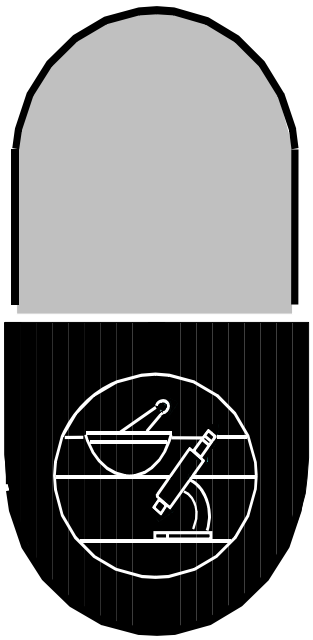
CUMULATIVE SUPPLEMENT 02
February 2010



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

30th EDITION

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

2010

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

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30th EDITION

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February 2010

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 30th 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
7500 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)
GOLDLINE LABORATORIES INC (GOLDLINE)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
HLR TECHNOLOGY (HLR)	HOFFMANN LA ROCHE INC (HOFFMANN LA ROCHE)
IVAX PHARMACEUTICALS INC (IVAX PHARMS)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
PROCTER AND GAMBLE CO (PROCTER AND GAMBLE)	WARNER CHILCOTT CO LLC (WARNER CHILCOTT)
PROCTER AND GAMBLE CO PHARMACEUTICALS INC SUB PROCTER AND GAMBLE CO (PROCTER AND GAMBLE)	WARNER CHILCOTT CO LLC (WARNER CHILCOTT)
TEVA PHARMACEUTICALS USA (TEVA PHARMS)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)

ZENITH GOLDLINE LABORATORIES INC (ZENITH GOLDLINE)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
ZENITH GOLDLINE PHARMACEUTICALS (ZENITH GOLDLINE)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
ZENITH GOLDLINE PHARMACEUTICALS INC (ZENITH GOLDLINE)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)

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 2009	MAR 2010	JUN 2010	SEPT 2010	DEC 2010
DRUG PRODUCTS LISTED	13065				
SINGLE SOURCE	2460 (18.8%)				
MULTISOURCE	10516 (80.5%)				
THERAPEUTICALLY EQUIVALENT	10367 (79.3%)				
NOT THERAPEUTICALLY EQUIVALENT	149 (1.1%)				
EXCEPTIONS[1]	89 (0.7%)				
NEW MOLECULAR ENTITIES APPROVED	3				
NUMBER OF APPLICANTS	718				

[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; BUTALBITAL

TABLET; ORAL

BUTAPAP

>D>	AB		MIKART	325MG;50MG	A089987	001	Oct 26, 1992	Feb	CTEC
>A>	AA			325MG;50MG	A089987	001	Oct 26, 1992	Feb	CTEC

PHRENILIN

>D>	AB	+	VALEANT	325MG;50MG	A087811	001	Jun 19, 1985	Feb	CTEC
>A>	AA	+		325MG;50MG	A087811	001	Jun 19, 1985	Feb	CTEC

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

>D>			NEXGEN PHARMA	300MG;50MG;40MG	A040885	001	Nov 16, 2009	Feb	CRLD
>A>		+		300MG;50MG;40MG	A040885	001	Nov 16, 2009	Feb	CRLD
>D>	AB		WEST WARD	500MG;50MG;40MG	A040261	001	Oct 28, 1998	Feb	CTEC
>A>	AA			500MG;50MG;40MG	A040261	001	Oct 28, 1998	Feb	CTEC

ESGIC-PLUS

>D>	AB	+	MIKART	500MG;50MG;40MG	A040085	001	Mar 28, 1996	Feb	CTEC
>A>	AA	+		500MG;50MG;40MG	A040085	001	Mar 28, 1996	Feb	CTEC

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

>D>	AB		CONCORD LABS NJ	325MG;50MG;40MG	A040864	001	Dec 01, 2008	Feb	CTEC
>A>	AA			325MG;50MG;40MG	A040864	001	Dec 01, 2008	Feb	CTEC
>D>	AB			500MG;50MG;40MG	A040883	001	Dec 23, 2008	Feb	CTEC
>A>	AA			500MG;50MG;40MG	A040883	001	Dec 23, 2008	Feb	CTEC
>D>	AB		MALLINCKRODT	325MG;50MG;40MG	A087804	001	Jan 24, 1985	Feb	CTEC
>A>	AA			325MG;50MG;40MG	A087804	001	Jan 24, 1985	Feb	CTEC
>D>	AB		MIKART	325MG;50MG;40MG	A089175	001	Jan 21, 1987	Feb	CTEC
>A>	AA			325MG;50MG;40MG	A089175	001	Jan 21, 1987	Feb	CTEC
>D>	AB		VINTAGE PHARMS	325MG;50MG;40MG	A040511	001	Aug 27, 2003	Feb	CTEC
>A>	AA			325MG;50MG;40MG	A040511	001	Aug 27, 2003	Feb	CTEC
>D>	AB			500MG;50MG;40MG	A040513	001	Aug 25, 2003	Feb	CTEC
>A>	AA			500MG;50MG;40MG	A040513	001	Aug 25, 2003	Feb	CTEC
>D>	AB		WATSON LABS	500MG;50MG;40MG	A040267	001	Jul 30, 1998	Feb	CTEC
>A>	AA			500MG;50MG;40MG	A040267	001	Jul 30, 1998	Feb	CTEC
>D>	AB		WEST WARD	325MG;50MG;40MG	A089718	001	Jun 12, 1995	Feb	CTEC
>A>	AA			325MG;50MG;40MG	A089718	001	Jun 12, 1995	Feb	CTEC
>D>	AB			500MG;50MG;40MG	A040336	001	Aug 18, 1999	Feb	CTEC
>A>	AA			500MG;50MG;40MG	A040336	001	Aug 18, 1999	Feb	CTEC

ESGIC-PLUS

>D>	AB	+	MIKART	500MG;50MG;40MG	A089451	001	May 23, 1988	Feb	CTEC
>A>	AA	+		500MG;50MG;40MG	A089451	001	May 23, 1988	Feb	CTEC

FIORICET

>D>	AB	+	WATSON PHARMS	325MG;50MG;40MG	A088616	001	Nov 09, 1984	Feb	CTEC
>A>	AA	+		325MG;50MG;40MG	A088616	001	Nov 09, 1984	Feb	CTEC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>A>		+	MIKART	300MG/15ML;10MG/15ML	A040881	001	Feb 25, 2010	Feb	NEWA

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

ACETAMINOPHEN AND PENTAZOCINE HYDROCHLORIDE

>D>	AB		WATSON LABS	650MG;EQ 25MG BASE	A074699	001	Mar 24, 2000	Feb	CRLD
>A>	AB	+		650MG;EQ 25MG BASE	A074699	001	Mar 24, 2000	Feb	CRLD
>D>			TALACEN						
>D>	AB	+	SANOFI AVENTIS US	650MG;EQ 25MG BASE	N018458	001	Sep 23, 1982	Feb	DISC
>A>		@		650MG;EQ 25MG BASE	N018458	001	Sep 23, 1982	Feb	DISC

ACITRETIN

CAPSULE; ORAL

SORIATANE

			STIEFEL LABS INC	17.5MG	N019821	003	Aug 06, 2009	Jan	NEWA
				22.5MG	N019821	004	Aug 06, 2009	Jan	NEWA

ALENDRONATE SODIUM

TABLET; ORAL

ALENDRONATE SODIUM

	AB		CADISTA PHARMS	EQ 5MG BASE	A090557	001	Feb 18, 2010	Jan	NEWA
	AB			EQ 10MG BASE	A090557	002	Feb 18, 2010	Jan	NEWA
	AB			EQ 35MG BASE	A090557	003	Feb 18, 2010	Jan	NEWA
	AB			EQ 70MG BASE	A090557	004	Feb 18, 2010	Jan	NEWA

ALPRAZOLAM

TABLET, ORALLY DISINTEGRATING; ORAL

ALPRAZOLAM

>A>	AB		ACTAVIS ELIZABETH	0.25MG	A078561	001	Mar 16, 2010	Feb	NEWA
>A>	AB			0.5MG	A078561	002	Mar 16, 2010	Feb	NEWA
>A>	AB			1MG	A078561	003	Mar 16, 2010	Feb	NEWA
>A>	AB			2MG	A078561	004	Mar 16, 2010	Feb	NEWA

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

CAPSULE; ORAL

AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE

	AB		LUPIN PHARMS	EQ 2.5MG BASE;10MG	A078466	001	Feb 05, 2010	Jan	NEWA
	AB			EQ 5MG BASE;10MG	A078466	002	Feb 05, 2010	Jan	NEWA
	AB			EQ 5MG BASE;20MG	A078466	003	Feb 05, 2010	Jan	NEWA
	AB			EQ 10MG BASE;20MG	A078466	004	Feb 05, 2010	Jan	NEWA

AMOXICILLIN

FOR SUSPENSION; ORAL

>D>			TRIMOX						
>D>	AB		APOTHECON	50MG/ML	A061886	001		Feb	DISC
>A>		@		50MG/ML	A061886	001		Feb	DISC
>D>	AB			125MG/5ML	A061886	002		Feb	DISC
>A>		@		125MG/5ML	A061886	002		Feb	DISC
>D>	AB			125MG/5ML	A062885	001	Mar 08, 1988	Feb	DISC
>A>		@		125MG/5ML	A062885	001	Mar 08, 1988	Feb	DISC
>D>	AB			250MG/5ML	A061886	003		Feb	DISC
>A>		@		250MG/5ML	A061886	003		Feb	DISC
>D>	AB			250MG/5ML	A062885	002	Mar 08, 1988	Feb	DISC
>A>		@		250MG/5ML	A062885	002	Mar 08, 1988	Feb	DISC

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AUGMENTIN '125'

>D>		@ GLAXOSMITHKLINE	125MG/5ML;EQ 31.25MG BASE/5ML	N050575	001	Aug 06, 1984	Feb	CMFD
>A>	AB		125MG/5ML;EQ 31.25MG BASE/5ML	N050575	001	Aug 06, 1984	Feb	CMFD

AUGMENTIN '250'

>D>		@ GLAXOSMITHKLINE	250MG/5ML;EQ 62.5MG BASE/5ML	N050575	002	Aug 06, 1984	Feb	CMFD
>A>	AB		250MG/5ML;EQ 62.5MG BASE/5ML	N050575	002	Aug 06, 1984	Feb	CMFD

TABLET; ORAL

AUGMENTIN '250'

>D>		@ GLAXOSMITHKLINE	250MG;EQ 125MG BASE	N050564	001	Aug 06, 1984	Feb	CMFD
>A>	AB		250MG;EQ 125MG BASE	N050564	001	Aug 06, 1984	Feb	CMFD

AUGMENTIN '500'

>D>		@ GLAXOSMITHKLINE	500MG;EQ 125MG BASE	N050564	002	Aug 06, 1984	Feb	CMFD
>A>	AB		500MG;EQ 125MG BASE	N050564	002	Aug 06, 1984	Feb	CMFD

AUGMENTIN '875'

>D>		@ GLAXOSMITHKLINE	875MG;EQ 125MG BASE	N050720	001	Feb 13, 1996	Feb	CMFD
>A>	AB		875MG;EQ 125MG BASE	N050720	001	Feb 13, 1996	Feb	CMFD

TABLET, EXTENDED RELEASE; ORAL

AUGMENTIN XR

>D>		@ GLAXOSMITHKLINE	1GM;EQ 62.5MG BASE	N050785	001	Sep 25, 2002	Feb	CMFD
>A>	AB		1GM;EQ 62.5MG BASE	N050785	001	Sep 25, 2002	Feb	CMFD

AMPHOTERICIN B

INJECTABLE, LIPID COMPLEX; INJECTION

ABELCET

>D>	+	ENZON	5MG/ML	N050724	001	Nov 20, 1995	Feb	CAHN
>A>	+	SIGMA TAU	5MG/ML	N050724	001	Nov 20, 1995	Feb	CAHN

ARMODAFINIL

TABLET; ORAL

NUVIGIL

>D>		CEPHALON	100MG	N021875	002	Mar 26, 2009	Feb	DISC
>A>		@	100MG	N021875	002	Mar 26, 2009	Feb	DISC
>D>			200MG	N021875	005	Mar 26, 2009	Feb	DISC
>A>		@	200MG	N021875	005	Mar 26, 2009	Feb	DISC

ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

INJECTABLE; INJECTION

>A> ARTICAINE HYDROCHLORIDE WITH EPINEPHRINE

>A>		PIERREL	4%;EQ 0.009MG BASE/1.8ML (EQ 0.005MG BASE/ML)	N022466	001	Feb 26, 2010	Feb	NEWA
>A>	+		4%;EQ 0.018MG BASE/1.8ML (EQ 0.01MG BASE/ML)	N022466	002	Feb 26, 2010	Feb	NEWA

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

FIORINAL

>D>	AB	+ WATSON PHARMS	325MG;50MG;40MG	N017534	005	Apr 16, 1986	Feb	CTEC
>A>	AA	+	325MG;50MG;40MG	N017534	005	Apr 16, 1986	Feb	CTEC

LANORINAL

>D>	AB	LANNETT	325MG;50MG;40MG	A086996	002	Oct 11, 1985	Feb	CTEC
>A>	AA		325MG;50MG;40MG	A086996	002	Oct 11, 1985	Feb	CTEC

TABLET; ORAL
BUTALBITAL, ASPIRIN AND CAFFEINE

>D>	AB		ACTAVIS ELIZABETH	325MG;50MG;40MG	A086710	002	Aug 23, 1983	Feb	CTEC
>A>	AA			325MG;50MG;40MG	A086710	002	Aug 23, 1983	Feb	CTEC
>D>	AB	+	WEST WARD	325MG;50MG;40MG	A086162	002	Feb 16, 1984	Feb	CTEC
>A>	AA	+		325MG;50MG;40MG	A086162	002	Feb 16, 1984	Feb	CTEC

AZELASTINE HYDROCHLORIDE

SPRAY, METERED; NASAL
ASTELIN

	AB	+	MEDA PHARMS	EQ 0.125MG BASE/SPRAY	N020114	001	Nov 01, 1996	Jan	CTEC

AZELASTINE HYDROCHLORIDE

	AB		APOTEX INC	EQ 0.125MG BASE/SPRAY	A077954	001	Apr 30, 2009	Jan	CMFD

AZITHROMYCIN

INJECTABLE; INJECTION
AZITHROMYCIN

>D>	AP		GENERAMEDIX	EQ 500MG BASE/VIAL	A065501	001	Nov 09, 2009	Feb	CAHN
>A>	AP		GLAND PHARMA LTD	EQ 500MG BASE/VIAL	A065501	001	Nov 09, 2009	Feb	CAHN

AZTREONAM

>A> FOR SOLUTION; INHALATION
>A> CAYSTON

>A>		+	GILEAD	75MG/VIAL	N050814	001	Feb 22, 2010	Feb	NEWA

BACLOFEN

TABLET; ORAL
BACLOFEN

	AB		MATRIX LABS LTD	10MG	A090334	001	Feb 18, 2010	Jan	NEWA
	AB			20MG	A090334	002	Feb 18, 2010	Jan	NEWA

TABLET, ORALLY DISINTEGRATING; ORAL
KEMSTRO

		@	SCHWARZ PHARMA	10MG	N021589	001	Oct 30, 2003	Jan	DISC
		@		20MG	N021589	002	Oct 30, 2003	Jan	DISC

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION
QVAR 40

>A>		+	TEVA BRANDED PHARM	0.04MG/INH	N020911	002	Sep 15, 2000	Feb	CAHN
>D>		+	TEVA GLOBAL	0.04MG/INH	N020911	002	Sep 15, 2000	Feb	CAHN

QVAR 80

>A>		+	TEVA BRANDED PHARM	0.08MG/INH	N020911	001	Sep 15, 2000	Feb	CAHN
>D>		+	TEVA GLOBAL	0.08MG/INH	N020911	001	Sep 15, 2000	Feb	CAHN

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE

>A>	AA	+	LANNETT	0.5MG	A088877	001	Apr 11, 1985	Feb	CAHN
>A>	AA	+		1MG	A088894	001	Apr 11, 1985	Feb	CAHN
>A>	AA	+		2MG	A088895	001	Apr 11, 1985	Feb	CAHN
>D>	AA	+	PAR PHARM	0.5MG	A088877	001	Apr 11, 1985	Feb	CAHN
>D>	AA	+		1MG	A088894	001	Apr 11, 1985	Feb	CAHN
>D>	AA	+		2MG	A088895	001	Apr 11, 1985	Feb	CAHN

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAXOLOL HYDROCHLORIDE

	AT		AKORN	EQ 0.5% BASE	A075386	001	Jun 30, 2000	Jan	CTNA
	AT		NOVEX	EQ 0.5% BASE	A075446	001	Sep 28, 2000	Jan	CTNA
	AT		WOCKHARDT	EQ 0.5% BASE	A078694	001	Nov 16, 2009	Jan	CAIN

TABLET; ORAL

BETAXOLOL HYDROCHLORIDE

>D>	AB		ACTAVIS TOTOWA	10MG	A075541	001	Oct 22, 1999	Feb	CAHN
>D>	AB	+		20MG	A075541	002	Oct 22, 1999	Feb	CAHN
>A>	AB		MIKAH PHARMA	10MG	A075541	001	Oct 22, 1999	Feb	CAHN
>A>	AB	+		20MG	A075541	002	Oct 22, 1999	Feb	CAHN

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

BUSPAR

>D>	AB	+	BRISTOL MYERS SQUIBB	15MG	N018731	003	Apr 22, 1996	Feb	DISC
>A>			@	15MG	N018731	003	Apr 22, 1996	Feb	DISC

BUSPIRONE HYDROCHLORIDE

>D>	AB		TEVA	30MG	A075022	004	Mar 25, 2004	Feb	CRLD
>A>	AB	+		30MG	A075022	004	Mar 25, 2004	Feb	CRLD

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

SOLUTION; IRRIGATION

BALANCED SALT

	AT		B BRAUN	0.48MG/ML;0.3MG/ML;0.75MG/ML;3.9MG/ML;6.4MG/ML;1.7MG/ML	A091387	001	Feb 03, 2010	Jan	NEWA

CARVEDILOL PHOSPHATE

CAPSULE, EXTENDED RELEASE; ORAL

COREG CR

>D>			SB PHARMCO	40MG	N022012	003	Oct 20, 2006	Feb	CRLD
>A>		+		40MG	N022012	003	Oct 20, 2006	Feb	CRLD
>D>		+		80MG	N022012	004	Oct 20, 2006	Feb	CRLD
>A>				80MG	N022012	004	Oct 20, 2006	Feb	CRLD

CEFADROXIL/CEFADROXIL HEMIHYDRATE

FOR SUSPENSION; ORAL

CEFADROXIL

	AB	+	LUPIN	EQ 500MG BASE/5ML	A065396	002	Feb 21, 2008	Jan	CRLD

DURICEF

			@ WARNER CHILCOTT	EQ 250MG BASE/5ML	N050527	003		Jan	DISC
			@	EQ 500MG BASE/5ML	N050527	001		Jan	DISC

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CEFOTAXIME SODIUM

	AP		CEPHAZONE PHARMA	EQ 10GM BASE/VIAL	A065348	001	Jan 25, 2010	Jan	NEWA

CEFOXITIN SODIUM

INJECTABLE; INJECTION

CEFOXITIN

>A>	AP		HIKMA FARMACEUTICA	EQ 1GM BASE/VIAL	A065238	001	Mar 12, 2010	Feb	NEWA
>A>	AP			EQ 2GM BASE/VIAL	A065238	002	Mar 12, 2010	Feb	NEWA

INJECTABLE; INJECTION
CEFOXITIN

>A>	AP		HIKMA FARMACEUTICA	EQ 10GM BASE/VIAL	A065239	001	Mar 02, 2010	Feb	NEWA

CEFPROZIL

FOR SUSPENSION; ORAL
CEFPROZIL

>D>	AB		LUPIN	250MG/5ML	A065261	002	Dec 19, 2005	Feb	CTEC
>A>	AB	+		250MG/5ML	A065261	002	Dec 19, 2005	Feb	CTEC

TABLET; ORAL
CEFPROZIL

>D>	AB		LUPIN	500MG	A065276	002	Dec 08, 2005	Feb	CRLD
>A>	AB	+		500MG	A065276	002	Dec 08, 2005	Feb	CRLD

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL
CETIRIZINE HYDROCHLORIDE

	AA		ACTAVIS MID ATLANTIC	5MG/5ML	A078617	001	Feb 02, 2010	Jan	NEWA

CICLOPIROX

SHAMPOO; TOPICAL
CICLOPIROX

	AT		PERRIGO	1%	A078594	001	Feb 16, 2010	Jan	NEWA

SOLUTION; TOPICAL
CICLOPIROX

	AT		VERSAPHARM	8%	A078975	001	Feb 17, 2010	Jan	NEWA

CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL
CIPRO

>D>	AB		BAYER HLTHCARE	EQ 500MG BASE	N019537	003	Oct 22, 1987	Feb	CRLD
>A>	AB	+		EQ 500MG BASE	N019537	003	Oct 22, 1987	Feb	CRLD
>D>	AB	+		EQ 750MG BASE	N019537	004	Oct 22, 1987	Feb	CRLD
>A>	AB			EQ 750MG BASE	N019537	004	Oct 22, 1987	Feb	CRLD

CYANOCOBALAMIN

SPRAY, METERED; NASAL
CALOMIST

			@ FLEMING	25MCG/SPRAY	N022102	001	Jul 27, 2007	Jan	DISC

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION
CYTOXAN

>D>			@ BAXTER HLTHCARE	500MG/VIAL	N012142	003		Feb	CMFD
>A>	AP	+		500MG/VIAL	N012142	003		Feb	CMFD
>D>			@	1GM/VIAL	N012142	004	Aug 30, 1982	Feb	CMFD
>A>	AP	+		1GM/VIAL	N012142	004	Aug 30, 1982	Feb	CMFD
>D>			@	2GM/VIAL	N012142	005	Aug 30, 1982	Feb	CMFD
>A>	AP	+		2GM/VIAL	N012142	005	Aug 30, 1982	Feb	CMFD
>D>			LYOPHILIZED CYTOXAN						
>D>		+	BAXTER HLTHCARE	100MG/VIAL	N012142	006	Dec 05, 1985	Feb	DISC
>A>			@	100MG/VIAL	N012142	006	Dec 05, 1985	Feb	DISC
>D>		+		200MG/VIAL	N012142	007	Dec 10, 1985	Feb	DISC
>A>			@	200MG/VIAL	N012142	007	Dec 10, 1985	Feb	DISC
>D>	AP	+		500MG/VIAL	N012142	008	Jan 04, 1984	Feb	DISC
>A>			@	500MG/VIAL	N012142	008	Jan 04, 1984	Feb	DISC

			INJECTABLE; INJECTION							
>D>			LYOPHILIZED CYTOXAN							
>D>	AP	+	BAXTER HLTHCARE	1GM/VIAL	N012142	010	Sep 24, 1985	Feb	DISC	
>A>			@	1GM/VIAL	N012142	010	Sep 24, 1985	Feb	DISC	
>D>	AP	+		2GM/VIAL	N012142	009	Dec 10, 1984	Feb	DISC	
>A>			@	2GM/VIAL	N012142	009	Dec 10, 1984	Feb	DISC	
			DALFAMPRIDINE							
			TABLET, EXTENDED RELEASE; ORAL							
			AMPYRA							
		+	ACORDA	10MG	N022250	001	Jan 22, 2010	Jan	NEWA	
			DESLORATADINE							
			TABLET; ORAL							
			CLARINEX							
	AB	+	SCHERING PLOUGH	5MG	N021165	001	Dec 21, 2001	Jan	CFTG	
			DESLORATADINE							
	AB		ORCHID HLTHCARE	5MG	A078357	001	Feb 19, 2010	Jan	NEWA	
			DESMOPRESSIN ACETATE							
			SPRAY, METERED; NASAL							
			STIMATE (NEEDS NO REFRIGERATION)							
			@ CSL BEHRING	1.5MG/SPRAY	N020355	002	Oct 24, 2007	Jan	DISC	
			DEXMEDETOMIDINE HYDROCHLORIDE							
			INJECTABLE; INJECTION							
			PRECEDEX							
		+	HOSPIRA	EQ 100MCG BASE/ML (EQ100MCG BASE/ML)	N021038	001	Dec 17, 1999	Jan	CAIN	
			DIAZOXIDE							
			CAPSULE; ORAL							
			PROGLYCEM							
>A>			@ TEVA BRANDED PHARM	50MG	N017425	001		Feb	CAHN	
>A>			@	100MG	N017425	002		Feb	CAHN	
>D>			@ TEVA GLOBAL	50MG	N017425	001		Feb	CAHN	
>D>			@	100MG	N017425	002		Feb	CAHN	
			DICLOFENAC POTASSIUM							
			TABLET; ORAL							
			DICLOFENAC POTASSIUM							
			@ SANDOZ	50MG	A075582	001	Feb 23, 2001	Jan	DISC	
			DIFLORASONE DIACETATE							
			CREAM; TOPICAL							
>D>			PSORCON							
>D>	AB1	+	SANOFI AVENTIS US	0.05%	N020205	001	Nov 20, 1992	Feb	DISC	
>A>			@	0.05%	N020205	001	Nov 20, 1992	Feb	DISC	
			DILTIAZEM HYDROCHLORIDE							
			TABLET, EXTENDED RELEASE; ORAL							
			CARDIZEM LA							
>D>			BIOVAIL LABS INTL	120MG	N021392	001	Feb 06, 2003	Feb	CFTG	
>A>	AB			120MG	N021392	001	Feb 06, 2003	Feb	CFTG	
>D>				180MG	N021392	002	Feb 06, 2003	Feb	CFTG	
>A>	AB			180MG	N021392	002	Feb 06, 2003	Feb	CFTG	

		TABLET, EXTENDED RELEASE; ORAL							
		CARDIZEM LA							
>D>		BIOVAIL LABS INTL	240MG	N021392	003	Feb 06, 2003	Feb	CFTG
>A>	AB		240MG	N021392	003	Feb 06, 2003	Feb	CFTG
>D>			300MG	N021392	004	Feb 06, 2003	Feb	CFTG
>A>	AB		300MG	N021392	004	Feb 06, 2003	Feb	CFTG
>D>			360MG	N021392	005	Feb 06, 2003	Feb	CFTG
>A>	AB		360MG	N021392	005	Feb 06, 2003	Feb	CFTG
>D>	+		420MG	N021392	006	Feb 06, 2003	Feb	CFTG
>A>	AB +		420MG	N021392	006	Feb 06, 2003	Feb	CFTG
>A>		DILTIAZEM HYDROCHLORIDE						
>A>	AB	WATSON LABS FLORIDA	120MG	A077686	006	Mar 15, 2010	Feb	NEWA
>A>	AB		180MG	A077686	005	Mar 15, 2010	Feb	NEWA
>A>	AB		240MG	A077686	004	Mar 15, 2010	Feb	NEWA
>A>	AB		300MG	A077686	003	Mar 15, 2010	Feb	NEWA
>A>	AB		360MG	A077686	002	Mar 15, 2010	Feb	NEWA
>A>	AB		420MG	A077686	001	Mar 15, 2010	Feb	NEWA
		EPINEPHRINE							
		INJECTABLE; IM-SC							
		TWINJECT 0.15							
	+	SHIONOGI PHARMA	EQ 0.15MG /DELIVERY	N020800	002	May 28, 2004	Jan	CAHN
		TWINJECT 0.3							
	+	SHIONOGI PHARMA	EQ 0.3MG /DELIVERY	N020800	001	May 30, 2003	Jan	CAHN
		ESTRADIOL VALERATE							
		INJECTABLE; INJECTION							
		ESTRADIOL VALERATE							
	AO	PHARMAFORCE	20MG/ML	A090920	001	Jan 19, 2010	Jan	NEWA
	AO		40MG/ML	A090920	002	Jan 19, 2010	Jan	NEWA
		ETHINYL ESTRADIOL; NORETHINDRONE							
		TABLET; ORAL-21							
		NORETHINDRONE AND ETHINYL ESTRADIOL							
>A>		WATSON LABS	0.035MG;0.4MG	A078379	001	Feb 23, 2010	Feb	NEWA
		TABLET; ORAL-28							
		NORETHINDRONE AND ETHINYL ESTRADIOL							
	AB	WATSON LABS	0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG	A076393	001	Feb 04, 2010	Jan	NEWA
	AB		0.035MG;0.4MG	A078323	001	Feb 04, 2010	Jan	NEWA
		ETHINYL ESTRADIOL; NORETHINDRONE ACETATE							
		TABLET; ORAL							
		NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE							
	AB	WATSON LABS	0.02MG;1MG	A078267	001	Sep 01, 2009	Jan	CDFR
		TABLET; ORAL-28							
		NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE							
>D>	AB	TEVA PHARMS	0.02MG;1MG	A077077	001	May 20, 2005	Feb	CAHN
>D>	AB		0.03MG;1.5MG	A077075	001	Apr 28, 2005	Feb	CAHN
>A>	AB	VINTAGE	0.02MG;1MG	A077077	001	May 20, 2005	Feb	CAHN
>A>	AB		0.03MG;1.5MG	A077075	001	Apr 28, 2005	Feb	CAHN
		ETHINYL ESTRADIOL; NORGESTIMATE							
		TABLET; ORAL-28							
		PREVIFEM							
>D>	AB	TEVA PHARMS	0.035MG;0.25MG	A076334	001	Jan 09, 2004	Feb	CAHN

		TABLET; ORAL-28							
		PREVIFEM							
>A>	AB	VINTAGE	0.035MG;0.25MG	A076334	001	Jan 09, 2004	Feb	CAHN	
		TRI-PREVIFEM							
>D>	AB	TEVA PHARMS	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335	001	Mar 26, 2004	Feb	CAHN	
>A>	AB	VINTAGE	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335	001	Mar 26, 2004	Feb	CAHN	
		FAMOTIDINE							
		INJECTABLE; INJECTION							
		FAMOTIDINE							
>D>	AP	BAXTER HLTHCARE	10MG/ML	A075488	001	Apr 16, 2001	Feb	CRLD	
>A>	AP	+	10MG/ML	A075488	001	Apr 16, 2001	Feb	CRLD	
>D>	AP		10MG/ML	A075799	001	Apr 30, 2002	Feb	CRLD	
>A>	AP	+	10MG/ML	A075799	001	Apr 30, 2002	Feb	CRLD	
		FAMOTIDINE PRESERVATIVE FREE							
>D>	AP	BAXTER HLTHCARE	10MG/ML	A075486	001	Apr 16, 2001	Feb	CRLD	
>A>	AP	+	10MG/ML	A075486	001	Apr 16, 2001	Feb	CRLD	
>D>	AP		10MG/ML	A075789	001	Apr 30, 2002	Feb	CRLD	
>A>	AP	+	10MG/ML	A075789	001	Apr 30, 2002	Feb	CRLD	
		FAMOTIDINE PRESERVATIVE FREE IN PLASTIC CONTAINER							
>D>	AP	BAXTER HLTHCARE	0.4MG/ML	A075591	001	May 10, 2001	Feb	CRLD	
>A>	AP	+	0.4MG/ML	A075591	001	May 10, 2001	Feb	CRLD	
		TABLET, ORALLY DISINTEGRATING; ORAL							
		FLUXID							
		@ SCHWARZ PHARMA	20MG	N021712	001	Sep 24, 2004	Jan	DISC	
		@	40MG	N021712	002	Sep 24, 2004	Jan	DISC	
		FENOFIBRATE							
		CAPSULE; ORAL							
		ANTARA (MICRONIZED)							
		LUPIN ATLANTIS	43MG	N021695	001	Nov 30, 2004	Jan	CAHN	
		@	87MG	N021695	002	Nov 30, 2004	Jan	CAHN	
		+	130MG	N021695	003	Nov 30, 2004	Jan	CAHN	
		TABLET; ORAL							
		FENOGLIDE							
		SHIONOGI PHARMA	40MG	N022118	001	Aug 10, 2007	Jan	CAHN	
		+	120MG	N022118	002	Aug 10, 2007	Jan	CAHN	
		FINASTERIDE							
		TABLET; ORAL							
		FINASTERIDE							
>A>	AB	ACCORD HLTHCARE INC	5MG	A090121	001	Feb 23, 2010	Feb	NEWA	
		FLUCONAZOLE							
		INJECTABLE; INJECTION							
		FLUCONAZOLE IN SODIUM CHLORIDE 0.9%							
		BEDFORD	100MG/50ML (2MG/ML)	A076087	002	Sep 26, 2008	Jan	CTNA	
		FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER							
>D>	AP	HOSPIRA	200MG/100ML (2MG/ML)	A076617	001	Jul 29, 2004	Feb	DISC	
>A>		@	200MG/100ML (2MG/ML)	A076617	001	Jul 29, 2004	Feb	DISC	
>D>	AP		400MG/200ML (2MG/ML)	A076617	002	Jul 29, 2004	Feb	DISC	
>A>		@	400MG/200ML (2MG/ML)	A076617	002	Jul 29, 2004	Feb	DISC	

FLUNISOLIDE

AEROSOL, METERED; INHALATION

AEROSPAN HFA

>A>		+	ACTON PHARMS	EQ 78MCG BASE/INH	N021247	001	Jan 27, 2006	Feb	CAHN
>D>		+	FOREST LABS	EQ 78MCG BASE/INH	N021247	001	Jan 27, 2006	Feb	CAHN

SPRAY, METERED; NASAL

NASAREL

>A>	AB	+	TEVA BRANDED PHARM	0.029MG/SPRAY	N020409	001	Mar 08, 1995	Feb	CAHN
>D>	AB	+	TEVA GLOBAL	0.029MG/SPRAY	N020409	001	Mar 08, 1995	Feb	CAHN

FLUOROURACIL

CREAM; TOPICAL

FLUOROURACIL

>A>	AB		TARO	5%	A090368	001	Mar 05, 2010	Feb	NEWA

FLUOXETINE HYDROCHLORIDE

SOLUTION; ORAL

FLUOXETINE HYDROCHLORIDE

>A>	AA		LANNETT	EQ 20MG BASE/5ML	A076458	001	May 14, 2004	Feb	CAHN
>D>	AA		PAR PHARM	EQ 20MG BASE/5ML	A076458	001	May 14, 2004	Feb	CAHN

FOLIC ACID

TABLET; ORAL

FOLIC ACID

	AA	+	PHARMAX	1MG	A040625	001	Jul 21, 2005	Jan	CRLD
	AA	+	WATSON LABS	1MG	A080680	001		Jan	CMFD

FOSPHENYTOIN SODIUM

INJECTABLE; INJECTION

FOSPHENYTOIN SODIUM

>D>	AP		IV THERAP	EQ 50MG PHENYTOIN NA/ML	A078277	001	Aug 06, 2007	Feb	CAHN
>A>	AP		PHARMAFORCE	EQ 50MG PHENYTOIN NA/ML	A078277	001	Aug 06, 2007	Feb	CAHN

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HYDROCHLORIDE

			@ TEVA	1.25MG;250MG	A076821	001	Jan 27, 2005	Jan	DISC
			@	2.5MG;500MG	A076821	002	Jan 27, 2005	Jan	DISC
			@	5MG;500MG	A076821	003	Jan 27, 2005	Jan	DISC

GLYCOPYRROLATE

TABLET; ORAL

ROBINUL

	AA	+	SHIONOGI PHARMA	1MG	N012827	001		Jan	CAHN

ROBINUL FORTE

	AA	+	SHIONOGI PHARMA	2MG	N012827	002		Jan	CAHN

GRISEOFULVIN, MICROCRYSTALLINE

TABLET; ORAL

FULVICIN-U/F

>A>			@ ELORAC	250MG	A060569	002		Feb	CAHN
>A>			@	500MG	A060569	001		Feb	CAHN
>D>			@ SCHERING	250MG	A060569	002		Feb	CAHN
>D>			@	500MG	A060569	001		Feb	CAHN

GUANFACINE HYDROCHLORIDE

TABLET; ORAL
GUANFACINE HYDROCHLORIDE

>D>	AB		ACTAVIS TOTOWA	EQ 1MG BASE	A074673	001	Feb 28, 1997	Feb	CAHN
>D>	AB			EQ 2MG BASE	A074673	002	Feb 28, 1997	Feb	CAHN
>A>	AB		MIKAH PHARMA	EQ 1MG BASE	A074673	001	Feb 28, 1997	Feb	CAHN
>A>	AB			EQ 2MG BASE	A074673	002	Feb 28, 1997	Feb	CAHN

HALOPERIDOL LACTATE

INJECTABLE; INJECTION
>D> HALDOL

>D>	AP	+	ORTHO MCNEIL JANSSEN	EQ 5MG BASE/ML	N015923	001		Feb	DISC
>A>			@	EQ 5MG BASE/ML	N015923	001		Feb	DISC

HALOPERIDOL

>D>	AP		TEVA PARENTERAL	EQ 5MG BASE/ML	A076035	001	Aug 29, 2001	Feb	CRLD
>A>	AP	+		EQ 5MG BASE/ML	A076035	001	Aug 29, 2001	Feb	CRLD

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HYDROCHLORIDE

	AA		HERITAGE PHARMS INC	10MG	A086242	001	Feb 04, 2010	Jan	NEWA
	AA			100MG	A086242	004	Feb 04, 2010	Jan	NEWA
>A>	AA		ZYDUS PHARMS USA	10MG	A040858	001	Feb 26, 2010	Feb	NEWA
>A>	AA			25MG	A040858	002	Feb 26, 2010	Feb	NEWA
>A>	AA			50MG	A040858	003	Feb 26, 2010	Feb	NEWA
>A>	AA			100MG	A040858	004	Feb 26, 2010	Feb	NEWA

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
HYDROCHLOROTHIAZIDE

	AB		UNICHEM	12.5MG	A090510	001	Jan 19, 2010	Jan	NEWA

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL
LISINOPRIL AND HYDROCHLOROTHIAZIDE

			@ TEVA	12.5MG;10MG	A075869	001	Jul 01, 2002	Jan	DISC
			@	12.5MG;20MG	A075869	002	Jul 01, 2002	Jan	DISC
			@	25MG;20MG	A075869	003	Jul 01, 2002	Jan	DISC

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET; ORAL
METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE

	AB	+	MYLAN	25MG;100MG	A076792	002	Aug 20, 2004	Jan	CRLD
				50MG;100MG	A076792	003	Aug 20, 2004	Jan	CTEC

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

>D>	AT		FOUGERA	1%	A080693	003		Feb	CRLD
>A>	AT	+		1%	A080693	003		Feb	CRLD
>D>	AT			2.5%	A089414	001	Dec 16, 1986	Feb	CRLD
>A>	AT	+		2.5%	A089414	001	Dec 16, 1986	Feb	CRLD
>D>			HYTONE						
>D>	AT	+	SANOFI AVENTIS US	1%	A080472	003		Feb	DISC
>A>			@	1%	A080472	003		Feb	DISC

CREAM; TOPICAL

>D>			HYTONE							
>D>	AT	+	SANOFI AVENTIS US	2.5%	A080472	004			Feb	DISC
>A>			@	2.5%	A080472	004			Feb	DISC

LOTION; TOPICAL

>D>			HYTONE							
>D>	AT	+	SANOFI AVENTIS US	1%	A080473	003			Feb	DISC
>A>			@	1%	A080473	003			Feb	DISC
>D>	AT	+		2.5%	A080473	004	Nov 30, 1982		Feb	DISC
>A>			@	2.5%	A080473	004	Nov 30, 1982		Feb	DISC

IBUPROFEN

TABLET; ORAL

			IBUPROFEN							
	AB		CONTRACT PHARMACAL	400MG	A071267	001	Oct 15, 1986		Jan	CAHN
	AB			600MG	A071268	001	Oct 15, 1986		Jan	CAHN
	AB			800MG	A072300	001	Jul 01, 1988		Jan	CAHN

IFOSFAMIDE

INJECTABLE; INJECTION

			IFEX							
>D>			@ BAXTER HLTHCARE	1GM/VIAL	N019763	001	Dec 30, 1988		Feb	CMFD
>A>	AP			1GM/VIAL	N019763	001	Dec 30, 1988		Feb	CMFD
>D>			@	3GM/VIAL	N019763	002	Dec 30, 1988		Feb	CMFD
>A>	AP			3GM/VIAL	N019763	002	Dec 30, 1988		Feb	CMFD
			IFOSFAMIDE							
>D>		+	APP PHARMS	1GM/VIAL	A076078	001	May 28, 2002		Feb	CTEC
>A>	AP	+		1GM/VIAL	A076078	001	May 28, 2002		Feb	CTEC
		+		1GM/VIAL	A076078	001	May 28, 2002		Jan	CTEC
	AP			1GM/20ML (50MG/ML)	A090181	001	Sep 22, 2009		Jan	CPOT
>D>		+		3GM/VIAL	A076078	002	May 28, 2002		Feb	CTEC
>A>	AP	+		3GM/VIAL	A076078	002	May 28, 2002		Feb	CTEC
		+		3GM/VIAL	A076078	002	May 28, 2002		Jan	CTEC
	AP			3GM/60ML (50MG/ML)	A090181	002	Sep 22, 2009		Jan	CPOT
	AP	+	TEVA PARENTERAL	1GM/20ML (50MG/ML)	A076657	001	Apr 04, 2007		Jan	CTEC
	AP	+		3GM/60ML (50MG/ML)	A076657	002	Apr 04, 2007		Jan	CTEC

IFOSFAMIDE; MESNA

INJECTABLE; INJECTION

>D>			IFEX/MESNEX KIT							
>D>		+	BAXTER HLTHCARE	1GM/VIAL;100MG/ML	N019763	003	Oct 10, 1992		Feb	DISC
>A>			@	1GM/VIAL;100MG/ML	N019763	003	Oct 10, 1992		Feb	DISC
>D>		+		3GM/VIAL;100MG/ML	N019763	004	Oct 10, 1992		Feb	DISC
>A>			@	3GM/VIAL;100MG/ML	N019763	004	Oct 10, 1992		Feb	DISC

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

			IMIPRAMINE HYDROCHLORIDE							
>A>	AB		LUPIN LTD	10MG	A090443	001	Mar 11, 2010		Feb	NEWA
>A>	AB			25MG	A090442	001	Mar 11, 2010		Feb	NEWA
>A>	AB			50MG	A090441	001	Mar 11, 2010		Feb	NEWA

IMIQUIMOD

CREAM; TOPICAL

			ALDARA							
>D>		+	GRACEWAY	5%	N020723	001	Feb 27, 1997		Feb	CFTG

			CREAM; TOPICAL						
			ALDARA						
>A>	AB	+	GRACEWAY	5%	N020723	001	Feb 27, 1997	Feb	CFTG
>A>			IMIQUIMOD						
>A>	AB		NYCOMED US	5%	A078548	001	Feb 25, 2010	Feb	NEWA
			INAMRINONE LACTATE						
			INJECTABLE; INJECTION						
			AMRINONE LACTATE						
>D>	AP		BAXTER HLTHCARE CORP	EQ 5MG BASE/ML	A075542	001	May 10, 2000	Feb	DISC
>A>			@	EQ 5MG BASE/ML	A075542	001	May 10, 2000	Feb	DISC
>D>	AP	+	BEDFORD	EQ 5MG BASE/ML	A075513	001	May 09, 2000	Feb	CTEC
>A>		+		EQ 5MG BASE/ML	A075513	001	May 09, 2000	Feb	CTEC
			LABETALOL HYDROCHLORIDE						
			INJECTABLE; INJECTION						
			LABETALOL HYDROCLORIDE						
	AP		SAGENT STRIDES	5MG/ML	A079134	001	Feb 03, 2010	Jan	NEWA
			TABLET; ORAL						
			TRANDATE						
>D>	AB		PROMETHEUS LABS	200MG	N018716	002	Aug 01, 1984	Feb	CRLD
>A>	AB	+		200MG	N018716	002	Aug 01, 1984	Feb	CRLD
>D>	AB	+		300MG	N018716	003	Aug 01, 1984	Feb	CRLD
>A>	AB			300MG	N018716	003	Aug 01, 1984	Feb	CRLD
			LENALIDOMIDE						
			CAPSULE; ORAL						
			REVLIMID						
		+	CELGENE	5MG	N021880	001	Dec 27, 2005	Jan	CRLD
			LEVETIRACETAM						
			SOLUTION; ORAL						
			LEVETIRACETAM						
>A>	AA		WOCKHARDT	100MG/ML	A090028	001	Mar 03, 2010	Feb	NEWA
			TABLET; ORAL						
			LEVETIRACETAM						
	AB		TARO	250MG	A078960	004	Feb 01, 2010	Jan	NEWA
	AB			500MG	A078960	003	Feb 01, 2010	Jan	NEWA
	AB			750MG	A078960	002	Feb 01, 2010	Jan	NEWA
	AB			1GM	A078960	001	Feb 01, 2010	Jan	NEWA
			LEVOTHYROXINE SODIUM						
			CAPSULE; ORAL						
			TIROSINT						
>D>			@ INST BIOCHIMIQUE	0.013MG	N022121	001	Aug 01, 2007	Feb	CMFD
>A>				0.013MG	N022121	001	Aug 01, 2007	Feb	CMFD
>D>			@	0.025MG	N021924	002	Oct 13, 2006	Feb	CMFD
>A>				0.025MG	N021924	002	Oct 13, 2006	Feb	CMFD
>D>			@	0.05MG	N021924	003	Oct 13, 2006	Feb	CMFD
>A>				0.05MG	N021924	003	Oct 13, 2006	Feb	CMFD
>D>			@	0.075MG	N021924	004	Oct 13, 2006	Feb	CMFD
>A>				0.075MG	N021924	004	Oct 13, 2006	Feb	CMFD
>A>				0.088MG	N021924	010	Oct 02, 2009	Feb	NEWA
>D>			@	0.1MG	N021924	005	Oct 13, 2006	Feb	CMFD
>A>				0.1MG	N021924	005	Oct 13, 2006	Feb	CMFD
>A>				0.112MG	N021924	008	Oct 02, 2009	Feb	NEWA

		CAPSULE; ORAL							
		TIROSINT							
>D>		@ INST BIOCHIMIQUE	0.125MG	N021924	006	Oct 13, 2006	Feb	CMFD
>A>			0.125MG	N021924	006	Oct 13, 2006	Feb	CMFD
>A>			0.137MG	N021924	009	Oct 02, 2009	Feb	NEWA
>D>		@	0.15MG	N021924	007	Oct 13, 2006	Feb	CMFD
>A>			0.15MG	N021924	007	Oct 13, 2006	Feb	CMFD
		LIRAGLUTIDE RECOMBINANT							
		SOLUTION; SUBCUTANEOUS							
		VICTOZA							
		+ NOVO NORDISK INC	18MG/3ML (6MG/ML)	N022341	001	Jan 25, 2010	Jan	NEWA
		LISINOPRIL							
		TABLET; ORAL							
		LISINOPRIL							
		@ TEVA	2.5MG	A075783	001	Jul 01, 2002	Jan	DISC
		@	5MG	A075783	002	Jul 01, 2002	Jan	DISC
		@	10MG	A075783	003	Jul 01, 2002	Jan	DISC
		@	20MG	A075783	004	Jul 01, 2002	Jan	DISC
		@	30MG	A075783	005	Jul 01, 2002	Jan	DISC
		@	40MG	A075783	006	Jul 01, 2002	Jan	DISC
		LITHIUM CARBONATE							
		CAPSULE; ORAL							
		ESKALITH							
		@ NOVEN THERAP	300MG	N016860	001		Jan	DISC
		MECLIZINE HYDROCHLORIDE							
		TABLET; ORAL							
		ANTIVERT							
	AA	+ PFIZER	50MG	N010721	001	Jan 20, 1982	Jan	CMFD
		TABLET, CHEWABLE; ORAL							
		ANTIVERT							
		@ PFIZER	25MG	N010721	005		Jan	DISC
		MEPERIDINE HYDROCHLORIDE							
		SYRUP; ORAL							
		MEPERIDINE HYDROCHLORIDE							
>D>	AA	ROXANE	50MG/5ML	A088744	001	Jan 30, 1985	Feb	CRLD
>A>		+	50MG/5ML	A088744	001	Jan 30, 1985	Feb	CRLD
		TABLET; ORAL							
>D>		DEMEROL							
>D>	AA	+ SANOFI AVENTIS US	50MG	N005010	001		Feb	DISC
>A>		@	50MG	N005010	001		Feb	DISC
		MEPERIDINE HYDROCHLORIDE							
>D>	AA	ACTAVIS TOTOWA	50MG	A040331	001	May 28, 1999	Feb	CAHN
>D>	AA		100MG	A040331	002	May 28, 1999	Feb	CAHN
>A>	AA	MIKAH PHARMA	50MG	A040331	001	May 28, 1999	Feb	CAHN
>A>	AA		100MG	A040331	002	May 28, 1999	Feb	CAHN
		MESALAMINE							
		TABLET, DELAYED RELEASE; ORAL							
		ASACOL							
>D>		+ PROCTER AND GAMBLE	400MG	N019651	001	Jan 31, 1992	Feb	CAHN
>A>		+ WARNER CHILCOTT INC	400MG	N019651	001	Jan 31, 1992	Feb	CAHN

TABLET, DELAYED RELEASE; ORAL
ASACOL HD

>D>		+	PROCTER AND GAMBLE	800MG	N021830	001	May 29, 2008	Feb	CAHN
>A>		+	WARNER CHILCOTT INC	800MG	N021830	001	May 29, 2008	Feb	CAHN

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
METFORMIN HYDROCHLORIDE

	AB		TORRENT PHARMS	750MG	A079226	001	Feb 18, 2010	Jan	NEWA

METHENAMINE HIPPURATE

TABLET; ORAL
UREX

>A>	AB		CNTY LINE PHARMS	1GM	N016151	001		Feb	CAHN
>D>	AB		VATRING PHARMS	1GM	N016151	001		Feb	CAHN

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HYDROCHLORIDE

>D>	AP		HOSPIRA	EQ 5MG BASE/ML	A074147	001	Aug 02, 1996	Feb	DISC
>A>			@	EQ 5MG BASE/ML	A074147	001	Aug 02, 1996	Feb	DISC

TABLET; ORAL
METOCLOPRAMIDE HYDROCHLORIDE

			@ SANDOZ	EQ 10MG BASE	A074478	002	Oct 05, 1995	Jan	DISC
			@ WATSON LABS	EQ 10MG BASE	A070511	001	Jan 22, 1986	Jan	DISC

MILRINONE LACTATE

INJECTABLE; INJECTION
MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER

>D>	AP		BAXTER HLTHCARE	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	A075834	001	May 28, 2002	Feb	CTEC
>A>	AP	+		EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	A075834	001	May 28, 2002	Feb	CTEC
>D>	AP			EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	A075834	002	May 28, 2002	Feb	CRLD
>A>	AP	+		EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	A075834	002	May 28, 2002	Feb	CRLD

MILRINONE LACTATE IN PLASTIC CONTAINER

	AP		HIKMA FARMACEUTICA	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	A090038	001	Jan 21, 2010	Jan	NEWA
	AP			EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	A090038	002	Jan 21, 2010	Jan	NEWA

>D> PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER

>D>	AP	+	SANOFI AVENTIS US	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	N020343	003	Aug 09, 1994	Feb	DISC
>A>			@	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	N020343	003	Aug 09, 1994	Feb	DISC
>D>	AP	+		EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	N020343	004	Aug 09, 1994	Feb	DISC
>A>			@	EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	N020343	004	Aug 09, 1994	Feb	DISC

MORPHINE SULFATE

SOLUTION; ORAL
MORPHINE SULFATE

			ROXANE	20MG/5ML	N022195	002	Mar 17, 2008	Jan	CRLD
		+		100MG/5ML	N022195	003	Jan 25, 2010	Jan	NEWA

TABLET, EXTENDED RELEASE; ORAL
MORPHINE SULFATE

>D>			@ AB GENERICS	15MG	A074862	001	Jul 07, 1998	Feb	CAHN

TABLET, EXTENDED RELEASE; ORAL
MORPHINE SULFATE

>D>		@ AB GENERICS	30MG	A074862	002	Jul 07, 1998	Feb	CAHN
>D>		@	60MG	A074862	003	Jul 07, 1998	Feb	CAHN
>D>		@	100MG	A074769	001	Jul 02, 1998	Feb	CAHN
>D>		@	200MG	A074769	002	Jul 02, 1998	Feb	CAHN
>A>		@ PURDUE PHARMA LP	15MG	A074862	001	Jul 07, 1998	Feb	CAHN
>A>		@	30MG	A074862	002	Jul 07, 1998	Feb	CAHN
>A>		@	60MG	A074862	003	Jul 07, 1998	Feb	CAHN
>A>		@	100MG	A074769	001	Jul 02, 1998	Feb	CAHN
>A>		@	200MG	A074769	002	Jul 02, 1998	Feb	CAHN

NALIDIXIC ACID

TABLET; ORAL
NEGGRAM

>D>		SANOFI AVENTIS US	250MG	N014214	002		Feb	DISC
>A>		@	250MG	N014214	002		Feb	DISC
>D>			500MG	N014214	004		Feb	DISC
>A>		@	500MG	N014214	004		Feb	DISC
>D>	+		1GM	N014214	005		Feb	DISC
>A>		@	1GM	N014214	005		Feb	DISC

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL
PENTAZOCINE AND NALOXONE HYDROCHLORIDES

>D>	AB		WATSON LABS	EQ 0.5MG BASE;EQ 50MG BASE	A074736	001	Jan 21, 1997	Feb	CRLD
>A>	AB	+		EQ 0.5MG BASE;EQ 50MG BASE	A074736	001	Jan 21, 1997	Feb	CRLD
>D>			TALWIN NX						
>D>	AB	+	SANOFI AVENTIS US	EQ 0.5MG BASE;EQ 50MG BASE	N018733	001	Dec 16, 1982	Feb	DISC
>A>			@	EQ 0.5MG BASE;EQ 50MG BASE	N018733	001	Dec 16, 1982	Feb	DISC

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL
SULAR

+		SHIONOGI PHARMA	8.5MG	N020356	008	Jan 02, 2008	Jan	CAHN
		@	10MG	N020356	001	Feb 02, 1995	Jan	CAHN
+			17MG	N020356	007	Jan 02, 2008	Jan	CAHN
		@	20MG	N020356	002	Feb 02, 1995	Jan	CAHN
			25.5MG	N020356	006	Jan 02, 2008	Jan	CAHN
		@	30MG	N020356	003	Feb 02, 1995	Jan	CAHN
+			34MG	N020356	005	Jan 02, 2008	Jan	CAHN
		@	40MG	N020356	004	Feb 02, 1995	Jan	CAHN

NITROFURANTOIN

SUSPENSION; ORAL
FURADANTIN

+		SHIONOGI PHARMA	25MG/5ML	N009175	001		Jan	CAHN

NITROGLYCERIN

AEROSOL; SUBLINGUAL
NITROLINGUAL

		@ SHIONOGI PHARMA	0.4MG/SPRAY	N018705	001	Oct 31, 1985	Jan	CAHN

SPRAY, METERED; SUBLINGUAL
NITROLINGUAL PUMPSPRAY

+		SHIONOGI PHARMA	0.4MG/SPRAY	N018705	002	Jan 10, 1997	Jan	CAHN

OFLOXACIN

TABLET; ORAL
OFLOXACIN

		@	LARKEN LABS	200MG	A076093	001	Sep 02, 2003	Jan	CAHN
		@		300MG	A076093	002	Sep 02, 2003	Jan	CAHN
		@		400MG	A076093	003	Sep 02, 2003	Jan	CAHN

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

>D>	AB		ACTAVIS TOTOWA	100MG	A040284	001	Jun 19, 1998	Feb	CAHN
>A>	AB		GAVIS PHARMS	100MG	A040284	001	Jun 19, 1998	Feb	CAHN

OXALIPLATIN

INJECTABLE; INJECTION
OXALIPLATIN

	AP	+	HOSPIRA INC	50MG/VIAL	A078815	001	Sep 30, 2009	Jan	CRLD
	AP	+		100MG/VIAL	A078815	002	Sep 30, 2009	Jan	CRLD

OXCARBAZEPINE

TABLET; ORAL
OXCARBAZEPINE

	AB		CADISTA PHARMS	150MG	A090239	001	Jan 25, 2010	Jan	NEWA
	AB			300MG	A090239	002	Jan 25, 2010	Jan	NEWA
	AB			600MG	A090239	003	Jan 25, 2010	Jan	NEWA

PALIPERIDONE PALMITATE

SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR
INVEGA SUSTENNA

		+	JOHNSON AND JOHNSON	234MG/1.5ML (156MG/ML)	N022264	005	Jul 31, 2009	Jan	CRLD

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION
PAMIDRONATE DISODIUM

>D>	AP		GENERAMEDIX	30MG/VIAL	A078300	001	Mar 10, 2009	Feb	CAHN
>D>	AP			90MG/VIAL	A078300	002	Mar 10, 2009	Feb	CAHN
>A>	AP		MN PHARMS	30MG/VIAL	A078300	001	Mar 10, 2009	Feb	CAHN
>A>	AP			90MG/VIAL	A078300	002	Mar 10, 2009	Feb	CAHN

PEGADEMASE BOVINE

INJECTABLE; INJECTION
ADAGEN

>D>		+	ENZON PHARMS	250 UNITS/ML	N019818	001	Mar 21, 1990	Feb	CAHN
>A>		+	SIGMA TAU	250 UNITS/ML	N019818	001	Mar 21, 1990	Feb	CAHN

PERINDOPRIL ERBUMINE

TABLET; ORAL
PERINDOPRIL ERBUMINE

	AB		LUPIN LTD	2MG	A078263	001	Jan 27, 2010	Jan	NEWA
	AB			4MG	A078263	002	Jan 27, 2010	Jan	NEWA
	AB			8MG	A078263	003	Jan 27, 2010	Jan	NEWA

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL

BONTRIL

>D>	BC	MALLINCKRODT	105MG	A088021	001	Sep 21, 1982	Feb	CAHN
>A>	BC	VALEANT	105MG	A088021	001	Sep 21, 1982	Feb	CAHN

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

FOR SOLUTION; ORAL

LAX-LYTE WITH FLAVOR PACKS

>A>	AA	PADDOCK	420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 1.2GM/BOT	A079232	001	Feb 25, 2010	Feb	NEWA

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE ANHYDROUS

FOR SOLUTION; ORAL

PEG 3350 AND ELECTROLYTES

	AA	MYLAN	236GM;2.97GM;6.74GM;5.86GM;22.74G M	A090928	001	Jan 28, 2010	Jan	NEWA

POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES

>A>	AA	PADDOCK LABS	240GM/BOT;2.98GM/BOT;6.72GM/BOT;5 .84GM/BOT;22.72GM/BOT	A090712	001	Feb 25, 2010	Feb	NEWA

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL

UROCIT-K

>A>		MISSION PHARMA	15MEQ	N019071	003	Dec 30, 2009	Feb	NEWA

PRAMIPEXOLE DIHYDROCHLORIDE

>A> TABLET, EXTENDED RELEASE; ORAL

>A> MIRAPEX ER

>A>	BOEHRINGER INGELHEIM	0.375MG	N022421	001	Feb 19, 2010	Feb	NEWA
>A>		0.75MG	N022421	002	Feb 19, 2010	Feb	NEWA
>A>		1.5MG	N022421	003	Feb 19, 2010	Feb	NEWA
>A>		3MG	N022421	004	Feb 19, 2010	Feb	NEWA
>A>	+	4.5MG	N022421	005	Feb 19, 2010	Feb	NEWA

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HYDROCHLORIDE

	@ WATSON LABS	EQ 1MG BASE	A072352	001	May 16, 1989	Jan	DISC
	@	EQ 2MG BASE	A072333	001	May 16, 1989	Jan	DISC

PREDNISONE

TABLET; ORAL

PREDNISONE

	AB	CONTRACT PHARMACAL	5MG	A080209	001		Jan	CAHN

PREGABALIN

SOLUTION; ORAL

LYRICA

+	PFIZER	20MG/ML	N022488	001	Jan 04, 2010	Jan	NEWA

PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROCAINE HYDROCHLORIDE

	@ WATSON LABS	1%	A080658	001		Jan	DISC

PROCHLORPERAZINE MALEATE

TABLET; ORAL
PROCHLORPERAZINE MALEATE

		@ DURAMED PHARMS BARR	EQ 5MG BASE	A040207	001	May 01, 1997	Jan	DISC
		@	EQ 10MG BASE	A040207	002	May 01, 1997	Jan	DISC
		PROCOMP						
	AB	CADISTA PHARMS	EQ 5MG BASE	A040268	001	Feb 27, 1998	Jan	CTNA
	AB		EQ 10MG BASE	A040268	002	Feb 27, 1998	Jan	CTNA

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HYDROCHLORIDE

		@ PAR PHARM	65MG	A080269	001		Jan	DISC

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

		@ CONTRACT PHARMACAL	200MG	A083808	001		Jan	CAHN

RISPERIDONE

INJECTABLE; INTRAMUSCULAR
RISPERDAL CONSTA

	+	ORTHO MCNEIL JANSSEN	25MG/VIAL	N021346	001	Oct 29, 2003	Jan	CRLD
			50MG/VIAL	N021346	003	Oct 29, 2003	Jan	CRLD

TABLET; ORAL
RISPERIDONE

>D>	AB	SYNTHON PHARMS	0.25MG	A078187	001	Oct 22, 2009	Feb	DISC
>A>		@	0.25MG	A078187	001	Oct 22, 2009	Feb	DISC
>D>	AB		0.5MG	A078187	002	Oct 22, 2009	Feb	DISC
>A>		@	0.5MG	A078187	002	Oct 22, 2009	Feb	DISC
>D>	AB		1MG	A078187	003	Oct 22, 2009	Feb	DISC
>A>		@	1MG	A078187	003	Oct 22, 2009	Feb	DISC
>D>	AB		2MG	A078187	004	Oct 22, 2009	Feb	DISC
>A>		@	2MG	A078187	004	Oct 22, 2009	Feb	DISC
>D>	AB		3MG	A078187	005	Oct 22, 2009	Feb	DISC
>A>		@	3MG	A078187	005	Oct 22, 2009	Feb	DISC
>D>	AB		4MG	A078187	006	Oct 22, 2009	Feb	DISC
>A>		@	4MG	A078187	006	Oct 22, 2009	Feb	DISC

RITONAVIR

>A>		TABLET; ORAL							
>A>		RITONAVIR							
>A>		+ ABBOTT LABS	100MG	N022417	001	Feb 10, 2010	Feb	NEWA

RIVASTIGMINE TARTRATE

CAPSULE; ORAL
EXELON

>D>	AB	+ NOVARTIS	EQ 6MG BASE	N020823	006	Apr 21, 2000	Feb	CRLD
>A>	AB		EQ 6MG BASE	N020823	006	Apr 21, 2000	Feb	CRLD

ROPINIROLE HYDROCHLORIDE

TABLET; ORAL
ROPINIROLE HYDROCHLORIDE

>A>	AB	GLENMARK GENERICS	EQ 0.25MG BASE	A090135	001	Feb 25, 2010	Feb	NEWA
>A>	AB		EQ 0.5MG BASE	A090135	002	Feb 25, 2010	Feb	NEWA

TABLET; ORAL
ROPINIROLE HYDROCHLORIDE

>A>	AB	GLENMARK GENERICS	EQ 1MG BASE	A090135	003	Feb 25, 2010	Feb	NEWA
>A>	AB		EQ 2MG BASE	A090135	004	Feb 25, 2010	Feb	NEWA
>A>	AB		EQ 3MG BASE	A090135	005	Feb 25, 2010	Feb	NEWA
>A>	AB		EQ 4MG BASE	A090135	006	Feb 25, 2010	Feb	NEWA
>A>	AB		EQ 5MG BASE	A090135	007	Feb 25, 2010	Feb	NEWA

SODIUM BICARBONATE

INJECTABLE; INJECTION
SODIUM BICARBONATE

>D>		HOSPIRA	0.9MEQ/ML	A077394	001	Nov 09, 2005	Feb	CRLD
>A>		+	0.9MEQ/ML	A077394	001	Nov 09, 2005	Feb	CRLD

STAVUDINE

CAPSULE; ORAL
STAVUDINE

>D>	AB	MATRIX LABS INC	15MG	A079069	001	Dec 29, 2008	Feb	CAHN
>D>	AB		20MG	A079069	002	Dec 29, 2008	Feb	CAHN
>D>	AB		30MG	A079069	003	Dec 29, 2008	Feb	CAHN
>D>	AB		40MG	A079069	004	Dec 29, 2008	Feb	CAHN
>A>	AB	MYLAN	15MG	A079069	001	Dec 29, 2008	Feb	CAHN
>A>	AB		20MG	A079069	002	Dec 29, 2008	Feb	CAHN
>A>	AB		30MG	A079069	003	Dec 29, 2008	Feb	CAHN
>A>	AB		40MG	A079069	004	Dec 29, 2008	Feb	CAHN

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

	AB	AUROBINDO PHARMA	400MG;80MG	A090624	001	Feb 16, 2010	Jan	NEWA
	AB		800MG;160MG	A090624	002	Feb 16, 2010	Jan	NEWA

TAMSULOSIN HYDROCHLORIDE

CAPSULE; ORAL
FLOMAX

>D>		+ BOEHRINGER INGELHEIM	0.4MG	N020579	001	Apr 15, 1997	Feb	CFTG
>A>	AB	+	0.4MG	N020579	001	Apr 15, 1997	Feb	CFTG
>A>		TAMSULOSIN HYDROCHLORIDE						
>A>	AB	IMPAX LABS	0.4MG	A090377	001	Mar 02, 2010	Feb	NEWA

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION; INJECTION, ORAL
TECHNELITE

>D>		LANTHEUS MEDCL	0.0083-2.7 CI/GENERATOR	N017771	001		Feb	CRLD
>A>		+	0.0083-2.7 CI/GENERATOR	N017771	001		Feb	CRLD

ULTRA-TECHNEKOW FM

>D>		MALLINCKRODT	0.25-3 CI/GENERATOR	N017243	002		Feb	CRLD
>A>		+	0.25-3 CI/GENERATOR	N017243	002		Feb	CRLD

TEMOZOLOMIDE

CAPSULE; ORAL
TEMODAR

>D>		SCHERING	5MG	N021029	001	Aug 11, 1999	Feb	CFTG
>A>	AB		5MG	N021029	001	Aug 11, 1999	Feb	CFTG
>D>			20MG	N021029	002	Aug 11, 1999	Feb	CFTG
>A>	AB		20MG	N021029	002	Aug 11, 1999	Feb	CFTG

CAPSULE; ORAL
TEMODAR

>D>			SCHERING	100MG	N021029	003	Aug 11, 1999	Feb	CFTG
>A>	AB			100MG	N021029	003	Aug 11, 1999	Feb	CFTG
>D>				140MG	N021029	005	Oct 19, 2006	Feb	CFTG
>A>	AB			140MG	N021029	005	Oct 19, 2006	Feb	CFTG
>D>				180MG	N021029	006	Oct 19, 2006	Feb	CFTG
>A>	AB			180MG	N021029	006	Oct 19, 2006	Feb	CFTG
>D>		+		250MG	N021029	004	Aug 11, 1999	Feb	CFTG
>A>	AB	+		250MG	N021029	004	Aug 11, 1999	Feb	CFTG

TEMOZOLOMIDE

>A>	AB		BARR	5MG	A078879	001	Mar 01, 2010	Feb	NEWA
>A>	AB			20MG	A078879	002	Mar 01, 2010	Feb	NEWA
>A>	AB			100MG	A078879	003	Mar 01, 2010	Feb	NEWA
>A>	AB			140MG	A078879	005	Mar 01, 2010	Feb	NEWA
>A>	AB			180MG	A078879	006	Mar 01, 2010	Feb	NEWA
>A>	AB			250MG	A078879	004	Mar 01, 2010	Feb	NEWA

TERCONAZOLE

CREAM; VAGINAL
TERCONAZOLE

	BX	+	NYCOMED US	0.8%	N021735	001	Oct 01, 2004	Jan	CAHN

TINZAPARIN SODIUM

INJECTABLE; INJECTION
INNOHEP

>D>		+	CELGENE	20,000 IU/ML	N020484	001	Jul 14, 2000	Feb	CAHN
>A>		+	LEO PHARMA AS	20,000 IU/ML	N020484	001	Jul 14, 2000	Feb	CAHN

TOPIRAMATE

TABLET; ORAL
TOPIRAMATE

			@ PLIVA HRVATSKA DOO	25MG	A077905	001	Mar 30, 2009	Jan	DISC
			@	50MG	A077905	002	Mar 30, 2009	Jan	DISC
			@	100MG	A077905	003	Mar 30, 2009	Jan	DISC
			@	200MG	A077905	004	Mar 30, 2009	Jan	DISC

TRANDOLAPRIL

TABLET; ORAL
TRANDOLAPRIL

>A>	AB		EPIC PHARMA	1MG	A078508	003	Jun 18, 2008	Feb	CAHN
>A>	AB			2MG	A078508	001	Jun 18, 2008	Feb	CAHN
>A>	AB			4MG	A078508	002	Jun 18, 2008	Feb	CAHN
>D>	AB		GLENMARK GENERICS	1MG	A078508	003	Jun 18, 2008	Feb	CAHN
>D>	AB			2MG	A078508	001	Jun 18, 2008	Feb	CAHN
>D>	AB			4MG	A078508	002	Jun 18, 2008	Feb	CAHN

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HYDROCHLORIDE

>D>	AB		TEVA	50MG	A072192	001	Feb 02, 1989	Feb	CAHN
>D>	AB			100MG	A072193	001	Feb 02, 1989	Feb	CAHN
>A>	AB		VINTAGE	50MG	A072192	001	Feb 02, 1989	Feb	CAHN
>A>	AB			100MG	A072193	001	Feb 02, 1989	Feb	CAHN

>A>		TABLET, EXTENDED RELEASE; ORAL							
>A>		OLEPTRO							
>A>		LABOPHARM	150MG	N022411	001	Feb 02, 2010	Feb	NEWA	
>A>	+		300MG	N022411	002	Feb 02, 2010	Feb	NEWA	
		TRETINOIN							
		CAPSULE; ORAL							
		TRETINOIN							
>D>	AB	BARR	10MG	A077684	001	Jun 22, 2007	Feb	CRLD	
>A>	+		10MG	A077684	001	Jun 22, 2007	Feb	CRLD	
>D>		VESANOID							
>D>	AB +	ROCHE	10MG	N020438	001	Nov 22, 1995	Feb	DISC	
>A>		@	10MG	N020438	001	Nov 22, 1995	Feb	DISC	
		UNOPROSTONE ISOPROPYL							
		SOLUTION/DROPS; OPHTHALMIC							
		RESCULA							
		@ SUCAMPO PHARMS	0.15%	N021214	001	Aug 03, 2000	Jan	DISC	
		UREA, C-14							
		CAPSULE; ORAL							
		PYTEST							
>A>	+	AVENT	1uCi	N020617	001	May 09, 1997	Feb	CAHN	
>D>	+	BALLARD MEDCL	1uCi	N020617	001	May 09, 1997	Feb	CAHN	
		PYTEST KIT							
>A>	+	AVENT	1uCi	N020617	002	May 09, 1997	Feb	CAHN	
>D>	+	BALLARD MEDCL	1uCi	N020617	002	May 09, 1997	Feb	CAHN	
		URSODIOL							
		CAPSULE; ORAL							
		URSODIOL							
>D>	AB	ACTAVIS TOTOWA	300MG	A075517	001	Mar 14, 2000	Feb	CAHN	
>A>	AB	MIKAH PHARMA	300MG	A075517	001	Mar 14, 2000	Feb	CAHN	
	AB	MYLAN	300MG	A090530	001	Feb 17, 2010	Jan	NEWA	
		VALPROATE SODIUM							
		INJECTABLE; INJECTION							
		VALPROATE SODIUM							
	AP	HIKMA FARMACEUTICA	EQ 100MG BASE/ML	A078523	001	Feb 17, 2010	Jan	NEWA	
>A>		VELAGLUCERASE ALFA							
>A>		INJECTABLE; IV (INFUSION)							
>A>		VPRIV							
>A>		SHIRE HUMAN GENETIC	400 UNITS/VIAL	N022575	001	Feb 26, 2010	Feb	NEWA	
>A>		POWDER; IV (INFUSION)							
>A>		VPRIV							
>A>	+	SHIRE HUMAN GENETIC	200 UNITS/VIAL	N022575	002	Feb 26, 2010	Feb	NEWA	

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

AUROBINDO PHARMA	5MG/5ML	A090750	002	Feb 02, 2010	Jan	NEWA

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

AUROBINDO PHARMA	5MG/5ML	A090750	001	Feb 02, 2010	Jan	NEWA

TABLET; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

AMNEAL PHARMS NY	5MG	A078780	001	Jan 21, 2010	Jan	NEWA
	10MG	A078780	004	Jan 21, 2010	Jan	NEWA

CETIRIZINE HYDROCHLORIDE HIVES RELIEF

AMNEAL PHARMS NY	5MG	A078780	003	Jan 21, 2010	Jan	NEWA
	10MG	A078780	002	Jan 21, 2010	Jan	NEWA

CIMETIDINE

TABLET; ORAL

CIMETIDINE

CONTRACT PHARMACAL	200MG	A074961	001	Jun 19, 1998	Jan	CAHN
	200MG	A074963	001	Jun 19, 1998	Jan	CAHN

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN

+	CONTRACT PHARMACAL	200MG	A074782	001	Jul 06, 1998	Jan	CAHN

TABLET; ORAL

IBUPROFEN

CONTRACT PHARMACAL	200MG	A071732	001	Sep 10, 1987	Jan	CAHN
	200MG	A071735	001	Sep 10, 1987	Jan	CAHN
	200MG	A072299	001	Jul 01, 1988	Jan	CAHN
	200MG	A073691	001	Feb 25, 1994	Jan	CAHN

PROFEN

CONTRACT PHARMACAL	200MG	A071265	001	Oct 15, 1986	Jan	CAHN

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

CONTRACT PHARMACAL	200MG;30MG	A075588	001	Apr 08, 2002	Jan	CAHN

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL

LOPERAMIDE HYDROCHLORIDE

CONTRACT PHARMACAL	2MG	A073254	001	Jul 30, 1993	Jan	CAHN

MICONAZOLE NITRATE

CREAM; VAGINAL

MICONAZOLE NITRATE

PERRIGO R AND D	4%	A091366	001	Jan 15, 2010	Jan	NEWA

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

VISINE-A

+	JOHNSON AND JOHNSON	0.025%;0.3%	N020485	001	Jan 31, 1996	Jan	CRLD

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

SUDAFED 24 HOUR

>D>	+	ALZA	240MG	N020021	002	Dec 15, 1992	Feb	CAHN
>A>	+	MCNEIL CONS	240MG	N020021	002	Dec 15, 1992	Feb	CAHN

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE HYDROCHLORIDE

		CONTRACT PHARMACAL	EQ 75MG BASE	A075094	001	Jun 21, 1999	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 02 FEBRUARY 2010

NO FEBRUARY 2010 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

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

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

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

NO FEBRUARY 2010 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2010

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APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ALISKIREN HEMIFUMARATE; VALSARTAN - VALTURNA							
N022217	001					**>A>** NCE	Mar 05, 2012
ALISKIREN HEMIFUMARATE; VALSARTAN - VALTURNA							
N022217	002					**>A>** NCE	Mar 05, 2012
ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE - MOVIPREP							
N021881	001	7658914	Sep 01, 2024	DS DP			
AZTREONAM - CAYSTON							
N050814	001	**>A>** 7208141	Dec 20, 2021	DP U-1031			
		>A> 7214364	Dec 20, 2021	DP			
		>A> 7427633	Dec 20, 2021	DP U-1031			
BALSALAZIDE DISODIUM - COLAZAL							
N020610	001	7452872	Aug 24, 2026	U-141			
		7452872*PED	Feb 24, 2027				
		7625884	Aug 24, 2026	U-141			
		7625884*PED	Feb 24, 2027				
BEXAROTENE - TARGRETIN							
N021055	001	**>A>** 7655699	Apr 22, 2012	DS DP U-509			
BEXAROTENE - TARGRETIN							
N021056	001	**>A>** 7655699	Apr 22, 2012	DS DP U-510			
BUDESONIDE - RHINOCORT							
N020746	001	6686346	Apr 29, 2017	DP U-557	Y		
		6686346*PED	Oct 29, 2017				
		6986904	Apr 29, 2017	DP U-699	Y		
		6986904*PED	Oct 29, 2017				
BUDESONIDE - RHINOCORT							
N020746	002	6686346	Apr 29, 2017	DP U-557			
		6686346*PED	Oct 29, 2017				
		6986904	Apr 29, 2017	DP U-699			
		6986904*PED	Oct 29, 2017				
BUPROPION HYDROBROMIDE - APLENZIN							
N022108	001	7645802	Jun 27, 2026	DP			
		7649019	Jun 27, 2026	DP			
		>A> 7662407	Jun 27, 2026	DP			
		>A> 7671094	Jun 27, 2026	DP			
BUPROPION HYDROBROMIDE - APLENZIN							
N022108	002	7645802	Jun 27, 2026	DP			
		7649019	Jun 27, 2026	DP			
		>A> 7662407	Jun 27, 2026	DP			
		>A> 7671094	Jun 27, 2026	DP			
BUPROPION HYDROBROMIDE - APLENZIN							
N022108	003	7645802	Jun 27, 2026	DP			
		7649019	Jun 27, 2026	DP			
		>A> 7662407	Jun 27, 2026	DP			
		>A> 7671094	Jun 27, 2026	DP			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2010

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CAPSAICIN - QUTENZA							
N022395	001					ODE	Nov 16, 2016
CEFTIBUTEN DIHYDRATE - CEDAX							
N050686	001	5599557	Feb 04, 2014	DP U-578			
		5599557	Feb 04, 2014	DP U-282			
CEFTIBUTEN DIHYDRATE - CEDAX							
N050686	002	5599557	Feb 04, 2014	DP U-578			
		5599557	Feb 04, 2014	DP U-282			
CLINDAMYCIN PHOSPHATE; TRETINOIN - ZIANA							
N050802	001	>A> RE41134	Feb 24, 2015	DP U-1033			
CLONIDINE HYDROCHLORIDE - JENLOGA							
N022331	001	5869100	Oct 13, 2013	DP			
COLESEVELAM HYDROCHLORIDE - WELCHOL							
N022362	001	>A> 5607669	Jun 10, 2014	U-757			
		>A> 5607669*PED	Dec 10, 2014				
		>A> 5679717	Apr 29, 2014	U-757			
		>A> 5679717*PED	Oct 29, 2014				
		>A> 5693675	Dec 02, 2014	DS			
		>A> 5693675*PED	Jun 02, 2015				
		>A> 5917007	Apr 29, 2014	DS U-757			
		>A> 5917007*PED	Oct 29, 2014				
		>A> 5919832	Apr 29, 2014	DS			
		>A> 5919832*PED	Oct 29, 2014				
		>A> 6066678	Apr 29, 2014	DS U-757			
		>A> 6066678*PED	Oct 29, 2014				
		>A> 6433026	Apr 29, 2014	DS			
		>A> 6433026*PED	Oct 29, 2014				
		>A> 6784254	Apr 29, 2014	DS DP			
		>A> 6784254*PED	Oct 29, 2014				
		>A> 7101960	Apr 29, 2014	DS DP U-757			
		>A> 7101960*PED	Oct 29, 2014				
		>A> 7229613	Apr 17, 2022	U-493			
		>A> 7229613*PED	Oct 17, 2022				

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COLESEVELAM HYDROCHLORIDE - WELCHOL						
N022362 002	**>A>** 5607669	Jun 10, 2014	U-757			
	>A> 5607669*PED	Dec 10, 2014				
	>A> 5679717	Apr 29, 2014	U-757			
	>A> 5679717*PED	Oct 29, 2014				
	>A> 5693675	Dec 02, 2014	DS			
	>A> 5693675*PED	Jun 02, 2015				
	>A> 5917007	Apr 29, 2014	DS U-757			
	>A> 5917007*PED	Oct 29, 2014				
	>A> 5919832	Apr 29, 2014	DS			
	>A> 5919832*PED	Oct 29, 2014				
	>A> 6066678	Apr 29, 2014	DS U-757			
	>A> 6066678*PED	Oct 29, 2014				
	>A> 6433026	Apr 29, 2014	DS			
	>A> 6433026*PED	Oct 29, 2014				
	>A> 6784254	Apr 29, 2014	DS DP			
	>A> 6784254*PED	Oct 29, 2014				
	>A> 7101960	Apr 29, 2014	DS DP U-757			
	>A> 7101960*PED	Oct 29, 2014				
	>A> 7229613	Apr 17, 2022	U-493			
	>A> 7229613*PED	Oct 17, 2022				
DALFAMPRIDINE - AMPYRA						
N022250 001	**>A>** 5370879	Dec 06, 2011	DP		NCE	Jan 22, 2015
	>A> 5540938	Jul 30, 2013	U-1030		**>A>** ODE	Jan 22, 2017
DICLOFENAC POTASSIUM - CAMBIA						
N022165 001					**>A>** NDF	Jun 17, 2012
DICLOFENAC POTASSIUM - ZIPSOR						
N022202 001	6365180	Jul 15, 2019	DP U-980			
	>A> 7662858	Feb 24, 2029	U-1035			
DULOXETINE HYDROCHLORIDE - CYMBALTA						
N021427 003	5023269	Jun 11, 2013	DS DP U-797			
	5508276	Jul 18, 2014	DP			
ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE						
N021840 001	**>A>** 7615545	Jun 15, 2023	U-1			
EZETIMIBE - ZETIA						
N021445 001	7612058	Jan 25, 2022	U-1027			
	7612058*PED	Jul 25, 2022				
FENOFIBRATE - FENOGLIDE						
N022118 001	**>A>** 7658944	Dec 09, 2024	DP			
FENOFIBRATE - FENOGLIDE						
N022118 002	**>A>** 7658944	Dec 09, 2024	DP			
HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR						
N020387 001	**>A>** 5608075****	Mar 04, 2009		Y		
	>A> 5608075*PED	Sep 04, 2009				

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HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR							
N020387 002	>A>	5608075****	Mar 04, 2009		Y		
	>A>	5608075*PED	Sep 04, 2009				
HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL - BENICAR HCT							
N021532 002	>A>	6878703	Nov 19, 2021	U-3	Y		
IMIQUIMOD - IMIQUIMOD							
A078548 001						>A> PC	Aug 24, 2010
INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR							
N021629 003		6221633	Jun 18, 2018	DS DP U-471			
		6960561	Jan 25, 2023	DP U-471			
		7452860	Mar 22, 2022	DP			
LAMOTRIGINE - LAMICTAL XR							
N022115 001						>A> I-622	Jan 29, 2013
						NDF	May 29, 2012
						PED	Nov 29, 2012
LAMOTRIGINE - LAMICTAL XR							
N022115 002						>A> I-622	Jan 29, 2013
						NDF	May 29, 2012
						PED	Nov 29, 2012
LAMOTRIGINE - LAMICTAL XR							
N022115 003						>A> I-622	Jan 29, 2013
						NDF	May 29, 2012
						PED	Nov 29, 2012
LAMOTRIGINE - LAMICTAL XR							
N022115 004						>A> I-622	Jan 29, 2013
						NDF	May 29, 2012
						PED	Nov 29, 2012
LAPATINIB DITOSYLATE - TYKERB							
N022059 001						I-620	Jan 29, 2013
LEVETIRACETAM - KEPPRA							
N021872 001						I-563	Mar 19, 2010
						PED	Sep 19, 2010
LIRAGLUTIDE RECOMBINANT - VICTOZA							
N022341 001		6268343	Aug 22, 2017	DS DP U-968		NCE	Jan 25, 2015
		6458924	Aug 22, 2017	DS DP U-968			
		7235627	Aug 22, 2017	DS DP			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE							
N021977 001		7655630	Feb 24, 2023	DS			
	>A>	7659253	Feb 24, 2023	DS DP U-727			
	>A>	7659254	Feb 24, 2023	U-1034			
	>A>	7662787	Feb 24, 2023	DS			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE							
N021977 002		7655630	Feb 24, 2023	DS			
	>A>	7659253	Feb 24, 2023	DS DP U-727			
	>A>	7659254	Feb 24, 2023	U-1034			
	>A>	7662787	Feb 24, 2023	DS			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 003	7655630	Feb 24, 2023	DS			
	>A> 7659253	Feb 24, 2023	DS DP U-727			
	>A> 7659254	Feb 24, 2023	U-1034			
	>A> 7662787	Feb 24, 2023	DS			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 004	7655630	Feb 24, 2023	DS			
	>A> 7659253	Feb 24, 2023	DS DP U-727			
	>A> 7659254	Feb 24, 2023	U-1034			
	>A> 7662787	Feb 24, 2023	DS			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 005	7655630	Feb 24, 2023	DS			
	>A> 7659253	Feb 24, 2023	DS DP U-727			
	>A> 7659254	Feb 24, 2023	U-1034			
	>A> 7662787	Feb 24, 2023	DS			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 006	7655630	Feb 24, 2023	DS			
	>A> 7659253	Feb 24, 2023	DS DP U-727			
	>A> 7659254	Feb 24, 2023	U-1034			
	>A> 7662787	Feb 24, 2023	DS			
LOSARTAN POTASSIUM - COZAAR						
N020386 001	**>A>** 5608075****	Mar 04, 2009		Y		
	>A> 5608075*PED	Sep 04, 2009				
LOSARTAN POTASSIUM - COZAAR						
N020386 002	**>A>** 5608075****	Mar 04, 2009		Y		
	>A> 5608075*PED	Sep 04, 2009				
LOSARTAN POTASSIUM - COZAAR						
N020386 003	**>A>** 5608075****	Mar 04, 2009		Y		
	>A> 5608075*PED	Sep 04, 2009				
MESALAMINE - SFROWASA						
N019618 002	7645801	Jul 24, 2027	DS DP			
NICARDIPINE HYDROCHLORIDE - CARDENE IN 0.83% SODIUM CHLORIDE IN PLASTIC CONTAINER						
N019734 004	**>A>** 7659291	Apr 18, 2027	U-1029			
NICARDIPINE HYDROCHLORIDE - CARDENE IN 0.86% SODIUM CHLORIDE IN PLASTIC CONTAINER						
N019734 003	**>A>** 7659291	Apr 18, 2027	U-1029			
NICARDIPINE HYDROCHLORIDE - CARDENE IN 4.8% DEXTROSE IN PLASTIC CONTAINER						
N019734 002	**>A>** 7659291	Apr 18, 2027	U-1029			
NICARDIPINE HYDROCHLORIDE - CARDENE IN 5.0% DEXTROSE IN PLASTIC CONTAINER						
N019734 005	**>A>** 7659291	Apr 18, 2027	U-1029			
OLMESARTAN MEDOXOMIL - BENICAR						
N021286 001					**>A>** NPP	Feb 04, 2013
					>A> PED	Aug 04, 2010
OLMESARTAN MEDOXOMIL - BENICAR						
N021286 003					**>A>** NPP	Feb 04, 2013
					>A> PED	Aug 04, 2010

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OLMESARTAN MEDOXOMIL - BENICAR						
N021286 004					**>A>** NPP	Feb 04, 2013
					>A> PED	Aug 04, 2010
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021087 001					**>A>** M-90	Feb 22, 2013
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021087 002					**>A>** M-90	Feb 22, 2013
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021087 003					**>A>** M-90	Feb 22, 2010
OSELTAMIVIR PHOSPHATE - TAMIFLU						
N021246 001					**>A>** M-90	Feb 22, 2013
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP						
N022210 001	**>A>** 7658918	Feb 20, 2028	DP			
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP						
N022210 002	**>A>** 7658918	Feb 20, 2028	DP			
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP						
N022210 003	**>A>** 7658918	Feb 20, 2028	DP			
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP						
N022210 004	**>A>** 7658918	Feb 20, 2028	DP			
PANTOPRAZOLE SODIUM - PROTONIX						
N022020 001	7544370	Jun 07, 2026	DP			
	7544370*PED	Dec 07, 2026				
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER						
N022421 001	**>A>** 4886812	Oct 08, 2010	DS DP			
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER						
N022421 002	**>A>** 4886812	Oct 08, 2010	DS DP			
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER						
N022421 003	**>A>** 4886812	Oct 08, 2010	DS DP			
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER						
N022421 004	**>A>** 4886812	Oct 08, 2010	DS DP			
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER						
N022421 005	**>A>** 4886812	Oct 08, 2010	DS DP			
PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE						
A077724 001					PC	Jul 03, 2010
PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE						
A077724 002					PC	Jul 03, 2010
PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE						
A077724 003					PC	Jul 03, 2010
PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE						
A077724 004					PC	Jul 03, 2010
PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE						
A077724 005					PC	Jul 03, 2010

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PREGABALIN - LYRICA						
N022488 001	5563175	Oct 08, 2013	U-661		I-535	Jun 21, 2010
	6001876	Dec 30, 2018	U-819			
	6001876	Dec 30, 2018	U-55			
	6197819	Dec 30, 2018	DS DP			
REGADENOSON - LEXISCAN						
N022161 001	7655636	Jun 22, 2019	U-869			
	7655637	Jun 22, 2019	DS DP U-869			
RITONAVIR - RITONAVIR						
N022417 001	**>A>** 5541206	Jul 30, 2013	DS DP U-688			
	>A> 5541206*PED	Jan 30, 2014				
	>A> 5635523	Jun 03, 2014	U-688			
	>A> 5635523*PED	Dec 03, 2014				
	>A> 5648497	Jul 15, 2014	DS			
	>A> 5648497*PED	Jan 15, 2015				
	>A> 5674882	Oct 07, 2014	U-688			
	>A> 5674882*PED	Apr 07, 2015				
	>A> 6037157	Jun 26, 2016	U-688			
	>A> 6037157*PED	Dec 26, 2016				
	>A> 6703403	Jun 26, 2016	U-688			
	>A> 6703403*PED	Dec 26, 2016				
	>A> 7148359	Jul 19, 2019	DP			
	>A> 7148359*PED	Jan 19, 2020				
	>A> 7364752	Nov 10, 2020	DP U-688			
	>A> 7364752*PED	May 10, 2021				
ROMIDEPSIN - ISTODAX						
N022393 001					ODE	Nov 05, 2016
ROSUVASTATIN CALCIUM - CRESTOR						
N021366 002	**>A>** 7030152	Apr 02, 2018	U-1032		**>A>** I-621	Feb 08, 2013
ROSUVASTATIN CALCIUM - CRESTOR						
N021366 003	**>A>** 7030152	Apr 02, 2018	U-1032		**>A>** I-621	Feb 08, 2013
ROSUVASTATIN CALCIUM - CRESTOR						
N021366 004	**>A>** 7030152	Apr 02, 2018	U-1032		**>A>** I-621	Feb 08, 2013
ROSUVASTATIN CALCIUM - CRESTOR						
N021366 005	**>A>** 7030152	Apr 02, 2018	U-1032		**>A>** I-621	Feb 08, 2013
SODIUM OXYBATE - XYREM						
N021196 001	**>A>** 7668730	Mar 07, 2024	U-1028			
TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA						
N021395 001	7642268	Sep 24, 2021	DS DP			
TOLTERODINE TARTRATE - DETROL						
N020771 001	5559269	Nov 05, 2013	U-318	Y		
	5559269*PED	May 05, 2014				
TOLTERODINE TARTRATE - DETROL						
N020771 002	5559269	Nov 05, 2013	U-318	Y		
	5559269*PED	May 05, 2014				

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TRAZODONE HYDROCHLORIDE - OLEPTRO						
N022411 001	**>A>** 6607748	Jun 29, 2020	DP		**>A>** NDF	Feb 02, 2013
TRAZODONE HYDROCHLORIDE - OLEPTRO						
N022411 002	**>A>** 6607748	Jun 29, 2020	DP		**>A>** NDF	Feb 02, 2013
VELAGLUCERASE ALFA - VPRIV						
N022575 001					**>A>** NCE	Feb 26, 2015
VELAGLUCERASE ALFA - VPRIV						
N022575 002					**>A>** NCE	Feb 26, 2015
VORINOSTAT - ZOLINZA						
N021991 001	7652069	Mar 04, 2023	DS			

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, 29th 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