNTHETIC - BYDUREON</u>						
N022200 001					>A> NP	Jan 27, 2015
<u>EZETIMIBE - ZETIA</u>						
N021445 001					>A> M-109	Jan 24, 2015
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
N021687 001					>A> M-109	Jan 24, 2015

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

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
N021687	002				>A> M-109	Jan 24, 2015
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
N021687	003				>A> M-109	Jan 24, 2015
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
N021687	004				>A> M-109	Jan 24, 2015
<u>FENTANYL - SUBSYS</u>						
N202788	001				>A> NP	Jan 04, 2015
<u>FENTANYL - SUBSYS</u>						
N202788	002				>A> NP	Jan 04, 2015
<u>FENTANYL - SUBSYS</u>						
N202788	003				>A> NP	Jan 04, 2015
<u>FENTANYL - SUBSYS</u>						
N202788	004				>A> NP	Jan 04, 2015
<u>FENTANYL - SUBSYS</u>						
N202788	005				>A> NP	Jan 04, 2015
<u>FENTANYL CITRATE - FENTORA</u>						
N021947	001 >A> 8092832	Dec 30, 2024	DP			
<u>FENTANYL CITRATE - FENTORA</u>						
N021947	002 >A> 8092832	Dec 30, 2024	DP			
<u>FENTANYL CITRATE - FENTORA</u>						
N021947	003 >A> 8092832	Dec 30, 2024	DP			
<u>FENTANYL CITRATE - FENTORA</u>						
N021947	004 >A> 8092832	Dec 30, 2024	DP			
<u>FENTANYL CITRATE - FENTORA</u>						
N021947	005 >A> 8092832	Dec 30, 2024	DP			
<u>FESOTERODINE FUMARATE - TOVIAZ</u>						
N022030	001 >A> 8088398	Jun 07, 2027	DP U-913			
<u>FESOTERODINE FUMARATE - TOVIAZ</u>						
N022030	002 >A> 8088398	Jun 07, 2027	DP U-913			
<u>IMATINIB MESYLATE - GLEEVEC</u>						
N021588	001				>A> ODE	Dec 19, 2015
<u>IMATINIB MESYLATE - GLEEVEC</u>						
N021588	002				>A> ODE	Dec 19, 2015
<u>INGENOL MEBUTATE - PICATO</u>						
N202833	001				>A> NCE	Jan 23, 2017
<u>INGENOL MEBUTATE - PICATO</u>						
N202833	002				>A> NCE	Jan 23, 2017
<u>IVACAFTOR - KALYDECO</u>						
N203188	001				>A> NCE	Jan 31, 2017
<u>IXABEPILONE - IXEMPRA KIT</u>						
N022065	001 >A> RE41911	Sep 28, 2020	DS DP U-961			
	>A> RE41911*PED	Mar 28, 2021				

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<u>IXABEPILONE - IXEMPRA KIT</u>						
N022065 002	>A> RE41911	Sep 28, 2020	DS DP U-961			
	>A> RE41911*PED	Mar 28, 2021				
<u>KETOCONAZOLE - EXTINA</u>						
N021738 001	>A> 8026238	Oct 19, 2018	DP U-1213			
<u>LAMIVUDINE; ZIDOVUDINE - LAMIVUDINE AND ZIDOVUDINE</u>						
A079081 001					>A> PC	May 15, 2012
<u>LENALIDOMIDE - REVLIMID</u>						
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			
<u>LENALIDOMIDE - REVLIMID</u>						
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			
<u>LENALIDOMIDE - REVLIMID</u>						
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			

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<u>LENALIDOMIDE - REVLMID</u>						
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			
<u>LENALIDOMIDE - REVLMID</u>						
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			
<u>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO</u>						
N201281 001					>A> NCE >A> NC	May 02, 2016 Jan 30, 2015
<u>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO</u>						
N201281 002					>A> NCE >A> NC	May 02, 2016 Jan 30, 2015
<u>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO</u>						
N201281 003					>A> NCE >A> NC	May 02, 2016 Jan 30, 2015
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 001	>A> 7662788	Feb 24, 2023	U-727		>A> I-645	Jan 31, 2015
	>A> 7713936	Feb 24, 2023	U-727			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 002	>A> 7662788	Feb 24, 2023	U-727		>A> I-645	Jan 31, 2015
	>A> 7713936	Feb 24, 2023	U-727			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 003	>A> 7662788	Feb 24, 2023	U-727		>A> I-645	Jan 31, 2015
	>A> 7713936	Feb 24, 2023	U-727			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 004	>A> 7662788	Feb 24, 2023	U-727		>A> I-645	Jan 31, 2015
	>A> 7713936	Feb 24, 2023	U-727			

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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 >A> PED	May 07, 2012
	>A> 5250534*PED	Sep 27, 2012				Nov 07, 2012
SILDENAFIL CITRATE - REVATIO						
N022473 001	>A> 5250534	Mar 27, 2012	DS DP		>A> NDF >A> PED	Nov 20, 2012
	>A> 5250534*PED	Sep 27, 2012				May 20, 2013

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SILDENAFIL CITRATE - VIAGRA						
N020895 001	>A> 5250534	Mar 27, 2012	U-155			
	>A> 5250534*PED	Sep 27, 2012				
	>A> 6469012	Oct 22, 2019				
	>A> 6469012*PED	Apr 22, 2020				
SILDENAFIL CITRATE - VIAGRA						
N020895 002	>A> 5250534	Mar 27, 2012	U-155			
	>A> 5250534*PED	Sep 27, 2012				
	>A> 6469012	Oct 22, 2019				
	>A> 6469012*PED	Apr 22, 2020				
SILDENAFIL CITRATE - VIAGRA						
N020895 003	>A> 5250534	Mar 27, 2012	U-155			
	>A> 5250534*PED	Sep 27, 2012				
	>A> 6469012	Oct 22, 2019				
	>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

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<u>VISMODEGIB - ERIVEDGE</u>						
N203388	001				>A> NCE	Jan 30, 2017
<u>VORINOSTAT - ZOLINZA</u>						
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>