APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

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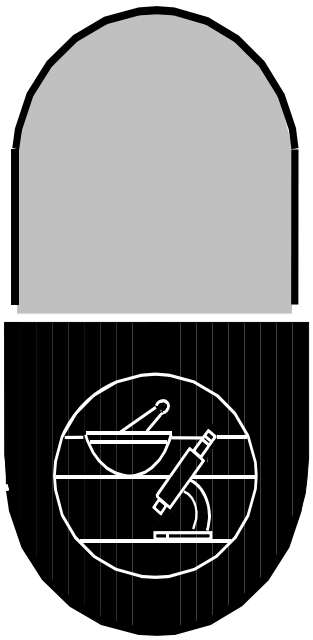
CUMULATIVE SUPPLEMENT 01
January 2010



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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

30th EDITION

Cumulative Supplement 01

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CUMULATIVE SUPPLEMENT 01
January 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, 29th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 29th 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)
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	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA
(ZENITH GOLDLINE)	(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.

ACITRETIN

CAPSULE; ORAL

SORIATANE

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

ALENDRONATE SODIUM

TABLET; ORAL

ALENDRONATE SODIUM

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

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

CAPSULE; ORAL

AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE

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

AZELASTINE HYDROCHLORIDE

SPRAY, METERED; NASAL

ASTELIN

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

AZELASTINE HYDROCHLORIDE

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

BACLOFEN

TABLET; ORAL

BACLOFEN

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

>D> TABLET, ORALLY DISINTEGRATING; ORAL

>D> KEMSTRO

>D>		SCHWARZ PHARMA	10MG	N021589	001	Oct 30, 2003	Jan	DISC
>A>		@	10MG	N021589	001	Oct 30, 2003	Jan	DISC
>D>		+	20MG	N021589	002	Oct 30, 2003	Jan	DISC
>A>		@	20MG	N021589	002	Oct 30, 2003	Jan	DISC

>D> BETAXOLOL

>D> SOLUTION/DROPS; OPHTHALMIC

>D> BETAXOLOL

>D>	AT	WOCKHARDT	EQ 0.5% BASE	A078694	001	Nov 16, 2009	Jan	CAIN

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

>D> BETAXOLOL

>D>	AT	AKORN	EQ 0.5% BASE	A075386	001	Jun 30, 2000	Jan	CTNA
>D>	AT	NOVEX	EQ 0.5% BASE	A075446	001	Sep 28, 2000	Jan	CTNA

SOLUTION/DROPS; OPHTHALMIC

BETAXOLOL HYDROCHLORIDE

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

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

SOLUTION; IRRIGATION

BALANCED SALT

>A>	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

CEFADROXIL/CEFADROXIL HEMIHYDRATE

FOR SUSPENSION; ORAL

CEFADROXIL

>D>	AB	LUPIN	EQ 500MG BASE/5ML	A065396	002	Feb 21, 2008	Jan	CRLD
>A>	AB +		EQ 500MG BASE/5ML	A065396	002	Feb 21, 2008	Jan	CRLD
>D>		DURICEF						
>D>	AB	WARNER CHILCOTT	EQ 250MG BASE/5ML	N050527	003		Jan	DISC
>A>		@	EQ 250MG BASE/5ML	N050527	003		Jan	DISC
>D>	AB +		EQ 500MG BASE/5ML	N050527	001		Jan	DISC
>A>		@	EQ 500MG BASE/5ML	N050527	001		Jan	DISC

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CEFOTAXIME SODIUM

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

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CETIRIZINE HYDROCHLORIDE

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

CICLOPIROX

SHAMPOO; TOPICAL

CICLOPIROX

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

SOLUTION; TOPICAL

CICLOPIROX

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

CYANOCOBALAMIN

SPRAY, METERED; NASAL

>D>		CALOMIST						
>D>	+	FLEMING	25MCG/SPRAY	N022102	001	Jul 27, 2007	Jan	DISC
>A>		@	25MCG/SPRAY	N022102	001	Jul 27, 2007	Jan	DISC

>A> DALFAMPRIDINE

>A> TABLET, EXTENDED RELEASE; ORAL

>A> AMPYRA

>A>	+	ACORDA	10MG	N022250	001	Jan 22, 2010	Jan	NEWA

DESLORATADINE

TABLET; ORAL

CLARINEX

>D>		+	SCHERING PLOUGH	5MG	N021165	001	Dec 21, 2001	Jan	CFTG
>A>	AB	+		5MG	N021165	001	Dec 21, 2001	Jan	CFTG

DESLORATADINE

>A>	AB		ORCHID HLTHCARE	5MG	A078357	001	Feb 19, 2010	Jan	NEWA

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

STIMATE (NEEDS NO REFRIGERATION)

>A>		@	CSL BEHRING	1.5MG/SPRAY	N020355	002	Oct 24, 2007	Jan	DISC

>D> DEXMEDETOMIDINE

>D> INJECTABLE; INJECTION

>D> PRECEDEX

>D>		+	HOSPIRA	EQ 100MCG BASE/ML	N021038	001	Dec 17, 1999	Jan	CAIN

>A> DEXMEDETOMIDINE HYDROCHLORIDE

>A> INJECTABLE; INJECTION

>A> PRECEDEX

>A>		+	HOSPIRA	EQ 100MCG BASE/ML (EQ100MCG BASE/ML	N021038	001	Dec 17, 1999	Jan	CAIN

DICLOFENAC POTASSIUM

TABLET; ORAL

DICLOFENAC POTASSIUM

>D>	AB		SANDOZ	50MG	A075582	001	Feb 23, 2001	Jan	DISC
>A>		@		50MG	A075582	001	Feb 23, 2001	Jan	DISC

EPINEPHRINE

INJECTABLE; IM-SC

TWINJECT 0.15

>D>		+	SCIELE PHARMA INC	EQ 0.15MG /DELIVERY	N020800	002	May 28, 2004	Jan	CAHN
>A>		+	SHIONOGI PHARMA	EQ 0.15MG /DELIVERY	N020800	002	May 28, 2004	Jan	CAHN

TWINJECT 0.3

>D>		+	SCIELE PHARMA INC	EQ 0.3MG /DELIVERY	N020800	001	May 30, 2003	Jan	CAHN
>A>		+	SHIONOGI PHARMA	EQ 0.3MG /DELIVERY	N020800	001	May 30, 2003	Jan	CAHN

ESTRADIOL VALERATE

INJECTABLE; INJECTION

ESTRADIOL VALERATE

>A>	AO		PHARMAFORCE	20MG/ML	A090920	001	Jan 19, 2010	Jan	NEWA
>A>	AO			40MG/ML	A090920	002	Jan 19, 2010	Jan	NEWA

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

NORETHINDRONE AND ETHINYL ESTRADIOL

>A>	AB		WATSON LABS	0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG	A076393	001	Feb 04, 2010	Jan	NEWA
>A>	AB			0.035MG;0.4MG	A078323	001	Feb 04, 2010	Jan	NEWA

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

>A>		TABLET; ORAL							
>A>		NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE							
>A>	AB	WATSON LABS	0.02MG;1MG	A078267	001	Sep 01, 2009	Jan	CDFR	
>D>		TABLET; ORAL-28							
>D>		NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE							
>D>	AB	WATSON LABS	0.02MG;1MG	A078267	001	Sep 01, 2009	Jan	CDFR	

FAMOTIDINE

>D>		TABLET, ORALLY DISINTEGRATING; ORAL							
>D>		FLUXID							
>D>		SCHWARZ PHARMA	20MG	N021712	001	Sep 24, 2004	Jan	DISC	
>A>		@	20MG	N021712	001	Sep 24, 2004	Jan	DISC	
>D>		+	40MG	N021712	002	Sep 24, 2004	Jan	DISC	
>A>		@	40MG	N021712	002	Sep 24, 2004	Jan	DISC	

FENOFIBRATE

		CAPSULE; ORAL							
		ANTARA (MICRONIZED)							
>A>		LUPIN ATLANTIS	43MG	N021695	001	Nov 30, 2004	Jan	CAHN	
>A>		@	87MG	N021695	002	Nov 30, 2004	Jan	CAHN	
>A>		+	130MG	N021695	003	Nov 30, 2004	Jan	CAHN	
>D>		OSCIENT	43MG	N021695	001	Nov 30, 2004	Jan	CAHN	
>D>		@	87MG	N021695	002	Nov 30, 2004	Jan	CAHN	
>D>		+	130MG	N021695	003	Nov 30, 2004	Jan	CAHN	
		TABLET; ORAL							
		FENOGLIDE							
>D>		SCIELE PHARMA INC	40MG	N022118	001	Aug 10, 2007	Jan	CAHN	
>D>		+	120MG	N022118	002	Aug 10, 2007	Jan	CAHN	
>A>		SHIONOGI PHARMA	40MG	N022118	001	Aug 10, 2007	Jan	CAHN	
>A>		+	120MG	N022118	002	Aug 10, 2007	Jan	CAHN	

FLUCONAZOLE

		INJECTABLE; INJECTION							
>A>		FLUCONAZOLE IN SODIUM CHLORIDE 0.9%							
>A>		BEDFORD	100MG/50ML (2MG/ML)	A076087	002	Sep 26, 2008	Jan	CTNA	
>D>		FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER							
>D>		BEDFORD	100MG/50ML (2MG/ML)	A076087	002	Sep 26, 2008	Jan	CTNA	

FOLIC ACID

		TABLET; ORAL							
		FOLIC ACID							
>D>	AA	PHARMAX	1MG	A040625	001	Jul 21, 2005	Jan	CRLD	
>A>	AA	+	1MG	A040625	001	Jul 21, 2005	Jan	CRLD	
>D>		@ WATSON LABS	1MG	A080680	001		Jan	CMFD	
>A>	AA	+	1MG	A080680	001		Jan	CMFD	

GLYBURIDE; METFORMIN HYDROCHLORIDE

		TABLET; ORAL							
		GLYBURIDE AND METFORMIN HYDROCHLORIDE							
>D>	AB	TEVA	1.25MG;250MG	A076821	001	Jan 27, 2005	Jan	DISC	
>A>		@	1.25MG;250MG	A076821	001	Jan 27, 2005	Jan	DISC	
>D>	AB		2.5MG;500MG	A076821	002	Jan 27, 2005	Jan	DISC	
>A>		@	2.5MG;500MG	A076821	002	Jan 27, 2005	Jan	DISC	
>D>	AB		5MG;500MG	A076821	003	Jan 27, 2005	Jan	DISC	

TABLET; ORAL
GLYBURIDE AND METFORMIN HYDROCHLORIDE

>A>			@ TEVA	5MG;500MG	A076821	003	Jan 27, 2005	Jan	DISC

GLYCOPYRROLATE

TABLET; ORAL
ROBINUL

>D>	AA	+	SCIELE PHARMA INC	1MG	N012827	001		Jan	CAHN
>A>	AA	+	SHIONOGI PHARMA	1MG	N012827	001		Jan	CAHN

ROBINUL FORTE

>D>	AA	+	SCIELE PHARMA INC	2MG	N012827	002		Jan	CAHN
>A>	AA	+	SHIONOGI PHARMA	2MG	N012827	002		Jan	CAHN

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HYDROCHLORIDE

>A>	AA		HERITAGE PHARMS INC	10MG	A086242	001	Feb 04, 2010	Jan	NEWA
>A>	AA			100MG	A086242	004	Feb 04, 2010	Jan	NEWA

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL
LISINOPRIL AND HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET; ORAL
METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE

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

IBUPROFEN

TABLET; ORAL
IBUPROFEN

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

IFOSFAMIDE

INJECTABLE; INJECTION
IFOSFAMIDE

>D>	AP	+	APP PHARMS	1GM/VIAL	A076078	001	May 28, 2002	Jan	CTEC

INJECTABLE; INJECTION
IFOSFAMIDE

>A>		+	APP PHARMS	1GM/VIAL	A076078	001	May 28, 2002	Jan	CTEC
>D>	AP			1GM/VIAL	A090181	001	Sep 22, 2009	Jan	CPOT
>A>	AP			1GM/20ML (50MG/ML)	A090181	001	Sep 22, 2009	Jan	CPOT
>D>	AP	+		3GM/VIAL	A076078	002	May 28, 2002	Jan	CTEC
>A>		+		3GM/VIAL	A076078	002	May 28, 2002	Jan	CTEC
>D>	AP			3GM/VIAL	A090181	002	Sep 22, 2009	Jan	CPOT
>A>	AP			3GM/60ML (50MG/ML)	A090181	002	Sep 22, 2009	Jan	CPOT
>D>		+	TEVA PARENTERAL	1GM/20ML (50MG/ML)	A076657	001	Apr 04, 2007	Jan	CTEC
>A>	AP	+		1GM/20ML (50MG/ML)	A076657	001	Apr 04, 2007	Jan	CTEC
>D>		+		3GM/60ML (50MG/ML)	A076657	002	Apr 04, 2007	Jan	CTEC
>A>	AP	+		3GM/60ML (50MG/ML)	A076657	002	Apr 04, 2007	Jan	CTEC

LABETALOL HYDROCHLORIDE

INJECTABLE; INJECTION
LABETALOL HYDROCLORIDE

>A>	AP		SAGENT STRIDES	5MG/ML	A079134	001	Feb 03, 2010	Jan	NEWA

LENALIDOMIDE

CAPSULE; ORAL
REVLIMID

>D>			CELGENE	5MG	N021880	001	Dec 27, 2005	Jan	CRLD
>A>		+		5MG	N021880	001	Dec 27, 2005	Jan	CRLD

LEVETIRACETAM

TABLET; ORAL
LEVETIRACETAM

>A>	AB		TARO	250MG	A078960	004	Feb 01, 2010	Jan	NEWA
>A>	AB			500MG	A078960	003	Feb 01, 2010	Jan	NEWA
>A>	AB			750MG	A078960	002	Feb 01, 2010	Jan	NEWA
>A>	AB			1GM	A078960	001	Feb 01, 2010	Jan	NEWA

>A> LIRAGLUTIDE RECOMBINANT

>A> SOLUTION; SUBCUTANEOUS
>A> VICTOZA

>A>		+	NOVO NORDISK INC	18MG/3ML (6MG/ML)	N022341	001	Jan 25, 2010	Jan	NEWA

LISINOPRIL

TABLET; ORAL
LISINOPRIL

>D>	AB		TEVA	2.5MG	A075783	001	Jul 01, 2002	Jan	DISC
>A>		@		2.5MG	A075783	001	Jul 01, 2002	Jan	DISC
>D>	AB			5MG	A075783	002	Jul 01, 2002	Jan	DISC
>A>		@		5MG	A075783	002	Jul 01, 2002	Jan	DISC
>D>	AB			10MG	A075783	003	Jul 01, 2002	Jan	DISC
>A>		@		10MG	A075783	003	Jul 01, 2002	Jan	DISC
>D>	AB			20MG	A075783	004	Jul 01, 2002	Jan	DISC
>A>		@		20MG	A075783	004	Jul 01, 2002	Jan	DISC
>D>	AB			30MG	A075783	005	Jul 01, 2002	Jan	DISC
>A>		@		30MG	A075783	005	Jul 01, 2002	Jan	DISC
>D>	AB			40MG	A075783	006	Jul 01, 2002	Jan	DISC
>A>		@		40MG	A075783	006	Jul 01, 2002	Jan	DISC

LITHIUM CARBONATE

CAPSULE; ORAL

>D>		ESKALITH							
>D>	AB	NOVEN THERAP	300MG	N016860	001			Jan	DISC
>A>		@	300MG	N016860	001			Jan	DISC

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

		ANTIVERT							
>D>		@ PFIZER	50MG	N010721	001	Jan 20, 1982		Jan	CMFD
>A>	AA	+	50MG	N010721	001	Jan 20, 1982		Jan	CMFD
>D>		TABLET, CHEWABLE; ORAL							
>D>		ANTIVERT							
>D>		+ PFIZER	25MG	N010721	005			Jan	DISC
>A>		@	25MG	N010721	005			Jan	DISC

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

		METFORMIN HYDROCHLORIDE							
>A>	AB	TORRENT PHARMS	750MG	A079226	001	Feb 18, 2010		Jan	NEWA

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

		METOCLOPRAMIDE HYDROCHLORIDE							
>D>	AB	SANDOZ	EQ 10MG BASE	A074478	002	Oct 05, 1995		Jan	DISC
>A>		@	EQ 10MG BASE	A074478	002	Oct 05, 1995		Jan	DISC
>D>	AB	WATSON LABS	EQ 10MG BASE	A070511	001	Jan 22, 1986		Jan	DISC
>A>		@	EQ 10MG BASE	A070511	001	Jan 22, 1986		Jan	DISC

MILRINONE LACTATE

INJECTABLE; INJECTION

		MILRINONE LACTATE IN PLASTIC CONTAINER							
>A>	AP	HIKMA FARMACEUTICA	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	A090038	001	Jan 21, 2010		Jan	NEWA
>A>	AP		EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	A090038	002	Jan 21, 2010		Jan	NEWA

MORPHINE SULFATE

SOLUTION; ORAL

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

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL

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

TABLET, EXTENDED RELEASE; ORAL
SULAR

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

NITROFURANTOIN

SUSPENSION; ORAL
FURADANTIN

>D>		+	SCIELE PHARMA INC	25MG/5ML	N009175	001		Jan	CAHN
>A>		+	SHIONOGI PHARMA	25MG/5ML	N009175	001		Jan	CAHN

NITROGLYCERIN

AEROSOL; SUBLINGUAL
NITROLINGUAL

>D>		@	POHL BOSKAMP	0.4MG/SPRAY	N018705	001	Oct 31, 1985	Jan	CAHN
>A>		@	SHIONOGI PHARMA	0.4MG/SPRAY	N018705	001	Oct 31, 1985	Jan	CAHN

SPRAY, METERED; SUBLINGUAL
NITROLINGUAL PUMPSPRAY

>D>		+	POHL BOSKAMP	0.4MG/SPRAY	N018705	002	Jan 10, 1997	Jan	CAHN
>A>		+	SHIONOGI PHARMA	0.4MG/SPRAY	N018705	002	Jan 10, 1997	Jan	CAHN

OFLOXACIN

TABLET; ORAL
OFLOXACIN

>A>		@	LARKEN LABS	200MG	A076093	001	Sep 02, 2003	Jan	CAHN
>A>		@		300MG	A076093	002	Sep 02, 2003	Jan	CAHN
>A>		@		400MG	A076093	003	Sep 02, 2003	Jan	CAHN
>D>		@	PAR PHARM	200MG	A076093	001	Sep 02, 2003	Jan	CAHN
>D>		@		300MG	A076093	002	Sep 02, 2003	Jan	CAHN
>D>		@		400MG	A076093	003	Sep 02, 2003	Jan	CAHN

OXALIPLATIN

INJECTABLE; INJECTION
OXALIPLATIN

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

OXCARBAZEPINE

TABLET; ORAL
OXCARBAZEPINE

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

PALIPERIDONE PALMITATE

SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR
INVEGA SUSTENNA

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

		SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR						
		INVEGA SUSTENNA						
>A>		+ JOHNSON AND JOHNSON	234MG/1.5ML (156MG/ML)	N022264	005	Jul 31, 2009	Jan	CRLD
		PERINDOPRIL ERBUMINE						
		TABLET; ORAL						
		PERINDOPRIL ERBUMINE						
>A>	AB	LUPIN LTD	2MG	A078263	001	Jan 27, 2010	Jan	NEWA
>A>	AB		4MG	A078263	002	Jan 27, 2010	Jan	NEWA
>A>	AB		8MG	A078263	003	Jan 27, 2010	Jan	NEWA
		POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE ANHYDROUS						
		FOR SOLUTION; ORAL						
		PEG 3350 AND ELECTROLYTES						
>A>	AA	MYLAN	236GM;2.97GM;6.74GM;5.86GM;22.74GM	A090928	001	Jan 28, 2010	Jan	NEWA
		PRAZOSIN HYDROCHLORIDE						
		CAPSULE; ORAL						
		PRAZOSIN HYDROCHLORIDE						
>D>	AB	WATSON LABS	EQ 1MG BASE	A072352	001	May 16, 1989	Jan	DISC
>A>		@	EQ 1MG BASE	A072352	001	May 16, 1989	Jan	DISC
>D>	AB		EQ 2MG BASE	A072333	001	May 16, 1989	Jan	DISC
>A>		@	EQ 2MG BASE	A072333	001	May 16, 1989	Jan	DISC
		PREDNISONE						
		TABLET; ORAL						
		PREDNISONE						
>A>	AB	CONTRACT PHARMACAL	5MG	A080209	001		Jan	CAHN
>D>	AB	LEINER	5MG	A080209	001		Jan	CAHN
		PREGABALIN						
>A>		SOLUTION; ORAL						
>A>		LYRICA						
>A>		+ PFIZER	20MG/ML	N022488	001	Jan 04, 2010	Jan	NEWA
>D>		PROCAINE HYDROCHLORIDE						
>D>		INJECTABLE; INJECTION						
>D>		PROCAINE HYDROCHLORIDE						
>D>		+ WATSON LABS	1%	A080658	001		Jan	DISC
>A>		@	1%	A080658	001		Jan	DISC
		PROCHLORPERAZINE MALEATE						
		TABLET; ORAL						
>D>		PROCHLORPERAZINE MALEATE						
>D>	AB	CADISTA PHARMS	EQ 5MG BASE	A040268	001	Feb 27, 1998	Jan	CTNA
>D>	AB		EQ 10MG BASE	A040268	002	Feb 27, 1998	Jan	CTNA
>D>	AB	DURAMED PHARMS BARR	EQ 5MG BASE	A040207	001	May 01, 1997	Jan	DISC
>A>		@	EQ 5MG BASE	A040207	001	May 01, 1997	Jan	DISC
>D>	AB		EQ 10MG BASE	A040207	002	May 01, 1997	Jan	DISC
>A>		@	EQ 10MG BASE	A040207	002	May 01, 1997	Jan	DISC
>A>		PROCOMP						
>A>	AB	CADISTA PHARMS	EQ 5MG BASE	A040268	001	Feb 27, 1998	Jan	CTNA
>A>	AB		EQ 10MG BASE	A040268	002	Feb 27, 1998	Jan	CTNA

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HYDROCHLORIDE

>D>	AA		PAR PHARM	65MG	A080269	001		Jan	DISC
>A>			@	65MG	A080269	001		Jan	DISC

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

>A>			@ CONTRACT PHARMACAL	200MG	A083808	001		Jan	CAHN
>D>			@ LEINER	200MG	A083808	001		Jan	CAHN

RISPERIDONE

INJECTABLE; INTRAMUSCULAR
RISPERDAL CONSTA

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

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

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

TERCONAZOLE

CREAM; VAGINAL
TERCONAZOLE

>D>	BX	+	ALTANA	0.8%	N021735	001	Oct 01, 2004	Jan	CAHN
>A>	BX	+	NYCOMED US	0.8%	N021735	001	Oct 01, 2004	Jan	CAHN

TOPIRAMATE

TABLET; ORAL
TOPIRAMATE

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

>D> UNOPROSTONE ISOPROPYL

>D> SOLUTION/DROPS; OPHTHALMIC
>D> RESCULA

>D>		+	R TECH UENO LTD	0.15%	N021214	001	Aug 03, 2000	Jan	DISC
>A>			@ SUCAMPO PHARMS	0.15%	N021214	001	Aug 03, 2000	Jan	DISC

URSODIOL

CAPSULE; ORAL
URSODIOL

>A>	AB		MYLAN	300MG	A090530	001	Feb 17, 2010	Jan	NEWA

VALPROATE SODIUM

INJECTABLE; INJECTION
VALPROATE SODIUM

>A>	AP	HIKMA FARMACEUTICA	EQ 100MG BASE/ML	A078523	001	Feb 17, 2010	Jan	NEWA

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

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

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

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

TABLET; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

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

CETIRIZINE HYDROCHLORIDE HIVES RELIEF

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

CIMETIDINE

TABLET; ORAL

CIMETIDINE

>A>	CONTRACT PHARMACAL	200MG	A074961	001	Jun 19, 1998	Jan	CAHN
>A>		200MG	A074963	001	Jun 19, 1998	Jan	CAHN
>D>	LEINER	200MG	A074961	001	Jun 19, 1998	Jan	CAHN
>D>		200MG	A074963	001	Jun 19, 1998	Jan	CAHN

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN

>A>	+ CONTRACT PHARMACAL	200MG	A074782	001	Jul 06, 1998	Jan	CAHN
>D>	+ LEINER	200MG	A074782	001	Jul 06, 1998	Jan	CAHN

TABLET; ORAL

IBUPROFEN

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

PROFEN

>A>	CONTRACT PHARMACAL	200MG	A071265	001	Oct 15, 1986	Jan	CAHN
>D>	LEINER	200MG	A071265	001	Oct 15, 1986	Jan	CAHN

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

>A>	CONTRACT PHARMACAL	200MG;30MG	A075588	001	Apr 08, 2002	Jan	CAHN
>D>	LEINER	200MG;30MG	A075588	001	Apr 08, 2002	Jan	CAHN

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL

LOPERAMIDE HYDROCHLORIDE

>A>	CONTRACT PHARMACAL	2MG	A073254	001	Jul 30, 1993	Jan	CAHN
>D>	LEINER	2MG	A073254	001	Jul 30, 1993	Jan	CAHN

MICONAZOLE NITRATE

CREAM; VAGINAL

MICONAZOLE NITRATE

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

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

VISINE-A

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

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE HYDROCHLORIDE

>A>	CONTRACT PHARMACAL	EQ 75MG BASE	A075094	001	Jun 21, 1999	Jan	CAHN
>D>	LEINER	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 01 JANUARY 2010

NO JANUARY 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 JANUARY 2010 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2010

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
ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE - MOVIPREP						
N021881 001	**>A>** 7658914	Sep 01, 2024	DS DP			
BALSALAZIDE DISODIUM - COLAZAL						
N020610 001	**>A>** 7452872	Aug 24, 2026	U-141			
	>A> 7452872*PED	Feb 24, 2027				
	>A> 7625884	Aug 24, 2026	U-141			
	>A> 7625884*PED	Feb 24, 2027				
BUDESONIDE - RHINOCORT						
N020746 001	**>A>** 6686346	Apr 29, 2017	DP U-557	Y		
	>A> 6686346*PED	Oct 29, 2017				
	>A> 6986904	Apr 29, 2017	DP U-699	Y		
	>A> 6986904*PED	Oct 29, 2017				
BUDESONIDE - RHINOCORT						
N020746 002	**>A>** 6686346	Apr 29, 2017	DP U-557			
	>A> 6686346*PED	Oct 29, 2017				
	>A> 6986904	Apr 29, 2017	DP U-699			
	>A> 6986904*PED	Oct 29, 2017				
BUPROPION HYDROBROMIDE - APLENZIN						
N022108 001	**>A>** 7645802	Jun 27, 2026	DP			
	>A> 7649019	Jun 27, 2026	DP			
BUPROPION HYDROBROMIDE - APLENZIN						
N022108 002	**>A>** 7645802	Jun 27, 2026	DP			
	>A> 7649019	Jun 27, 2026	DP			
BUPROPION HYDROBROMIDE - APLENZIN						
N022108 003	**>A>** 7645802	Jun 27, 2026	DP			
	>A> 7649019	Jun 27, 2026	DP			
CAPSAICIN - QUTENZA						
N022395 001					**>A>** ODE	Nov 16, 2016
CEFTIBUTEN DIHYDRATE - CEDAX						
N050686 001	**>A>** 5599557	Feb 04, 2014	DP U-578			
	>A> 5599557	Feb 04, 2014	DP U-282			
CEFTIBUTEN DIHYDRATE - CEDAX						
N050686 002	**>A>** 5599557	Feb 04, 2014	DP U-578			
	>A> 5599557	Feb 04, 2014	DP U-282			
CLONIDINE HYDROCHLORIDE - JENLOGA						
N022331 001	**>A>** 5869100	Oct 13, 2013	DP			
DALFAMPRIDINE - AMPYRA						
N022250 001					**>A>** NCE	Jan 22, 2015
DICLOFENAC POTASSIUM - ZIPSOR						
N022202 001	**>A>** 6365180	Jul 15, 2019	DP U-980			
DULOXETINE HYDROCHLORIDE - CYMBALTA						
N021427 003	**>A>** 5023269	Jun 11, 2013	DS DP U-797			
	>A> 5508276	Jul 18, 2014	DP			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
EZETIMIBE - ZETIA						
N021445 001	**>A>** 7612058	Jan 25, 2022	U-1027			
	>A> 7612058*PED	Jul 25, 2022				
INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR						
N021629 003	**>A>** 6221633	Jun 18, 2018	DS DP U-471			
	>A> 6960561	Jan 25, 2023	DP U-471			
	>A> 7452860	Mar 22, 2022	DP			
LAMOTRIGINE - LAMICTAL XR						
N022115 001					**>A>** NDF	May 29, 2012
					>A> PED	Nov 29, 2012
LAMOTRIGINE - LAMICTAL XR						
N022115 002					**>A>** NDF	May 29, 2012
					>A> PED	Nov 29, 2012
LAMOTRIGINE - LAMICTAL XR						
N022115 003					**>A>** NDF	May 29, 2012
					>A> PED	Nov 29, 2012
LAMOTRIGINE - LAMICTAL XR						
N022115 004					**>A>** NDF	May 29, 2012
					>A> PED	Nov 29, 2012
LAPATINIB DITOSYLATE - TYKERB						
N022059 001					**>A>** I-620	Jan 29, 2013
LEVETIRACETAM - KEPPRA						
N021872 001					**>A>** I-563	Mar 19, 2010
					>A> PED	Sep 19, 2010
LIRAGLUTIDE RECOMBINANT - VICTOZA						
N022341 001	**>A>** 6268343	Aug 22, 2017	DS DP U-968		**>A>** NCE	Jan 25, 2015
	>A> 6458924	Aug 22, 2017	DS DP			
	>A> 7235627	Aug 22, 2017	DS DP			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 001	**>A>** 7655630	Feb 24, 2023	DS			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 002	**>A>** 7655630	Feb 24, 2023	DS			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 003	**>A>** 7655630	Feb 24, 2023	DS			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 004	**>A>** 7655630	Feb 24, 2023	DS			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 005	**>A>** 7655630	Feb 24, 2023	DS			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 006	**>A>** 7655630	Feb 24, 2023	DS			
MESALAMINE - SFROWASA						
N019618 002	**>A>** 7645801	Jul 24, 2027	DS DP			
PANTOPRAZOLE SODIUM - PROTONIX						
N022020 001	**>A>** 7544370	Jun 07, 2026	DP			
	>A> 7544370*PED	Dec 07, 2026				

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE						
A077724 001					**>A>** PC	Jul 03, 2010
PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE						
A077724 002					**>A>** PC	Jul 03, 2010
PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE						
A077724 003					**>A>** PC	Jul 03, 2010
PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE						
A077724 004					**>A>** PC	Jul 03, 2010
PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE						
A077724 005					**>A>** PC	Jul 03, 2010
PREGABALIN - LYRICA						
N022488 001	**>A>** 5563175	Oct 08, 2013	U-661		**>A>** I-535	Jun 21, 2010
	>A> 6001876	Dec 30, 2018	U-819			
	>A> 6001876	Dec 30, 2018	U-55			
	>A> 6197819	Dec 30, 2018	DS DP			
REGADENOSON - LEXISCAN						
N022161 001	**>A>** 7655636	Jun 22, 2019	U-869			
	>A> 7655637	Jun 22, 2019	DS DP U-869			
ROMIDEPSIN - ISTODAX						
N022393 001					**>A>** ODE	Nov 05, 2016
TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA						
N021395 001	**>A>** 7642268	Sep 24, 2021	DS DP			
TOLTERODINE TARTRATE - DETROL						
N020771 001	**>A>** 5559269	Nov 05, 2013	U-318	Y		
	>A> 5559269*PED	May 05, 2014				
TOLTERODINE TARTRATE - DETROL						
N020771 002	**>A>** 5559269	Nov 05, 2013	U-318	Y		
	>A> 5559269*PED	May 05, 2014				

Footnote:

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

PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 30th 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