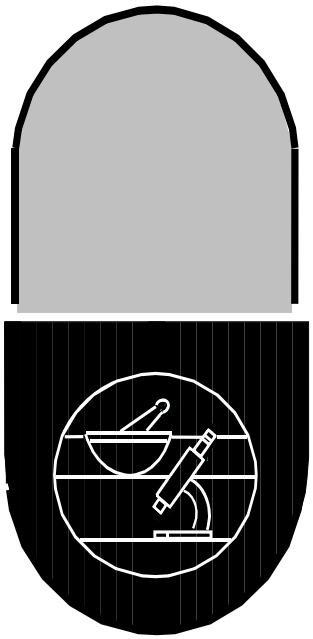
CUMULATIVE SUPPLEMENT 1
January 2011



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

31st EDITION

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

2011

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

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CONTENTS

PAGE

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1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 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 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.

1.5 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 2008) 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 2010	MAR 2011	JUN 2011	SEPT 2011	DEC 2011
DRUG PRODUCTS LISTED	13838				
SINGLE SOURCE	2482 (17.9%)				
MULTISOURCE	11267 (81.4%)				
THERAPEUTICALLY EQUIVALENT	11107 (80.3%)				
NOT THERAPEUTICALLY EQUIVALENT	160 (1.2%)				
EXCEPTIONS[1]	89 (0.6%)				
NEW MOLECULAR ENTITIES APPROVED	8				
NUMBER OF APPLICANTS	752				

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

1.6 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The application number preceded by “N” is a New Drug Application (NDA or innovator). The application number preceded by an “A” is an Abbreviated New Drug Application (ANDA or generic). The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

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

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

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not

being marketed and will be moved to the discontinued section in the next edition.

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

>D>	AA		E5 PHARMA INC	356.4MG;30MG;16MG	A040688	001	Apr 03, 2007	Jan	CAHN
>A>	AA		WRASER PHARMS LLC	356.4MG;30MG;16MG	A040688	001	Apr 03, 2007	Jan	CAHN

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>A>	AB		BOCA PHARMA	300MG;5MG	A090415	001	Jan 24, 2011	Jan	NEWA
>A>	AB			300MG;7.5MG	A090415	002	Jan 24, 2011	Jan	NEWA
>A>	AB			300MG;10MG	A090415	003	Jan 24, 2011	Jan	NEWA

LORTAB

>D>	AA		MALLINCKRODT	500MG;5MG	A087722	001	Jul 09, 1982	Jan	CAHN
>A>	AA		UCB INC	500MG;5MG	A087722	001	Jul 09, 1982	Jan	CAHN

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

DARVOCET-N 100

>D>	AB	+	XANODYNE PHARM	650MG;100MG	N017122	002		Jan	DISC
>A>			@	650MG;100MG	N017122	002		Jan	DISC

DARVOCET-N 50

>D>	AB		XANODYNE PHARM	325MG;50MG	N017122	001		Jan	DISC
>A>			@	325MG;50MG	N017122	001		Jan	DISC

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

CAPSULE; ORAL

LOTREL

>D>			NOVARTIS	EQ 5MG BASE;40MG	N020364	007	Apr 11, 2006	Jan	CFTG
>A>	AB			EQ 5MG BASE;40MG	N020364	007	Apr 11, 2006	Jan	CFTG
>D>		+		EQ 10MG BASE;40MG	N020364	006	Apr 11, 2006	Jan	CFTG
>A>	AB	+		EQ 10MG BASE;40MG	N020364	006	Apr 11, 2006	Jan	CFTG

ATOVAQUONE; PROGUANIL HYDROCHLORIDE

TABLET; ORAL

ATOVAQUONE AND PROGUANIL HYDROCHLORIDE

>A>	AB		GLENMARK GENERICS	250MG;100MG	A091211	001	Jan 12, 2011	Jan	NEWA

MALARONE

>D>		+	GLAXOSMITHKLINE	250MG;100MG	N021078	001	Jul 14, 2000	Jan	CFTG
>A>	AB	+		250MG;100MG	N021078	001	Jul 14, 2000	Jan	CFTG

BACITRACIN

OINTMENT; OPHTHALMIC

BACITRACIN

>D>		+	ALTANA	500 UNITS/GM	A061212	001		Jan	CAHN
>A>		+	NYCOMED US	500 UNITS/GM	A061212	001		Jan	CAHN

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC

>D>	AT		ALTANA	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A060764	002		Jan	CAHN
>A>	AT		NYCOMED US	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A060764	002		Jan	CAHN

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

BACITRACIN ZINC AND POLYMYXIN B SULFATE

>D>	AT		ALTANA	500 UNITS/GM;10,000 UNITS/GM	A065022	001	Feb 27, 2002	Jan	CAHN
>A>	AT		NYCOMED US	500 UNITS/GM;10,000 UNITS/GM	A065022	001	Feb 27, 2002	Jan	CAHN

BACITRACIN; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

BACITRACIN-NEOMYCIN-POLYMYXIN W/ HYDROCORTISONE ACETATE

>A>		+	NYCOMED US	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A062166	002		Jan	CAHN
>D>		+	PHARMADERM	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A062166	002		Jan	CAHN

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL

CARBAMAZEPINE

>D>			@ CADISTA PHARMS	100MG	A071940	001	Feb 01, 1988	Jan	CAHN
>A>			@ JUBILANT CADISTA	100MG	A071940	001	Feb 01, 1988	Jan	CAHN

CARBIDOPA; LEVODOPA

TABLET; ORAL

SINEMET

>D>	AB		BRISTOL MYERS SQUIBB	10MG;100MG	N017555	001		Jan	CAHN
>D>	AB			25MG;100MG	N017555	003		Jan	CAHN
>D>	AB	+		25MG;250MG	N017555	002		Jan	CAHN
>A>	AB		MERCK SHARP DOHME	10MG;100MG	N017555	001		Jan	CAHN
>A>	AB			25MG;100MG	N017555	003		Jan	CAHN
>A>	AB	+		25MG;250MG	N017555	002		Jan	CAHN

TABLET, EXTENDED RELEASE; ORAL

SINEMET CR

>D>	AB		BRISTOL MYERS SQUIBB	25MG;100MG	N019856	002	Dec 24, 1992	Jan	CAHN
>D>	AB	+		50MG;200MG	N019856	001	May 30, 1991	Jan	CAHN
>A>	AB		MERCK SHARP DOHME	25MG;100MG	N019856	002	Dec 24, 1992	Jan	CAHN
>A>	AB	+		50MG;200MG	N019856	001	May 30, 1991	Jan	CAHN

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

>A>	AP		HOSPIRA INC	EQ 500MG BASE/VIAL	A065226	001	Apr 21, 2005	Jan	CAHN
>A>	AP			EQ 1GM BASE/VIAL	A065244	001	Aug 12, 2005	Jan	CAHN
>A>	AP			EQ 1GM BASE/VIAL	A065226	002	Apr 21, 2005	Jan	CAHN
>A>	AP			EQ 10GM BASE/VIAL	A065247	001	Aug 12, 2005	Jan	CAHN
>D>	AP		ORCHID HLTHCARE	EQ 500MG BASE/VIAL	A065226	001	Apr 21, 2005	Jan	CAHN
>D>	AP			EQ 1GM BASE/VIAL	A065244	001	Aug 12, 2005	Jan	CAHN
>D>	AP			EQ 1GM BASE/VIAL	A065226	002	Apr 21, 2005	Jan	CAHN
>D>	AP			EQ 10GM BASE/VIAL	A065247	001	Aug 12, 2005	Jan	CAHN

CEFEPIME HYDROCHLORIDE

INJECTABLE; INJECTION

CEFEPIME HYDROCHLORIDE

>A>	AP		HOSPIRA INC	EQ 500MG BASE/VIAL	A065369	001	Jun 18, 2007	Jan	CAHN
>A>	AP			EQ 1GM BASE/VIAL	A065369	002	Jun 18, 2007	Jan	CAHN
>A>	AP			EQ 2GM BASE/VIAL	A065369	003	Jun 18, 2007	Jan	CAHN
>D>	AP		ORCHID HLTHCARE	EQ 500MG BASE/VIAL	A065369	001	Jun 18, 2007	Jan	CAHN

INJECTABLE; INJECTION
CEFEPIME HYDROCHLORIDE

>D>	AP	ORCHID HLTHCARE	EQ 1GM BASE/VIAL	A065369	002	Jun 18, 2007	Jan	CAHN
>D>	AP		EQ 2GM BASE/VIAL	A065369	003	Jun 18, 2007	Jan	CAHN

CEFOTAXIME SODIUM

INJECTABLE; INJECTION
CEFOTAXIME SODIUM

>A>	AP	HOSPIRA INC	EQ 500MG BASE/VIAL	A065290	001	Aug 11, 2006	Jan	CAHN
>A>	AP		EQ 1GM BASE/VIAL	A065293	001	Aug 10, 2006	Jan	CAHN
>A>	AP		EQ 1GM BASE/VIAL	A065290	002	Aug 11, 2006	Jan	CAHN
>A>	AP		EQ 2GM BASE/VIAL	A065293	002	Aug 10, 2006	Jan	CAHN
>A>	AP		EQ 2GM BASE/VIAL	A065290	003	Aug 11, 2006	Jan	CAHN
>A>	AP		EQ 10GM BASE/VIAL	A065292	001	Aug 10, 2006	Jan	CAHN
>D>	AP	ORCHID HLTHCARE	EQ 500MG BASE/VIAL	A065290	001	Aug 11, 2006	Jan	CAHN
>D>	AP		EQ 1GM BASE/VIAL	A065293	001	Aug 10, 2006	Jan	CAHN
>D>	AP		EQ 1GM BASE/VIAL	A065290	002	Aug 11, 2006	Jan	CAHN
>D>	AP		EQ 2GM BASE/VIAL	A065293	002	Aug 10, 2006	Jan	CAHN
>D>	AP		EQ 2GM BASE/VIAL	A065290	003	Aug 11, 2006	Jan	CAHN
>D>	AP		EQ 10GM BASE/VIAL	A065292	001	Aug 10, 2006	Jan	CAHN

CEFOXITIN SODIUM

INJECTABLE; INJECTION
CEFOXITIN

>A>	AP	HOSPIRA INC	EQ 1GM BASE/VIAL	A065313	001	Jan 23, 2006	Jan	CAHN
>A>	AP		EQ 2GM BASE/VIAL	A065313	002	Jan 23, 2006	Jan	CAHN
>A>	AP		EQ 10GM BASE/VIAL	A065312	001	Feb 13, 2006	Jan	CAHN
>D>	AP	ORCHID HLTHCARE	EQ 1GM BASE/VIAL	A065313	001	Jan 23, 2006	Jan	CAHN
>D>	AP		EQ 2GM BASE/VIAL	A065313	002	Jan 23, 2006	Jan	CAHN
>D>	AP		EQ 10GM BASE/VIAL	A065312	001	Feb 13, 2006	Jan	CAHN

CEFPODOXIME PROXETIL

TABLET; ORAL
CEFPODOXIME PROXETIL

>D>	AB	SANDOZ	EQ 200MG BASE	A065462	002	May 28, 2008	Jan	CRLD
>A>	AB +		EQ 200MG BASE	A065462	002	May 28, 2008	Jan	CRLD
>D>		VANTIN						
>D>	AB	PHARMACIA AND UPJOHN	EQ 100MG BASE	N050674	001	Aug 07, 1992	Jan	DISC
>A>		@	EQ 100MG BASE	N050674	001	Aug 07, 1992	Jan	DISC
>D>	AB +		EQ 200MG BASE	N050674	002	Aug 07, 1992	Jan	DISC
>A>		@	EQ 200MG BASE	N050674	002	Aug 07, 1992	Jan	DISC

CEFTRIAXONE SODIUM

INJECTABLE; IM-IV
CEFTRIAXONE

>A>	AP	HOSPIRA INC	EQ 250MG BASE/VIAL	A065230	001	Aug 02, 2005	Jan	CAHN
>A>	AP		EQ 500MG BASE/VIAL	A065230	002	Aug 02, 2005	Jan	CAHN
>A>	AP		EQ 1GM BASE/VIAL	A065230	003	Aug 02, 2005	Jan	CAHN
>A>	AP		EQ 2GM BASE/VIAL	A065230	004	Aug 02, 2005	Jan	CAHN
>D>	AP	ORCHID HLTHCARE	EQ 250MG BASE/VIAL	A065230	001	Aug 02, 2005	Jan	CAHN
>D>	AP		EQ 500MG BASE/VIAL	A065230	002	Aug 02, 2005	Jan	CAHN
>D>	AP		EQ 1GM BASE/VIAL	A065230	003	Aug 02, 2005	Jan	CAHN
>D>	AP		EQ 2GM BASE/VIAL	A065230	004	Aug 02, 2005	Jan	CAHN

INJECTABLE; INJECTION
CEFTRIAXONE

>A>	AP	HOSPIRA INC	EQ 1GM BASE/VIAL	A065231	001	Aug 02, 2005	Jan	CAHN

INJECTABLE; INJECTION
CEFTRIAXONE

>A>	AP	HOSPIRA INC	EQ 2GM BASE/VIAL	A065231	002	Aug 02, 2005	Jan	CAHN
>A>	AP		EQ 10GM BASE/VIAL	A065232	001	Aug 02, 2005	Jan	CAHN
>D>	AP	ORCHID HLTHCARE	EQ 1GM BASE/VIAL	A065231	001	Aug 02, 2005	Jan	CAHN
>D>	AP		EQ 2GM BASE/VIAL	A065231	002	Aug 02, 2005	Jan	CAHN
>D>	AP		EQ 10GM BASE/VIAL	A065232	001	Aug 02, 2005	Jan	CAHN
>D>	AP	SANDOZ	EQ 10GM BASE/VIAL	A065168	001	May 17, 2005	Jan	CRLD
>A>	AP	+	EQ 10GM BASE/VIAL	A065168	001	May 17, 2005	Jan	CRLD

CEFUROXIME SODIUM

INJECTABLE; IM-IV
CEFUROXIME SODIUM

>A>	AP	HOSPIRA INC	EQ 750MG BASE/VIAL	A065483	001	Oct 15, 2008	Jan	CAHN
>D>	AP	ORCHID HLTHCARE	EQ 750MG BASE/VIAL	A065483	001	Oct 15, 2008	Jan	CAHN

INJECTABLE; INJECTION
CEFUROXIME SODIUM

>A>	AP	HOSPIRA INC	EQ 1.5GM BASE/VIAL	A065503	001	Oct 15, 2008	Jan	CAHN
>A>	AP		EQ 1.5GM BASE/VIAL	A065483	002	Oct 15, 2008	Jan	CAHN
>A>	AP		EQ 7.5GM BASE/VIAL	A065484	001	Oct 15, 2008	Jan	CAHN
>D>	AP	ORCHID HLTHCARE	EQ 1.5GM BASE/VIAL	A065503	001	Oct 15, 2008	Jan	CAHN
>D>	AP		EQ 1.5GM BASE/VIAL	A065483	002	Oct 15, 2008	Jan	CAHN
>D>	AP		EQ 7.5GM BASE/VIAL	A065484	001	Oct 15, 2008	Jan	CAHN

CEPHALEXIN

FOR SUSPENSION; ORAL
CEPHALEXIN

>A>		@ ACS DOBFAR	EQ 100MG BASE/ML	A062117	001		Jan	CAHN
>A>	AB		EQ 125MG BASE/5ML	A062117	002		Jan	CAHN
>A>	AB	+	EQ 250MG BASE/5ML	A062117	003		Jan	CAHN
>D>		@ ACS DOBFAR INFO SA	EQ 100MG BASE/ML	A062117	001		Jan	CAHN
>D>	AB		EQ 125MG BASE/5ML	A062117	002		Jan	CAHN
>D>	AB	+	EQ 250MG BASE/5ML	A062117	003		Jan	CAHN

CHLOROQUINE PHOSPHATE

TABLET; ORAL
CHLOROQUINE PHOSPHATE

>A>	AA	NATCO PHARMA LTD	EQ 150MG BASE	A091621	001	Jan 21, 2011	Jan	NEWA
>A>	AA		EQ 300MG BASE	A090612	001	Jan 21, 2011	Jan	NEWA

CLONIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CLONIDINE HYDROCHLORIDE

>A>	AP	WEST WARD	1MG/10ML (0.1MG/ML)	A200300	001	Jan 26, 2011	Jan	NEWA
>A>	AP		5MG/10ML (0.5MG/ML)	A200300	002	Jan 26, 2011	Jan	NEWA

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HYDROCHLORIDE

>D>	AB	CADISTA PHARMS	5MG	A077563	001	Apr 19, 2006	Jan	CAHN
>D>	AB		10MG	A077563	002	Apr 19, 2006	Jan	CAHN
>A>	AB	JUBILANT CADISTA	5MG	A077563	001	Apr 19, 2006	Jan	CAHN
>A>	AB		10MG	A077563	002	Apr 19, 2006	Jan	CAHN

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

>D>	AT		FOUGERA	0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A062938	001	Jul 31, 1989	Jan	CAHN
>A>	AT		NYCOMED US	0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A062938	001	Jul 31, 1989	Jan	CAHN

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE

>A>	AA		AMNEAL PHARMS	15MG/5ML;6.25MG/5ML	A090575	001	Feb 08, 2011	Jan	NEWA

DOXYCYCLINE

CAPSULE; ORAL
DOXYCYCLINE

>A>	AB		IMPAX LABS INC	EQ 150MG BASE	A200065	001	Feb 17, 2011	Jan	NEWA
>A>	AB		MYLAN	40MG	A090855	001	Jul 01, 2010	Jan	CDFR
>D>		+	PAR PHARM	EQ 150MG BASE	A065055	003	Jul 15, 2005	Jan	CFTG
>A>	AB	+		EQ 150MG BASE	A065055	003	Jul 15, 2005	Jan	CFTG

CAPSULE, DELAYED RELEASE; ORAL
DOXYCYCLINE

>D>	AB		MYLAN	40MG	A090855	001	Jul 01, 2010	Jan	CDFR

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL
ERYTHROMYCIN

>D>	AB		ABBOTT	250MG	A062746	001	Dec 22, 1986	Jan	CAHN
>A>	AB		ARBOR PHARMS INC	250MG	A062746	001	Dec 22, 1986	Jan	CAHN

OINTMENT; OPHTHALMIC
ERYTHROMYCIN

>D>	AT	+	FOUGERA	0.5%	A062447	001	Sep 26, 1983	Jan	CAHN
>A>	AT	+	NYCOMED US	0.5%	A062447	001	Sep 26, 1983	Jan	CAHN

SOLUTION; TOPICAL
ERYDERM

>D>			@ ABBOTT	2%	A062290	001		Jan	CAHN
>A>			@ ARBOR PHARMS INC	2%	A062290	001		Jan	CAHN

TABLET; ORAL
ERYTHROMYCIN

>D>			ABBOTT	250MG	A061621	001		Jan	CAHN
>D>		+		500MG	A061621	002		Jan	CAHN
>A>			ARBOR PHARMS INC	250MG	A061621	001		Jan	CAHN
>A>		+		500MG	A061621	002		Jan	CAHN

TABLET, COATED PARTICLES; ORAL
PCE

>D>			ABBOTT	333MG	N050611	001	Sep 09, 1986	Jan	CAHN
>D>		+		500MG	N050611	002	Aug 22, 1990	Jan	CAHN
>A>			ARBOR PHARMS INC	333MG	N050611	001	Sep 09, 1986	Jan	CAHN
>A>		+		500MG	N050611	002	Aug 22, 1990	Jan	CAHN

TABLET, DELAYED RELEASE; ORAL
E-MYCIN

>D>			@ ABBOTT	250MG	A060272	001		Jan	CAHN
>D>			@	333MG	A060272	002		Jan	CAHN
>A>			@ ARBOR PHARMS INC	250MG	A060272	001		Jan	CAHN
>A>			@	333MG	A060272	002		Jan	CAHN

TABLET, DELAYED RELEASE; ORAL
ERY-TAB

>D>		+	ABBOTT	250MG	A062298	001		Jan	CAHN
>D>		+		333MG	A062298	003	Mar 29, 1982	Jan	CAHN
>D>		+		500MG	A062298	002		Jan	CAHN
>A>		+	ARBOR PHARMS INC	250MG	A062298	001		Jan	CAHN
>A>		+		333MG	A062298	003	Mar 29, 1982	Jan	CAHN
>A>		+		500MG	A062298	002		Jan	CAHN

ERYTHROMYCIN ETHYLSUCCINATE

GRANULE; ORAL
E.E.S.

>D>	AB		ABBOTT	EQ 200MG BASE/5ML	N050207	001		Jan	CAHN
>A>	AB		ARBOR PHARMS INC	EQ 200MG BASE/5ML	N050207	001		Jan	CAHN

ERYPED

>D>	AB		ABBOTT	EQ 200MG BASE/5ML	N050207	003	Mar 30, 1987	Jan	CAHN
>D>		+		EQ 400MG BASE/5ML	N050207	002		Jan	CAHN
>A>	AB		ARBOR PHARMS INC	EQ 200MG BASE/5ML	N050207	003	Mar 30, 1987	Jan	CAHN
>A>		+		EQ 400MG BASE/5ML	N050207	002		Jan	CAHN

SUSPENSION; ORAL
E.E.S. 200

>D>	AB		ABBOTT	EQ 200MG BASE/5ML	A061639	001		Jan	CAHN
>A>	AB		ARBOR PHARMS INC	EQ 200MG BASE/5ML	A061639	001		Jan	CAHN

E.E.S. 400

>D>	AB	+	ABBOTT	EQ 400MG BASE/5ML	A061639	002		Jan	CAHN
>A>	AB	+	ARBOR PHARMS INC	EQ 400MG BASE/5ML	A061639	002		Jan	CAHN

PEDIAMYCIN

>A>	AB		ARBOR PHARMS INC	EQ 200MG BASE/5ML	A062304	001		Jan	CAHN
>D>	AB		ROSS LABS	EQ 200MG BASE/5ML	A062304	001		Jan	CAHN

PEDIAMYCIN 400

>A>	AB		ARBOR PHARMS INC	EQ 400MG BASE/5ML	A062304	002		Jan	CAHN
>D>	AB		ROSS LABS	EQ 400MG BASE/5ML	A062304	002		Jan	CAHN

TABLET; ORAL
E.E.S. 400

>D>			@ ABBOTT	EQ 400MG BASE	A061905	001		Jan	CAHN
>D>	BX	+		EQ 400MG BASE	A061905	002	Aug 12, 1982	Jan	CAHN
>A>			@ ARBOR PHARMS INC	EQ 400MG BASE	A061905	001		Jan	CAHN
>A>	BX	+		EQ 400MG BASE	A061905	002	Aug 12, 1982	Jan	CAHN

ERYTHROMYCIN ETHYLSUCCINATE

>D>	BX	+	ABBOTT	EQ 400MG BASE	A061904	001		Jan	CAHN
>A>	BX	+	ARBOR PHARMS INC	EQ 400MG BASE	A061904	001		Jan	CAHN

TABLET, CHEWABLE; ORAL
E.E.S.

>D>			@ ABBOTT	EQ 200MG BASE	N050297	002		Jan	CAHN
>A>			@ ARBOR PHARMS INC	EQ 200MG BASE	N050297	002		Jan	CAHN

ERYPED

>D>			@ ABBOTT	EQ 200MG BASE	N050297	003	Jul 05, 1988	Jan	CAHN
>A>			@ ARBOR PHARMS INC	EQ 200MG BASE	N050297	003	Jul 05, 1988	Jan	CAHN

ERYTHROMYCIN STEARATE

TABLET; ORAL
ERYTHROCIN STEARATE

>D>			@ ABBOTT	EQ 125MG BASE	A060359	002		Jan	CAHN
>D>				EQ 250MG BASE	A060359	001		Jan	CAHN
>D>		+		EQ 500MG BASE	A060359	003		Jan	CAHN
>A>			@ ARBOR PHARMS INC	EQ 125MG BASE	A060359	002		Jan	CAHN

TABLET; ORAL
ERYTHROCIN STEARATE

>A>		ARBOR PHARMS INC	EQ 250MG BASE	A060359	001		Jan	CAHN
>A>	+		EQ 500MG BASE	A060359	003		Jan	CAHN

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET, CHEWABLE; ORAL
NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

>D>		WARNER CHILCOTT	0.025MG;0.8MG	N022573	001	Dec 22, 2010	Jan	CRLD
>A>	+		0.025MG;0.8MG	N022573	001	Dec 22, 2010	Jan	CRLD

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-28
GILDESS FE 1.5/30

>A>	AB	VINTAGE	0.03MG;1.5MG	A077075	001	Apr 28, 2005	Jan	CTNA

GILDESS FE 1/20

>A>	AB	VINTAGE	0.02MG;1MG	A077077	001	May 20, 2005	Jan	CTNA

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

>D>	AB	VINTAGE	0.02MG;1MG	A077077	001	May 20, 2005	Jan	CTNA
>D>	AB		0.03MG;1.5MG	A077075	001	Apr 28, 2005	Jan	CTNA

ETRAVIRINE

TABLET; ORAL
INTELENCE

>D>	+	TIBOTEC	100MG	N022187	001	Jan 18, 2008	Jan	CRLD
>A>			100MG	N022187	001	Jan 18, 2008	Jan	CRLD
>A>	+		200MG	N022187	002	Dec 22, 2010	Jan	NEWA

FAMOTIDINE

INJECTABLE; INJECTION
PEPCID

>D>	AP	+ MERCK	10MG/ML	N019510	001	Nov 04, 1986	Jan	DISC
>A>		@	10MG/ML	N019510	001	Nov 04, 1986	Jan	DISC

PEPCID PRESERVATIVE FREE

>D>	AP	+ MERCK	10MG/ML	N019510	004	Nov 04, 1986	Jan	DISC
>A>		@	10MG/ML	N019510	004	Nov 04, 1986	Jan	DISC

PEPCID PRESERVATIVE FREE IN PLASTIC CONTAINER

>D>	AP	+ MERCK	0.4MG/ML	N020249	001	Feb 18, 1994	Jan	DISC
>A>		@	0.4MG/ML	N020249	001	Feb 18, 1994	Jan	DISC

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL
FENTANYL-100

>A>	AB	MALLINCKRODT INC	100MCG/HR	A077154	004	Feb 09, 2011	Jan	NEWA

FENTANYL-25

>A>	AB	MALLINCKRODT INC	25MCG/HR	A077154	001	Feb 09, 2011	Jan	NEWA

FENTANYL-50

>A>	AB	MALLINCKRODT INC	50MCG/HR	A077154	002	Feb 09, 2011	Jan	NEWA

FENTANYL-75

>A>	AB	MALLINCKRODT INC	75MCG/HR	A077154	003	Feb 09, 2011	Jan	NEWA

FENTANYL CITRATE

TABLET; SUBLINGUAL
ABSTRAL

>A>		PROSTRAKAN INC	EQ 0.1MG BASE	N022510	001	Jan 07, 2011	Jan	NEWA
>A>			EQ 0.2MG BASE	N022510	002	Jan 07, 2011	Jan	NEWA

>A>		TABLET; SUBLINGUAL							
>A>		ABSTRAL							
>A>		PROSTRAKAN INC	EQ 0.3MG BASE	N022510	003	Jan 07, 2011	Jan	NEWA	
>A>	+		EQ 0.4MG BASE	N022510	004	Jan 07, 2011	Jan	NEWA	
>A>			EQ 0.6MG BASE	N022510	005	Jan 07, 2011	Jan	NEWA	
>A>			EQ 0.8MG BASE	N022510	006	Jan 07, 2011	Jan	NEWA	

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

		TABLET, EXTENDED RELEASE; ORAL							
		FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE							
>D>	AB	DR REDDYS LABS LTD	180MG;240MG	A079043	001	Mar 17, 2010	Jan	CTEC	
>A>			180MG;240MG	A079043	001	Mar 17, 2010	Jan	CTEC	

FLUDARABINE PHOSPHATE

>D>		TABLET; ORAL							
>D>		OFORTA							
>D>	+	SANOFI AVENTIS US	10MG	N022273	001	Dec 18, 2008	Jan	DISC	
>A>		@	10MG	N022273	001	Dec 18, 2008	Jan	DISC	

FOLIC ACID

		TABLET; ORAL							
		FOLIC ACID							
>D>	AA	CADISTA PHARMS	1MG	A040514	001	Jun 14, 2005	Jan	CAHN	
>A>	AA	JUBILANT CADISTA	1MG	A040514	001	Jun 14, 2005	Jan	CAHN	

GABAPENTIN

		CAPSULE; ORAL							
		GABAPENTIN							
>A>	AB	MATRIX LABS LTD	100MG	A090158	001	Feb 14, 2011	Jan	NEWA	
>A>	AB		300MG	A090158	002	Feb 14, 2011	Jan	NEWA	
>A>	AB		400MG	A090158	003	Feb 14, 2011	Jan	NEWA	
		TABLET; ORAL							
		GABAPENTIN							
>A>	AB	ZYDUS PHARMS USA INC	600MG	A078926	001	Feb 11, 2011	Jan	NEWA	
>A>	AB		800MG	A078926	002	Feb 11, 2011	Jan	NEWA	
>A>		GRALISE							
>A>	BX	+ ABBOTT PRODS	300MG	N022544	001	Jan 28, 2011	Jan	NEWA	
>A>	BX	+	600MG	N022544	002	Jan 28, 2011	Jan	NEWA	

GALANTAMINE HYDROBROMIDE

		CAPSULE, EXTENDED RELEASE; ORAL							
		GALANTAMINE HYDROBROMIDE							
>A>	AB	MYLAN	EQ 8MG BASE	A090900	001	Jan 24, 2011	Jan	NEWA	
>A>	AB		EQ 16MG BASE	A090900	002	Jan 24, 2011	Jan	NEWA	
>A>	AB		EQ 24MG BASE	A090900	003	Jan 24, 2011	Jan	NEWA	
>A>	AB	SUN PHARMA GLOBAL	EQ 8MG BASE	A090178	001	Feb 02, 2011	Jan	NEWA	
>A>	AB		EQ 16MG BASE	A090178	002	Feb 02, 2011	Jan	NEWA	
>A>	AB		EQ 24MG BASE	A090178	003	Feb 02, 2011	Jan	NEWA	
		TABLET; ORAL							
		GALANTAMINE HYDROBROMIDE							
>A>	AB	ZYDUS PHARMS USA INC	EQ 4MG BASE	A078898	001	Feb 17, 2011	Jan	NEWA	
>A>	AB		EQ 8MG BASE	A078898	002	Feb 17, 2011	Jan	NEWA	
>A>	AB		EQ 12MG BASE	A078898	003	Feb 17, 2011	Jan	NEWA	

GEMCITABINE HYDROCHLORIDE

INJECTABLE; INJECTION

>A>		GEMCITABINE HYDROCHLORIDE						
>A>	AP	TEVA PARENTERAL	EQ 200MG BASE/VIAL	A077983	002	Jan 25, 2011	Jan	NEWA
>A>	AP		EQ 1GM BASE/VIAL	A077983	001	Jan 25, 2011	Jan	NEWA
		GEMZAR						
>D>	+	LILLY	EQ 200MG BASE/VIAL	N020509	001	May 15, 1996	Jan	CFTG
>A>	AP +		EQ 200MG BASE/VIAL	N020509	001	May 15, 1996	Jan	CFTG
>D>	+		EQ 1GM BASE/VIAL	N020509	002	May 15, 1996	Jan	CFTG
>A>	AP +		EQ 1GM BASE/VIAL	N020509	002	May 15, 1996	Jan	CFTG

GENTAMICIN SULFATE

OINTMENT; OPHTHALMIC

		GENTAMICIN SULFATE						
>D>	AT	ALTANA	EQ 0.3% BASE	A065024	001	Jul 30, 2004	Jan	CAHN
>A>	AT	NYCOMED US	EQ 0.3% BASE	A065024	001	Jul 30, 2004	Jan	CAHN

GLIPIZIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

		GLIPIZIDE AND METFORMIN HYDROCHLORIDE						
>A>	AB	ZYDUS PHARMS USA INC	2.5MG;250MG	A078905	001	Jan 31, 2011	Jan	NEWA
>A>	AB		2.5MG;500MG	A078905	002	Jan 31, 2011	Jan	NEWA
>A>	AB		5MG;500MG	A078905	003	Jan 31, 2011	Jan	NEWA

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL

		FULVICIN P/G						
>A>		@ ELORAC	125MG	A061996	001		Jan	CAHN
>A>		@	250MG	A061996	002		Jan	CAHN
>D>		@ SCHERING	125MG	A061996	001		Jan	CAHN
>D>		@	250MG	A061996	002		Jan	CAHN
		FULVICIN P/G 165						
>A>		@ ELORAC	165MG	A061996	003	Apr 06, 1982	Jan	CAHN
>D>		@ SCHERING	165MG	A061996	003	Apr 06, 1982	Jan	CAHN
		FULVICIN P/G 330						
>A>		@ ELORAC	330MG	A061996	004	Apr 06, 1982	Jan	CAHN
>D>		@ SCHERING	330MG	A061996	004	Apr 06, 1982	Jan	CAHN

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

		HYDROCHLOROTHIAZIDE						
>D>	AB	CADISTA PHARMS	12.5MG	A078391	001	Feb 11, 2008	Jan	CAHN
>A>	AB	JUBILANT CADISTA	12.5MG	A078391	001	Feb 11, 2008	Jan	CAHN

TABLET; ORAL

		HYDROCHLOROTHIAZIDE						
>D>	AB	CADISTA PHARMS	25MG	A040809	001	Sep 04, 2007	Jan	CAHN
>D>	AB		50MG	A040809	002	Sep 04, 2007	Jan	CAHN
>A>	AB	JUBILANT CADISTA	25MG	A040809	001	Sep 04, 2007	Jan	CAHN
>A>	AB		50MG	A040809	002	Sep 04, 2007	Jan	CAHN

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL

		LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE						
>A>	AB	WATSON LABS	12.5MG;50MG	A200180	001	Jan 12, 2011	Jan	NEWA
>A>	AB		12.5MG;100MG	A200180	002	Jan 12, 2011	Jan	NEWA

TABLET; ORAL
LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

>A>	AB	WATSON LABS	25MG;100MG	A200180	003	Jan 12, 2011	Jan	NEWA

HYDROXYAMPHETAMINE HYDROBROMIDE

SOLUTION/DROPS; OPHTHALMIC
PAREDRINE

>D>		@ AKORN	1%	N000004	004		Jan	CAHN
>A>		@ PHARMICS	1%	N000004	004		Jan	CAHN

ILOPERIDONE

TABLET; ORAL
FANAPT

>A>		NOVARTIS	2MG	N022192	002	May 06, 2009	Jan	CAHN
>A>			4MG	N022192	003	May 06, 2009	Jan	CAHN
>A>			6MG	N022192	004	May 06, 2009	Jan	CAHN
>A>			8MG	N022192	005	May 06, 2009	Jan	CAHN
>A>			10MG	N022192	006	May 06, 2009	Jan	CAHN
>D>		VANDA PHARMS INC	2MG	N022192	002	May 06, 2009	Jan	CAHN
>D>			4MG	N022192	003	May 06, 2009	Jan	CAHN
>D>			6MG	N022192	004	May 06, 2009	Jan	CAHN
>D>			8MG	N022192	005	May 06, 2009	Jan	CAHN
>D>			10MG	N022192	006	May 06, 2009	Jan	CAHN

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

>D>		INDOCIN SR						
>D>	AB	+ SANDOZ	75MG	A074464	001	May 28, 1998	Jan	CTNA
>A>		INDOMETHACIN						
>A>	AB	+ SANDOZ	75MG	A074464	001	May 28, 1998	Jan	CTNA

>A> IOFLUPANE I-123

>A> SOLUTION; INTRAVENOUS
>A> DATSCAN

>A>		+ GE HLTHCARE INC	5MCI/2.5ML (2MCI/ML)	N022454	001	Jan 14, 2011	Jan	NEWA

LAMOTRIGINE

TABLET; ORAL
LAMOTRIGINE

>A>	AB	ALEMBIC LTD	25MG	A090607	001	Jan 13, 2011	Jan	NEWA
>A>	AB		100MG	A090607	002	Jan 13, 2011	Jan	NEWA
>A>	AB		150MG	A090607	003	Jan 13, 2011	Jan	NEWA
>A>	AB		200MG	A090607	004	Jan 13, 2011	Jan	NEWA

LEVETIRACETAM

TABLET; ORAL
LEVETIRACETAM

>A>	AB	ACCORD HLTHCARE	250MG	A090843	001	Feb 14, 2011	Jan	NEWA
>A>	AB		500MG	A090843	002	Feb 14, 2011	Jan	NEWA
>A>	AB		750MG	A090843	003	Feb 14, 2011	Jan	NEWA
>A>	AB		1GM	A090843	004	Feb 14, 2011	Jan	NEWA

LEVOFLOXACIN

SOLUTION/DROPS; OPHTHALMIC
LEVOFLOXACIN

>A>	AT	HI TECH PHARMA	0.5%	A076826	001	Feb 10, 2011	Jan	NEWA

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE; ORAL
LITHIUM CARBONATE

>A>	AB	GLENMARK GENERICS	450MG	A091616	001	Feb 14, 2011	Jan	NEWA

LOSARTAN POTASSIUM

TABLET; ORAL
LOSARTAN POTASSIUM

>A>	AB	MYLAN	25MG	A091590	001	Oct 06, 2010	Jan	NEWA
>A>	AB		50MG	A091590	002	Oct 06, 2010	Jan	NEWA
>A>	AB		100MG	A091590	003	Oct 06, 2010	Jan	NEWA

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
MECLIZINE HYDROCHLORIDE

>D>	AA	CADISTA PHARMS	12.5MG	A040659	001	Jun 04, 2010	Jan	CAHN
>D>	AA		25MG	A040659	002	Jun 04, 2010	Jan	CAHN
>A>	AA	JUBILANT CADISTA	12.5MG	A040659	001	Jun 04, 2010	Jan	CAHN
>A>	AA		25MG	A040659	002	Jun 04, 2010	Jan	CAHN

METHYLPREDNISOLONE

TABLET; ORAL
METHYLPREDNISOLONE

>D>	AB	CADISTA PHARMS	4MG	A040189	001	Oct 31, 1997	Jan	CAHN
>D>	AB		8MG	A040189	002	Oct 31, 1997	Jan	CAHN
>D>	AB		16MG	A040189	003	Jul 20, 2007	Jan	CAHN
>D>	AB		32MG	A040189	004	Jul 20, 2007	Jan	CAHN
>A>	AB	JUBILANT CADISTA	4MG	A040189	001	Oct 31, 1997	Jan	CAHN
>A>	AB		8MG	A040189	002	Oct 31, 1997	Jan	CAHN
>A>	AB		16MG	A040189	003	Jul 20, 2007	Jan	CAHN
>A>	AB		32MG	A040189	004	Jul 20, 2007	Jan	CAHN

METRONIDAZOLE

GEL; TOPICAL
METRONIDAZOLE

>A>	AB	G AND W LABS INC	0.75%	A078178	001	Jan 19, 2011	Jan	NEWA

MICAFUNGIN SODIUM

INJECTABLE; IV (INFUSION)
MYCAMINE

>D>		ASTELLAS	100MG/VIAL	N021506	003	Jun 27, 2006	Jan	CRLD
>A>	+		100MG/VIAL	N021506	003	Jun 27, 2006	Jan	CRLD

MIRTAZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL
MIRTAZAPINE

>A>	AB	ACTAVIS ELIZABETH	15MG	A077959	001	Feb 14, 2011	Jan	NEWA
>A>	AB		30MG	A077959	002	Feb 14, 2011	Jan	NEWA
>A>	AB		45MG	A077959	003	Feb 14, 2011	Jan	NEWA

MUPIROCIN CALCIUM

>A> CREAM; TOPICAL
>A> BACTROBAN

>A>	+	GLAXOSMITHKLINE	EQ 2% BASE	N050746	001	Dec 11, 1997	Jan	CDFR

>D>		CREAM, AUGMENTED; TOPICAL							
>D>		BACTROBAN							
>D>	+	GLAXOSMITHKLINE	EQ 2% BASE	N050746	001	Dec 11, 1997	Jan	CDFR	
		NABUMETONE							
		TABLET; ORAL							
		NABUMETONE							
>A>	AB	LUPIN LTD	500MG	A090445	001	Jan 12, 2011	Jan	NEWA	
>A>	AB		750MG	A090445	002	Jan 12, 2011	Jan	NEWA	
		NAPROXEN							
		TABLET; ORAL							
		NAPROXEN							
>A>	AB	MARKSANS PHARMA	250MG	A091416	001	Feb 14, 2011	Jan	NEWA	
>A>	AB		375MG	A091416	002	Feb 14, 2011	Jan	NEWA	
>A>	AB		500MG	A091416	003	Feb 14, 2011	Jan	NEWA	
		NARATRIPTAN							
		TABLET; ORAL							
		NARATRIPTAN							
>A>	AB	SUN PHARM INDS LTD	EQ 2.5MG BASE	A091552	001	Feb 14, 2011	Jan	NEWA	
		NISOLDIPINE							
		TABLET, EXTENDED RELEASE; ORAL							
>A>		NISOLDIPINE							
>A>	AB	MYLAN	8.5MG	A091001	001	Jan 26, 2011	Jan	NEWA	
>A>	AB		17MG	A091001	002	Jan 26, 2011	Jan	NEWA	
>A>	AB		25.5MG	A091001	003	Jan 26, 2011	Jan	NEWA	
>A>	AB		34MG	A091001	004	Jan 26, 2011	Jan	NEWA	
		SULAR							
>D>	+	SHIONOGI PHARMA	8.5MG	N020356	008	Jan 02, 2008	Jan	CFTG	
>A>	AB +		8.5MG	N020356	008	Jan 02, 2008	Jan	CFTG	
>D>	+		17MG	N020356	007	Jan 02, 2008	Jan	CFTG	
>A>	AB +		17MG	N020356	007	Jan 02, 2008	Jan	CFTG	
>D>			25.5MG	N020356	006	Jan 02, 2008	Jan	CFTG	
>A>	AB		25.5MG	N020356	006	Jan 02, 2008	Jan	CFTG	
>D>	+		34MG	N020356	005	Jan 02, 2008	Jan	CFTG	
>A>	AB +		34MG	N020356	005	Jan 02, 2008	Jan	CFTG	
		OCTREOTIDE ACETATE							
		INJECTABLE; INJECTION							
		OCTREOTIDE ACETATE (PRESERVATIVE FREE)							
>A>	AP	BIONICHE PHARMA USA	EQ 0.05MG BASE/ML	A079198	001	Feb 10, 2011	Jan	NEWA	
>A>	AP		EQ 0.1MG BASE/ML	A079198	002	Feb 10, 2011	Jan	NEWA	
>A>	AP		EQ 0.5MG BASE/ML	A079198	003	Feb 10, 2011	Jan	NEWA	
		ONDANSETRON HYDROCHLORIDE							
		INJECTABLE; INJECTION							
		ONDANSETRON HYDROCHLORIDE							
>D>		@ TEVA	EQ 2MG BASE/ML	A076876	001	Nov 22, 2006	Jan	CMFD	
>A>	AP		EQ 2MG BASE/ML	A076876	001	Nov 22, 2006	Jan	CMFD	
		SOLUTION; ORAL							
		ONDANSETRON HYDROCHLORIDE							
>A>	AA	AMNEAL PHARMS	EQ 4MG BASE/5ML	A091483	001	Jan 31, 2011	Jan	NEWA	
>A>	AA	SILARX	EQ 4MG BASE/5ML	A091342	001	Jan 27, 2011	Jan	NEWA	

OXALIPLATIN

INJECTABLE; IV (INFUSION)

OXALIPLATIN

>A>	AP	SANDOZ	50MG/10ML (5MG/ML)	A078817	001	Jan 24, 2011	Jan	NEWA
>A>	AP		100MG/20ML (5MG/ML)	A078817	002	Jan 24, 2011	Jan	NEWA

OXYMORPHONE HYDROCHLORIDE

TABLET; ORAL

OXYMORPHONE HYDROCHLORIDE

>A>	AB	TEVA	5MG	A091443	002	Feb 15, 2011	Jan	NEWA
>A>	AB		10MG	A091443	001	Feb 15, 2011	Jan	NEWA

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL

PANTOPRAZOLE SODIUM

>A>	AB	ACTAVIS TOTOWA	EQ 20MG BASE	A090797	001	Feb 07, 2011	Jan	NEWA
>A>	AB		EQ 40MG BASE	A090797	002	Feb 07, 2011	Jan	NEWA
>A>	AB	DR REDDYS LABS LTD	EQ 20MG BASE	A077619	001	Jan 19, 2011	Jan	NEWA
>A>	AB		EQ 40MG BASE	A077619	002	Jan 19, 2011	Jan	NEWA
>A>	AB	KUDCO IRELAND	EQ 20MG BASE	A078281	001	Jan 20, 2011	Jan	NEWA
>A>	AB		EQ 40MG BASE	A078281	002	Jan 20, 2011	Jan	NEWA
>A>	AB	MATRIX LABS LTD	EQ 20MG BASE	A090970	001	Jan 19, 2011	Jan	NEWA
>A>	AB		EQ 40MG BASE	A090970	002	Jan 19, 2011	Jan	NEWA
>A>	AB	TORRENT PHARMS	EQ 20MG BASE	A090074	001	Jan 19, 2011	Jan	NEWA
>A>	AB		EQ 40MG BASE	A090074	002	Jan 19, 2011	Jan	NEWA
>A>	AB	WOCKHARDT	EQ 20MG BASE	A091231	001	Jan 19, 2011	Jan	NEWA
>A>	AB		EQ 40MG BASE	A091231	002	Jan 19, 2011	Jan	NEWA

PHENTERMINE HYDROCHLORIDE

TABLET; ORAL

PHENTERMINE HYDROCHLORIDE

>A>	AA	EPIC PHARMA LLC	37.5MG	A200272	001	Jan 31, 2011	Jan	NEWA

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE; INJECTION

PIPERACILLIN AND TAZOBACTAM

>A>	AP	HOSPIRA INC	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	A065386	001	Sep 15, 2009	Jan	CAHN
>A>	AP		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	A065386	002	Sep 15, 2009	Jan	CAHN
>A>	AP		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A065386	003	Sep 15, 2009	Jan	CAHN
>A>	AP		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A065446	001	Sep 15, 2009	Jan	CAHN
>D>	AP	ORCHID HLTHCARE	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	A065386	001	Sep 15, 2009	Jan	CAHN
>D>	AP		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	A065386	002	Sep 15, 2009	Jan	CAHN
>D>	AP		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A065386	003	Sep 15, 2009	Jan	CAHN
>D>	AP		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A065446	001	Sep 15, 2009	Jan	CAHN

PREDNISONE

TABLET; ORAL

PREDNISONE

>D>	AB	CADISTA PHARMS	1MG	A040611	001	Jun 06, 2005	Jan	CAHN
>D>	AB		5MG	A040362	002	Aug 29, 2001	Jan	CAHN

TABLET; ORAL
PREDNISONE

>D>	AB	CADISTA PHARMS	10MG	A040362	001	Aug 29, 2001	Jan	CAHN
>D>	AB		20MG	A040362	003	Jun 29, 2005	Jan	CAHN
>A>	AB	JUBILANT CADISTA	1MG	A040611	001	Jun 06, 2005	Jan	CAHN
>A>	AB		5MG	A040362	002	Aug 29, 2001	Jan	CAHN
>A>	AB		10MG	A040362	001	Aug 29, 2001	Jan	CAHN
>A>	AB		20MG	A040362	003	Jun 29, 2005	Jan	CAHN

PROCHLORPERAZINE MALEATE

TABLET; ORAL
PROCOMP

>D>	AB	CADISTA PHARMS	EQ 5MG BASE	A040268	001	Feb 27, 1998	Jan	CAHN
>D>	AB		EQ 10MG BASE	A040268	002	Feb 27, 1998	Jan	CAHN
>A>	AB	JUBILANT CADISTA	EQ 5MG BASE	A040268	001	Feb 27, 1998	Jan	CAHN
>A>	AB		EQ 10MG BASE	A040268	002	Feb 27, 1998	Jan	CAHN

PROPANTHELINE BROMIDE

TABLET; ORAL
PROPANTHELINE BROMIDE

>D>		@ ROXANE	15MG	A080927	002		Jan	CMFD
>A>		+	15MG	A080927	002		Jan	CMFD

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
>D> DARVON

>D>	AA	+ XANODYNE PHARM	65MG	N010997	003		Jan	DISC
>A>		@	65MG	N010997	003		Jan	DISC

PROPOXYPHENE HYDROCHLORIDE

>D>	AA	WEST WARD	65MG	A083501	001		Jan	DISC
>A>		@	65MG	A083501	001		Jan	DISC

>D> PROPOXYPHENE NAPSYLATE

>D> TABLET; ORAL
>D> DARVON-N

>D>		+ XANODYNE PHARM	100MG	N016862	002		Jan	DISC
>A>		@	100MG	N016862	002		Jan	DISC

RISPERIDONE

SOLUTION; ORAL
RISPERIDONE

>A>	AA	TARO	1MG/ML	A090347	001	Feb 07, 2011	Jan	NEWA

ROCURONIUM BROMIDE

INJECTABLE; INJECTION
ROCURONIUM BROMIDE

>D>	AP	SAGENT PHARMS	50MG/5ML (10MG/ML)	A091458	001	Jul 28, 2010	Jan	CAHN
>D>	AP		100MG/10ML (10MG/ML)	A091458	002	Jul 28, 2010	Jan	CAHN
>A>	AP	SAGENT STRIDES	50MG/5ML (10MG/ML)	A091458	001	Jul 28, 2010	Jan	CAHN
>A>	AP		100MG/10ML (10MG/ML)	A091458	002	Jul 28, 2010	Jan	CAHN

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECONAL SODIUM

>A>		+ MARATHON PHARMS	50MG	A086101	001	Oct 03, 1983	Jan	CAHN
>A>		+	100MG	A086101	002	Oct 03, 1983	Jan	CAHN

CAPSULE; ORAL
SECONAL SODIUM

>D>		+	RANBAXY	50MG	A086101	001	Oct 03, 1983	Jan	CAHN
>D>		+		100MG	A086101	002	Oct 03, 1983	Jan	CAHN

SODIUM FLUORIDE F-18

INJECTABLE; INTRAVENOUS
SODIUM FLUORIDE F 18

>A>		+	NIH NCI DCTD	10-200mCi/ML	N022494	001	Jan 26, 2011	Jan	NEWA

SODIUM NITRITE; SODIUM THIOSULFATE

SOLUTION, SOLUTION; INTRAVENOUS, INTRAVENOUS
SODIUM NITRITE

>A>		+	HOPE PHARMS	300MG/10ML(30MG/ML),N/A;N/A,12.5GM/50ML(250MG/ML)	N201444	001	Jan 14, 2011	Jan	NEWA

SPINOSAD

SUSPENSION; TOPICAL
NATROBA

>A>		+	PARAPRO PHARMS	0.9%	N022408	001	Jan 18, 2011	Jan	NEWA

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
TERAZOSIN HYDROCHLORIDE

>D>	AB		CADISTA PHARMS	EQ 1MG BASE	A075317	001	Dec 20, 2004	Jan	CAHN
>D>	AB			EQ 2MG BASE	A075317	002	Dec 20, 2004	Jan	CAHN
>D>	AB			EQ 5MG BASE	A075317	003	Dec 20, 2004	Jan	CAHN
>D>	AB			EQ 10MG BASE	A075317	004	Dec 20, 2004	Jan	CAHN
>A>	AB		JUBILANT CADISTA	EQ 1MG BASE	A075317	001	Dec 20, 2004	Jan	CAHN
>A>	AB			EQ 2MG BASE	A075317	002	Dec 20, 2004	Jan	CAHN
>A>	AB			EQ 5MG BASE	A075317	003	Dec 20, 2004	Jan	CAHN
>A>	AB			EQ 10MG BASE	A075317	004	Dec 20, 2004	Jan	CAHN

TERBUTALINE SULFATE

TABLET; ORAL
TERBUTALINE SULFATE

>D>	AB		IMPAX LABS	5MG	A075877	002	Jun 26, 2001	Jan	CRLD
>A>	AB	+		5MG	A075877	002	Jun 26, 2001	Jan	CRLD

TOPOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION
TOPOTECAN HYDROCHLORIDE

>A>	AP		SAGENT PHARMS	EQ 4MG BASE/VIAL	A091284	001	Jan 26, 2011	Jan	NEWA

TRAMADOL HYDROCHLORIDE

TABLET; ORAL
TRAMADOL HYDROCHLORIDE

>A>	AB		ZYDUS PHARMS USA INC	50MG	A090404	001	Jan 31, 2011	Jan	NEWA

VILAZODONE HYDROCHLORIDE

TABLET; ORAL
VIIBRYD

>A>			TROVIS PHARMS	10MG	N022567	001	Jan 21, 2011	Jan	NEWA
>A>				20MG	N022567	002	Jan 21, 2011	Jan	NEWA
>A>		+		40MG	N022567	003	Jan 21, 2011	Jan	NEWA

VINCRISTINE SULFATE

INJECTABLE; INJECTION

>D>		VINCRISTINE SULFATE							
>D>	AP	APP PHARMS	1MG/ML	A076401	001	Oct 28, 2003	Jan	DISC	
>A>		@	1MG/ML	A076401	001	Oct 28, 2003	Jan	DISC	

>A>	FEXOFENADINE HYDROCHLORIDE							
>A>	SUSPENSION; ORAL							
>A>	CHILDREN'S ALLEGRA ALLERGY							
>A>	+ SANOFI AVENTIS US	30MG/5ML	N201373	001	Jan 24, 2011	Jan	NEWA	
>A>	CHILDREN'S ALLEGRA HIVES							
>A>	+ SANOFI AVENTIS US	30MG/5ML	N201373	002	Jan 24, 2011	Jan	NEWA	
>A>	TABLET, ORALLY DISINTEGRATING; ORAL							
>A>	CHILDREN'S ALLEGRA ALLERGY							
>A>	+ SANOFI AVENTIS US	30MG	N021909	002	Jan 24, 2011	Jan	NEWA	
>A>	CHILDREN'S ALLEGRA HIVES							
>A>	+ SANOFI AVENTIS US	30MG	N021909	003	Jan 24, 2011	Jan	NEWA	
>A>	TABLET; ORAL							
>A>	ALLEGRA ALLERGY							
>A>	SANOFI AVENTIS US	60MG	N020872	007	Jan 24, 2011	Jan	NEWA	
>A>	+	180MG	N020872	010	Jan 24, 2011	Jan	NEWA	
>A>	ALLEGRA HIVES							
>A>	SANOFI AVENTIS US	60MG	N020872	008	Jan 24, 2011	Jan	NEWA	
>A>	+	180MG	N020872	009	Jan 24, 2011	Jan	NEWA	
>A>	CHILDREN'S ALLEGRA ALLERGY							
>A>	SANOFI AVENTIS US	30MG	N020872	005	Jan 24, 2011	Jan	NEWA	
>A>	CHILDREN'S ALLEGRA HIVES							
>A>	SANOFI AVENTIS US	30MG	N020872	006	Jan 24, 2011	Jan	NEWA	
	FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE							
	TABLET, EXTENDED RELEASE; ORAL							
>A>	ALLEGRA-D 12 HOUR ALLERGY AND CONGESTION							
>A>	+ SANOFI AVENTIS US	60MG;120MG	N020786	002	Jan 24, 2011	Jan	NEWA	
>A>	ALLEGRA-D 24 HOUR ALLERGY AND CONGESTION							
>A>	+ SANOFI AVENTIS US	180MG;240MG	N021704	002	Jan 24, 2011	Jan	NEWA	
	IBUPROFEN							
	TABLET; ORAL							
	IBUPROFEN							
>A>	MARKSANS PHARMA	200MG	A091237	001	Feb 08, 2011	Jan	NEWA	
>A>		200MG	A091239	001	Feb 01, 2011	Jan	NEWA	
>A>	MERRO PHARM	200MG	A070985	001	Oct 02, 1987	Jan	CAHN	
>D>	PAR PHARM	200MG	A070985	001	Oct 02, 1987	Jan	CAHN	
	INSULIN SUSP ISOPHANE RECOMBINANT HUMAN							
	INJECTABLE; INJECTION							
	NOVOLIN N							
>D>	NOVO NORDISK INC	100 UNITS/ML	N019959	001	Jul 01, 1991	Jan	CRLD	
>A>	+	100 UNITS/ML	N019959	001	Jul 01, 1991	Jan	CRLD	

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

CUMULATIVE SUPPLEMENT NUMBER 1 JANUARY 2011

NO JANUARY 2011 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 2011 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2011

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ADAPALENE - DIFFERIN						
N021753 001	**>A>** 7868044	Mar 12, 2023	U-1078			
ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO						
N022545 001					**>A>** NCE	Mar 05, 2012
ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO						
N022545 002					**>A>** NCE	Mar 05, 2012
ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO						
N022545 003					**>A>** NCE	Mar 05, 2012
ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO						
N022545 004					**>A>** NCE	Mar 05, 2012
ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE						
N200045 001	**>A>** 5559111	Jul 21, 2018	DS DP U-3		**>A>** NCE	Mar 05, 2012
ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE						
N200045 002	**>A>** 5559111	Jul 21, 2018	DS DP U-3		**>A>** NCE	Mar 05, 2012
ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE						
N200045 003	**>A>** 5559111	Jul 21, 2018	DS DP U-3		**>A>** NCE	Mar 05, 2012
ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE						
N200045 004	**>A>** 5559111	Jul 21, 2018	DS DP U-3		**>A>** NCE	Mar 05, 2012
ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE						
N200045 005	**>A>** 5559111	Jul 21, 2018	DS DP U-3		**>A>** NCE	Mar 05, 2012
AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE - AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE						
A078381 005					**>A>** PC	Jul 02, 2011
AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE - AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE						
A078381 006					**>A>** PC	Jul 02, 2011
ATAZANAVIR SULFATE - REYATAZ						
N021567 001					**>A>** D-130	Feb 04, 2014
ATAZANAVIR SULFATE - REYATAZ						
N021567 002					**>A>** D-130	Feb 04, 2014
ATAZANAVIR SULFATE - REYATAZ						
N021567 003					**>A>** D-130	Feb 04, 2014
ATAZANAVIR SULFATE - REYATAZ						
N021567 004					**>A>** D-130	Feb 04, 2014
CLOPIDOGREL BISULFATE - PLAVIX						
N020839 001	**>A>** 4847265	Nov 17, 2011	DS DP			
	>A> 4847265*PED	May 17, 2012				
	>A> 5576328	Jan 31, 2014	U-432	Y		
	>A> 5576328*PED	Jul 31, 2014				
	>A> 6429210	Jun 10, 2019	DS DP			
	>A> 6429210*PED	Dec 10, 2019				
	>A> 6504030	Jun 10, 2019	DS			
	>A> 6504030*PED	Dec 10, 2019				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2011

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
CLOPIDOGREL BISULFATE - PLAVIX						
N020839 002	**>A>** 4847265	Nov 17, 2011	DS DP			
	>A> 4847265*PED	May 17, 2012				
	>A> 6429210	Jun 10, 2019	DS DP			
	>A> 6429210*PED	Dec 10, 2019				
	>A> 6504030	Jun 10, 2019	DS			
	>A> 6504030*PED	Dec 10, 2019				
DESIRUDIN RECOMBINANT - IPRIVASK						
N021271 001	**>A>** 6103515	Aug 15, 2017	DS			
DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - SAFYRAL						
N022574 001	**>A>** 5798338	Jul 10, 2015	DP			
	>A> 6441168	Apr 17, 2020	DS			
	>A> 6958326	Dec 20, 2021	DP			
	>A> 7163931	Mar 03, 2022	U-1			
ETHINYL ESTRADIOL; LEVONORGESTREL - LOSEASONIQUE						
N022262 001	**>A>** 7858605	Jun 23, 2023	DP			
ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE						
N021840 001	**>A>** 7858605	Jun 23, 2023	DP			
ETHINYL ESTRADIOL; NORETHINDRONE - NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE						
N022573 001	**>A>** 5552394	Jul 22, 2014	U-828			
	>A> 6667050	Apr 06, 2019	DP U-828			
ETRAVIRINE - INTELENCE						
N022187 002	**>A>** 6878717	Nov 05, 2019	U-1016		**>A>** NCE	Jan 18, 2013
	>A> 7037917	Nov 05, 2019	DS DP U-1016			
EXENATIDE SYNTHETIC - BYETTA						
N021773 001	**>A>** 5424286	Dec 01, 2016	U-653			
	>A> 5424286	Dec 01, 2016	U-1108			
EXENATIDE SYNTHETIC - BYETTA						
N021773 002	**>A>** 5424286	Dec 01, 2016	U-653			
	>A> 5424286	Dec 01, 2016	U-1108			
FAMCICLOVIR - FAMVIR						
N020363 001					**>A>** M-98	Jan 31, 2014
FAMCICLOVIR - FAMVIR						
N020363 002					**>A>** M-98	Jan 31, 2014
FAMCICLOVIR - FAMVIR						
N020363 003					**>A>** M-98	Jan 31, 2014
FENOFIBRATE - ANTARA (MICRONIZED)						
N021695 001	**>A>** 7863331	Aug 08, 2020	U-1107			
	>A> 7863331	Aug 08, 2020	U-1106			
FENOFIBRATE - ANTARA (MICRONIZED)						
N021695 002	**>A>** 7863331	Aug 08, 2020	U-1107			
	>A> 7863331	Aug 08, 2020	U-1106			
FERUMOXYTOL - FERAHEME						
N022180 001	**>A>** 7871597	Mar 08, 2020	DS DP			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2011

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
FESOTERODINE FUMARATE - TOVIAZ						
N022030 001	**>A>** 7855230	May 11, 2019	U-913			
FESOTERODINE FUMARATE - TOVIAZ						
N022030 002	**>A>** 7855230	May 11, 2019	U-913			
FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE						
A079043 001					**>A>** PC	Jul 27, 2011
FULVESTRANT - FASLODEX						
N021344 001	**>A>** 6774122	Jan 09, 2021	U-596		**>A>** D-126	Sep 09, 2013
	>A> 6774122*PED	Jul 09, 2021			**>A>** PED	Mar 09, 2014
	>A> 7456160	Jan 09, 2021	U-596			
	>A> 7456160*PED	Jul 09, 2021				
GABAPENTIN - GRALISE						
N022544 001					**>A>** NP	Jan 28, 2014
GABAPENTIN - GRALISE						
N022544 002					**>A>** NP	Jan 28, 2014
GEMCITABINE HYDROCHLORIDE - GEMCITABINE						
A079183 001					**>A>** PC	May 14, 2011
GEMCITABINE HYDROCHLORIDE - GEMCITABINE HYDROCHLORIDE						
A077983 001					**>A>** PC	Jul 24, 2011
GEMCITABINE HYDROCHLORIDE - GEMCITABINE HYDROCHLORIDE						
A077983 002					**>A>** PC	Jul 24, 2011
IOFLUPANE I-123 - DATSCAN						
N022454 001					**>A>** NCE	Jan 14, 2016
LANREOTIDE ACETATE - SOMATULINE DEPOT						
N022074 001	**>A>** 5595760	Mar 08, 2020	DP U-831			
LANREOTIDE ACETATE - SOMATULINE DEPOT						
N022074 002	**>A>** 5595760	Mar 08, 2020	DP U-831			
LANREOTIDE ACETATE - SOMATULINE DEPOT						
N022074 003	**>A>** 5595760	Mar 08, 2020	DP U-831			
LENALIDOMIDE - REVLIMID						
N021880 001	**>A>** 7855217	Nov 24, 2024	DS DP			
LENALIDOMIDE - REVLIMID						
N021880 002	**>A>** 7855217	Nov 24, 2024	DS DP			
LENALIDOMIDE - REVLIMID						
N021880 004	**>A>** 7855217	Nov 24, 2024	DS DP			
METRONIDAZOLE - VANDAZOLE						
N021806 001	**>A>** 7456207	Sep 22, 2024	DP			
MOMETASONE FUROATE MONOHYDRATE - NASONEX						
N020762 001					**>A>** M-99	Jan 19, 2014
PERFLUTREN - DEFINITY						
N021064 001	**>A>** 5585112	Dec 17, 2013	DP			
RETAPAMULIN - ALTABAX						
N022055 001	**>A>** 7875630	Feb 14, 2027	DS			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2011

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
SPINOSAD - NATROBA						
N022408 001	**>A>** 5496931	Mar 05, 2013	DS U-1105		**>A>** NCE	Jan 18, 2016
	>A> 6063771	Jun 22, 2019	DP U-1105			
	>A> 6342482	Jun 22, 2019	DP U-1105			
	>A> 7030095	Jul 02, 2021	DP U-1105			
THALIDOMIDE - THALOMID						
N020785 001	**>A>** 7874984	Aug 28, 2018	U-733			
	>A> 7874984	Aug 28, 2018	U-732			
	>A> 7874984	Aug 28, 2018	U-442			
	>A> 7874984	Aug 28, 2018	U-371			
	>A> 7874984	Aug 28, 2018	U-1109			
THALIDOMIDE - THALOMID						
N020785 002	**>A>** 7874984	Aug 28, 2018	U-733			
	>A> 7874984	Aug 28, 2018	U-732			
	>A> 7874984	Aug 28, 2018	U-442			
	>A> 7874984	Aug 28, 2018	U-371			
	>A> 7874984	Aug 28, 2018	U-1109			
THALIDOMIDE - THALOMID						
N020785 003	**>A>** 7874984	Aug 28, 2018	U-733			
	>A> 7874984	Aug 28, 2018	U-732			
	>A> 7874984	Aug 28, 2018	U-442			
	>A> 7874984	Aug 28, 2018	U-371			
	>A> 7874984	Aug 28, 2018	U-1109			
THALIDOMIDE - THALOMID						
N020785 004	**>A>** 7874984	Aug 28, 2018	U-733			
	>A> 7874984	Aug 28, 2018	U-732			
	>A> 7874984	Aug 28, 2018	U-442			
	>A> 7874984	Aug 28, 2018	U-371			
	>A> 7874984	Aug 28, 2018	U-1109			
TIGECYCLINE - TYGACIL						
N021821 001	**>A>** 7879828	Feb 05, 2029	DP			
VILAZODONE HYDROCHLORIDE - VIIBRYD						
N022567 001	**>A>** 5532241	Sep 29, 2014	DS DP		**>A>** NCE	Jan 21, 2016
	>A> 7834020	Jun 05, 2022	DS DP U-839			
VILAZODONE HYDROCHLORIDE - VIIBRYD						
N022567 002	**>A>** 5532241	Sep 29, 2014	DS DP U-839		**>A>** NCE	Jan 21, 2016
	>A> 7834020	Jun 05, 2022	DS DP			
VILAZODONE HYDROCHLORIDE - VIIBRYD						
N022567 003	**>A>** 5532241	Sep 29, 2014	DS DP U-839		**>A>** NCE	Jan 21, 2016
	>A> 7834020	Jun 05, 2022	DS DP			
ZOLPIDEM TARTRATE - ZOLPIDEM TARTRATE						
A078148 001					**>A>** PC	Jun 04, 2011

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2011

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE

Footnote:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.
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