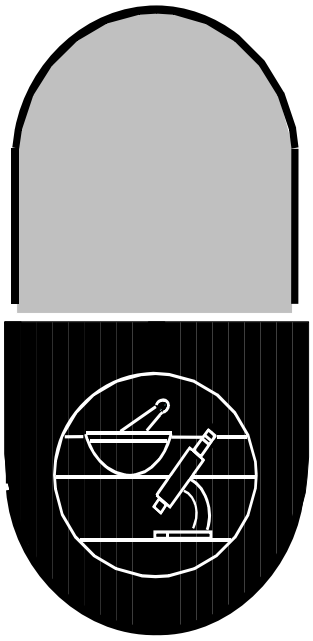
CUMULATIVE SUPPLEMENT 01
January 2007



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

27th EDITION

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

2007

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

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1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 27th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 26th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 27th 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.

1.3 APPLICANT NAME CHANGES

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

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

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

1.4 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) http://www.fda.gov/cder/ob/default.htm, 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 Annual Edition. 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://www.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/cder/rxotcdpl/pdplarchive.htm

There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at http://www.fda.gov/cder/orange/obreadme.htm . The drug product text files are provided in eobzip.exe and 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 2004) 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 2006	MAR 2007	JUN 2007	SEPT 2007
DRUG PRODUCTS LISTED	11896			
SINGLE SOURCE	2471 (20.8%)			
MULTISOURCE	9336 (78.5%)			
THERAPEUTICALLY EQUIVALENT	9139 (76.8%)			
NOT THERAPEUTICALLY EQUIVALENT	197 (1.7%)			

EXCEPTIONS[1]	89
	(0.7%)
NEW MOLECULAR ENTITIES APPROVED	10
NUMBER OF APPLICANTS	666

[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 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.

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

>A>	AN	APOTEX INC	EQ 0.083% BASE	N75717	001	Feb 02, 2007	Jan	NEWA

TABLET, EXTENDED RELEASE; ORAL
ALBUTEROL SULFATE

>A>								
>A>	AB	MYLAN	EQ 4MG BASE	N78092	002	Jan 29, 2007	Jan	NEWA
>A>	AB		EQ 8MG BASE	N78092	001	Jan 29, 2007	Jan	NEWA

VOSPIRE ER

>D>		DAVA PHARMS INC	EQ 4MG BASE	N76130	002	Sep 26, 2002	Jan	CTEC
>A>	AB		EQ 4MG BASE	N76130	002	Sep 26, 2002	Jan	CTEC
>D>	+		EQ 8MG BASE	N76130	003	Sep 26, 2002	Jan	CTEC
>A>	AB +		EQ 8MG BASE	N76130	003	Sep 26, 2002	Jan	CTEC

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM

>A>	AB	APOTEX INC	0.25MG	N77741	001	Jan 19, 2007	Jan	NEWA
>A>	AB		0.5MG	N77741	002	Jan 19, 2007	Jan	NEWA
>A>	AB		1MG	N77741	003	Jan 19, 2007	Jan	NEWA
>A>	AB		2MG	N77741	004	Jan 19, 2007	Jan	NEWA

TABLET, EXTENDED RELEASE; ORAL
ALPRAZOLAM

>A>	AB	ACTAVIS ELIZABETH	0.5MG	N78056	001	Feb 13, 2007	Jan	NEWA
>A>	AB		1MG	N78056	002	Feb 13, 2007	Jan	NEWA
>A>	AB		2MG	N78056	003	Feb 13, 2007	Jan	NEWA
>A>	AB		3MG	N78056	004	Feb 13, 2007	Jan	NEWA
>A>	AB	COREPHARMA	0.5MG	N77996	001	Jan 31, 2007	Jan	NEWA
>A>	AB		1MG	N77996	002	Jan 31, 2007	Jan	NEWA
>A>	AB		2MG	N77996	003	Jan 31, 2007	Jan	NEWA
>A>	AB		3MG	N77996	004	Jan 31, 2007	Jan	NEWA

TABLET, ORALLY DISINTEGRATING; ORAL
NIRAVAM

>D>		SCHWARZ PHARMA	1MG	N21726	003	Jan 19, 2005	Jan	CRLD
>A>	+		1MG	N21726	003	Jan 19, 2005	Jan	CRLD
>D>	+		2MG	N21726	004	Jan 19, 2005	Jan	CRLD
>A>			2MG	N21726	004	Jan 19, 2005	Jan	CRLD

AMINO ACIDS

INJECTABLE; INJECTION
NOVAMINE 11.4%

>D>		HOSPIRA	11.4% (11.4GM/100ML)	N17957	003	Aug 09, 1982	Jan	CRLD
>A>	+		11.4% (11.4GM/100ML)	N17957	003	Aug 09, 1982	Jan	CRLD

NOVAMINE 15%

>D>		HOSPIRA	15% (15GM/100ML)	N17957	004	Nov 28, 1986	Jan	CRLD
>A>	+		15% (15GM/100ML)	N17957	004	Nov 28, 1986	Jan	CRLD

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

>A>	AB	HIKMA PHARMS	250MG	N65291	001	Feb 05, 2007	Jan	NEWA
>A>	AB		500MG	N65291	002	Feb 05, 2007	Jan	NEWA

TABLET, FOR SUSPENSION; ORAL
AMOXICILLIN

>A>	AB		AUROBINDO PHARMA	200MG		N65324	001	Jan 17, 2007	Jan NEWA
>A>	AB			400MG		N65324	002	Jan 17, 2007	Jan NEWA

DISPERMOX

>D>			RANBAXY	200MG		N65080	002	Aug 11, 2003	Jan CTEC
>A>	AB			200MG		N65080	002	Aug 11, 2003	Jan CTEC
>D>		+		400MG		N65080	001	Aug 11, 2003	Jan CTEC
>A>	AB	+		400MG		N65080	001	Aug 11, 2003	Jan CTEC

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL
AMOXICILLIN AND CLAVULANATE POTASSIUM

>A>	AB		RANBAXY	600MG/5ML;EQ 42.9MG BASE/5ML		N65207	002	Jan 30, 2007	Jan NEWA

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
NORGESIC

>D>	AB		3M	385MG;30MG;25MG		N13416	003	Oct 27, 1982	Jan CAHN
>A>	AB		GRACEWAY	385MG;30MG;25MG		N13416	003	Oct 27, 1982	Jan CAHN

NORGESIC FORTE

>D>	AB	+	3M	770MG;60MG;50MG		N13416	004	Oct 27, 1982	Jan CAHN
>A>	AB	+	GRACEWAY	770MG;60MG;50MG		N13416	004	Oct 27, 1982	Jan CAHN

AZITHROMYCIN

INJECTABLE; INJECTION
AZITHROMYCIN

>A>	AP		PLIVA HRVATSKA DOO	EQ 500MG BASE/VIAL		N65265	001	Jan 18, 2007	Jan NEWA

>D> BUDESONIDE; FORMOTEROL FUMARATE

>D> SPRAY, METERED; INHALATION
>D> SYMBICORT

>D>			ASTRAZENECA	0.08MG/INH;EQ 0.045MG BASE		N21929	001	Jul 21, 2006	Jan CAIN
>D>		+		0.016MG/INH;EQ 0.045MG BASE		N21929	002	Jul 21, 2006	Jan CAIN

>A> BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE

>A> SPRAY, METERED; INHALATION
>A> SYMBICORT

>A>		+	ASTRAZENECA	0.08MG/INH;0.045MG/INH		N21929	001	Jul 21, 2006	Jan CAIN
>A>		+		0.16MG/INH;0.045MG/INH		N21929	002	Jul 21, 2006	Jan CAIN

CARBOPLATIN

INJECTABLE; IV (INFUSION)
CARBOPLATIN

>A>	AP		WATSON LABS	EQ 50MG/5ML (10MG/ML)		N77861	001	Jan 18, 2007	Jan NEWA
>A>	AP			EQ 150MG/15ML (10MG/ML)		N77861	002	Jan 18, 2007	Jan NEWA
>A>	AP			EQ 450MG/45ML (10MG/ML)		N77861	003	Jan 18, 2007	Jan NEWA
>A>	AP			EQ 600MG/60ML (10MG/ML)		N77861	004	Jan 18, 2007	Jan NEWA

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL
CEFADROXIL

>A>	AB		AUROBINDO PHARMA	500MG		N65352	001	Jan 25, 2007	Jan NEWA

CEFPROZIL

FOR SUSPENSION; ORAL

CEFPROZIL

>A>	AB	AUROBINDO PHARMA	125MG/5ML	N65381	001	Jan 30, 2007	Jan	NEWA
>A>	AB		250MG/5ML	N65381	002	Jan 30, 2007	Jan	NEWA

CELECOXIB

CAPSULE; ORAL

CELEBREX

>A>		GD SEARLE	50MG	N20998	004	Dec 15, 2006	Jan	NEWA

CLOBETASOL PROPIONATE

AEROSOL, FOAM; TOPICAL

OLUX E

>A>	+	CONNETICS	0.05%	N22013	001	Jan 12, 2007	Jan	NEWA

DEXMETHYLPHENIDATE HYDROCHLORIDE

TABLET; ORAL

DEXMETHYLPHENIDATE HYDROCHLORIDE

>A>	AB	TEVA PHARMS	2.5MG	N77107	003	Jan 29, 2007	Jan	NEWA
>A>	AB		5MG	N77107	001	Jan 29, 2007	Jan	NEWA
>A>	AB		10MG	N77107	002	Jan 29, 2007	Jan	NEWA

FOCALIN

>D>		NOVARTIS	2.5MG	N21278	001	Nov 13, 2001	Jan	CFTG
>A>	AB		2.5MG	N21278	001	Nov 13, 2001	Jan	CFTG
>D>			5MG	N21278	002	Nov 13, 2001	Jan	CFTG
>A>	AB		5MG	N21278	002	Nov 13, 2001	Jan	CFTG
>D>	+		10MG	N21278	003	Nov 13, 2001	Jan	CFTG
>A>	AB +		10MG	N21278	003	Nov 13, 2001	Jan	CFTG

>A> DICLOFENAC EPOLAMINE

>A> PATCH; TOPICAL

>A> FLECTOR

>A>	+	INST BIOCHEM	1.3%	N21234	001	Jan 31, 2007	Jan	NEWA

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

>A>	AB	MURTY PHARMS	25MG	N40733	001	Feb 13, 2007	Jan	NEWA
>A>	AB		50MG	N40733	002	Feb 13, 2007	Jan	NEWA
>A>	AB		75MG	N40733	003	Feb 13, 2007	Jan	NEWA

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

>D>		RANBAXY	EQ 75MG BASE	N65053	003	Sep 10, 2003	Jan	CTEC
>A>	AB		EQ 75MG BASE	N65053	003	Sep 10, 2003	Jan	CTEC

MONODOX

>A>	AB	OCLASSEN	EQ 75MG BASE	N50641	003	Oct 18, 2006	Jan	NEWA

EDETATE CALCIUM DISODIUM

INJECTABLE; INJECTION

CALCIUM DISODIUM VERSENATE

>D>	+	3M	200MG/ML	N08922	001		Jan	CAHN

INJECTABLE; INJECTION
CALCIUM DISODIUM VERSENATE

>A>		+	GRACEWAY	200MG/ML	N08922	001		Jan	CAHN

TABLET; ORAL
CALCIUM DISODIUM VERSENATE

>D>		@	3M	500MG	N08922	002		Jan	CAHN
>A>		@	GRACEWAY	500MG	N08922	002		Jan	CAHN

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL
ERGOMAR

>D>		+	HARVEST PHARMS	2MG	N87693	001	Feb 24, 1983	Jan	CAHN
>A>		+	ROSEDALE THERAPEUTIC	2MG	N87693	001	Feb 24, 1983	Jan	CAHN

ESTRADIOL

GEL, METERED; TRANSDERMAL
ELESTRIN

>D>	BX	+	BIOSANTE	0.06%	N21813	001	Dec 15, 2006	Jan	CAHN
>A>	BX	+	BRADLEY PHARMS	0.06%	N21813	001	Dec 15, 2006	Jan	CAHN

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET, CHEWABLE; ORAL-28
>D> OVCON-35

>D>		+	WARNER CHILCOTT	0.035MG;0.4MG	N21490	001	Nov 14, 2003	Jan	CTNA

>A> OVCON-35 FE

>A>		+	WARNER CHILCOTT	0.035MG;0.4MG	N21490	001	Nov 14, 2003	Jan	CTNA

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-21
>A> MICROGESTIN 1.5/30

>A>	AB		WATSON LABS	0.03MG;1.5MG	N75548	002	Jul 30, 2003	Jan	NEWA

>A> MICROGESTIN 1/20

>A>	AB		WATSON LABS	0.02MG;1MG	N75647	002	Jul 30, 2003	Jan	NEWA

FENOFIBRATE

TABLET; ORAL
TRIGLIDE

>D>			SKYEPHARMA	50MG	N21350	001	May 07, 2005	Jan	CAHN
>D>	BX			160MG	N21350	002	May 07, 2005	Jan	CAHN
>A>			SKYEPHARMA AG	50MG	N21350	001	May 07, 2005	Jan	CAHN
>A>	BX			160MG	N21350	002	May 07, 2005	Jan	CAHN

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL
DURAGESIC-12

>D>			ALZA	12.5UGM/HR	N19813	005	Feb 04, 2005	Jan	CFTG
>A>	AB			12.5UGM/HR	N19813	005	Feb 04, 2005	Jan	CFTG

>D> FENTANYL

>D>	AB		LAVIPHARM LABS	25UGM/HR	N77051	001	Aug 04, 2006	Jan	CTNA
>D>	AB			50UGM/HR	N77051	002	Aug 04, 2006	Jan	CTNA
>D>	AB			75UGM/HR	N77051	003	Aug 04, 2006	Jan	CTNA
>D>	AB			100UGM/HR	N77051	004	Aug 04, 2006	Jan	CTNA
>D>	AB		MYLAN TECHNOLOGIES	25UGM/HR	N76258	001	Jan 28, 2005	Jan	CTNA
>D>	AB			50UGM/HR	N76258	002	Jan 28, 2005	Jan	CTNA
>D>	AB			75UGM/HR	N76258	003	Jan 28, 2005	Jan	CTNA

FILM, EXTENDED RELEASE; TRANSDERMAL

FENTANYL

>D>	AB	MYLAN TECHNOLOGIES	100UGM/HR	N76258	004	Jan 28, 2005	Jan	CTNA

FENTANYL-100

>A>	AB	LAVIPHARM LABS	100UGM/HR	N77051	004	Aug 04, 2006	Jan	CTNA
>A>	AB	MYLAN TECHNOLOGIES	100UGM/HR	N76258	004	Jan 28, 2005	Jan	CTNA

FENTANYL-12

>A>	AB	MYLAN TECHNOLOGIES	12.5UGM/HR	N76258	005	Jan 23, 2007	Jan	NEWA

FENTANYL-25

>A>	AB	LAVIPHARM LABS	25UGM/HR	N77051	001	Aug 04, 2006	Jan	CTNA
>A>	AB	MYLAN TECHNOLOGIES	25UGM/HR	N76258	001	Jan 28, 2005	Jan	CTNA

FENTANYL-50

>A>	AB	LAVIPHARM LABS	50UGM/HR	N77051	002	Aug 04, 2006	Jan	CTNA
>A>	AB	MYLAN TECHNOLOGIES	50UGM/HR	N76258	002	Jan 28, 2005	Jan	CTNA

FENTANYL-75

>A>	AB	LAVIPHARM LABS	75UGM/HR	N77051	003	Aug 04, 2006	Jan	CTNA
>A>	AB	MYLAN TECHNOLOGIES	75UGM/HR	N76258	003	Jan 28, 2005	Jan	CTNA

FLECAINIDE ACETATE

TABLET; ORAL

TAMBOCOR

>D>	AB	3M	50MG	N18830	004	Aug 23, 1988	Jan	CAHN
>D>	AB		100MG	N18830	001	Oct 31, 1985	Jan	CAHN
>D>	AB	+	150MG	N18830	003	Jun 03, 1988	Jan	CAHN
>D>		@	200MG	N18830	002	Oct 31, 1985	Jan	CAHN
>A>	AB	GRACEWAY	50MG	N18830	004	Aug 23, 1988	Jan	CAHN
>A>	AB		100MG	N18830	001	Oct 31, 1985	Jan	CAHN
>A>	AB	+	150MG	N18830	003	Jun 03, 1988	Jan	CAHN
>A>		@	200MG	N18830	002	Oct 31, 1985	Jan	CAHN

FLUOXETINE HYDROCHLORIDE

SOLUTION; ORAL

FLUOXETINE HYDROCHLORIDE

>A>	AA	SILARX	EQ 20MG BASE/5ML	N77849	001	Feb 09, 2007	Jan	NEWA

FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION

FLUPHENAZINE DECANOATE

>D>	AO	BEDFORD	25MG/ML	N74531	001	Aug 30, 1996	Jan	CRLD
>A>	AO	+	25MG/ML	N74531	001	Aug 30, 1996	Jan	CRLD

PROLIXIN DECANOATE

>D>	AO	+ BRISTOL MYERS SQUIBB	25MG/ML	N16727	001		Jan	DISC
>A>		@	25MG/ML	N16727	001		Jan	DISC

FLUPHENAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

FLUPHENAZINE HYDROCHLORIDE

>D>	AP	ABRAXIS PHARM	2.5MG/ML	N89556	001	Apr 16, 1987	Jan	CRLD
>A>		+	2.5MG/ML	N89556	001	Apr 16, 1987	Jan	CRLD

PROLIXIN

>D>	AP	+ APOTHECON	2.5MG/ML	N11751	005		Jan	DISC
>A>		@	2.5MG/ML	N11751	005		Jan	DISC

TABLET; ORAL

PROLIXIN

>D>	AB	APOTHECON	1MG	N11751	004		Jan	DISC

TABLET; ORAL
PROLIXIN

>D>			@ APOTHECON	1MG	N11751	004		Jan	DISC
>D>	AB			2.5MG	N11751	001		Jan	DISC
>A>			@	2.5MG	N11751	001		Jan	DISC
>D>	AB			5MG	N11751	003		Jan	DISC
>A>			@	5MG	N11751	003		Jan	DISC
>D>	AB	+		10MG	N11751	002		Jan	DISC
>A>			@	10MG	N11751	002		Jan	DISC

FOLIC ACID

INJECTABLE; INJECTION
FOLIC ACID

>D>	AP	+	ABRAXIS PHARM	5MG/ML	N89202	001	Feb 18, 1986	Jan	CTEC
>A>		+		5MG/ML	N89202	001	Feb 18, 1986	Jan	CTEC
>A>			@ BEN VENUE	5MG/ML	N81066	001		Jan	DISC
>D>	AP		LOCH	5MG/ML	N81066	001	Dec 29, 1993	Jan	DISC

FORMOTEROL FUMARATE

POWDER; INHALATION
FORADIL CERTIHALER

>D>			NOVARTIS	EQ 0.0085MG BASE/INH	N21592	001	Dec 15, 2006	Jan	CRLD
>A>		+		0.0085MG/INH	N21592	001	Dec 15, 2006	Jan	CRLD

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

>A>	AB		MYLAN	12.5MG	N40770	001	Jan 23, 2007	Jan	NEWA
>A>	AB			25MG	N40735	002	Jan 23, 2007	Jan	NEWA
>A>	AB			50MG	N40735	003	Jan 23, 2007	Jan	NEWA

ILOPROST

SOLUTION; INHALATION
VENTAVIS

>A>		+	ACTELION	10UGM/ML (10UGM/ML)	N21779	002	Dec 08, 2005	Jan	CAHN
>A>		+		20UGM/2ML (10UGM/ML)	N21779	001	Dec 29, 2004	Jan	CAHN
>D>		+	COTHERIX	10UGM/ML (10UGM/ML)	N21779	002	Dec 08, 2005	Jan	CAHN
>D>		+		20UGM/2ML (10UGM/ML)	N21779	001	Dec 29, 2004	Jan	CAHN

IMIQUIMOD

CREAM; TOPICAL
ALDARA

>D>		+	3M	5%	N20723	001	Feb 27, 1997	Jan	CAHN
>A>		+	GRACEWAY	5%	N20723	001	Feb 27, 1997	Jan	CAHN

ISOSORBIDE DINITRATE

TABLET; ORAL
ISOSORBIDE DINITRATE

>A>	AB		WEST WARD	30MG	N40591	001	Jan 10, 2007	Jan	NEWA

LEUCOVORIN CALCIUM

TABLET; ORAL
LEUCOVORIN CALCIUM

>D>	AB		PHARMACHEMIE	EQ 5MG BASE	N73099	001	Mar 28, 1997	Jan	DISC
>A>			@	EQ 5MG BASE	N73099	001	Mar 28, 1997	Jan	DISC

TABLET; ORAL
LEUCOVORIN CALCIUM

>D>	AB		PHARMACHEMIE	EQ 25MG BASE	N73101	001	Mar 28, 1997	Jan	DISC
>A>			@	EQ 25MG BASE	N73101	001	Mar 28, 1997	Jan	DISC

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS
ELIGARD

>D>		+	QLT USA	7.5MG/VIAL	N21343	001	Jan 23, 2002	Jan	CAHN
>D>		+		22.5MG/VIAL	N21379	001	Jul 24, 2002	Jan	CAHN
>D>		+		30MG/VIAL	N21488	001	Feb 13, 2003	Jan	CAHN
>D>		+		45MG/VIAL	N21731	001	Dec 14, 2004	Jan	CAHN
>A>		+	SANOFI AVENTIS US	7.5MG/VIAL	N21343	001	Jan 23, 2002	Jan	CAHN
>A>		+		22.5MG/VIAL	N21379	001	Jul 24, 2002	Jan	CAHN
>A>		+		30MG/VIAL	N21488	001	Feb 13, 2003	Jan	CAHN
>A>		+		45MG/VIAL	N21731	001	Dec 14, 2004	Jan	CAHN

LIDOCAINE

>D> FILM, EXTENDED RELEASE; BUCCAL
>D> LIDOCAINE

>D>		+	NOVEN	46.1MG/PATCH	N20575	002	May 21, 1996	Jan	CDFR

>A> PATCH; TOPICAL
>A> LIDOCAINE

>A>		+	NOVEN	46.1MG/PATCH	N20575	002	May 21, 1996	Jan	CDFR

MAGNESIUM SULFATE

INJECTABLE; INJECTION
MAGNESIUM SULFATE IN PLASTIC CONTAINER

>A>			HOSPIRA	2GM/50ML (40MG/ML)	N20309	003	Jan 26, 2007	Jan	NEWA
>D>		+		80MG/ML	N20309	002	Jun 24, 1994	Jan	CPOT
>D>		+		4GM/100ML	N20309	001	Jun 24, 1994	Jan	CPOT
>A>		+		4GM/50ML (80MG/ML)	N20309	002	Jun 24, 1994	Jan	CPOT
>A>		+		4GM/100ML (40MG/ML)	N20309	001	Jun 24, 1994	Jan	CPOT

MESALAMINE

>A> TABLET, DELAYED RELEASE; ORAL
>A> LIALDA

>A>		+	SHIRE	1.2GM	N22000	001	Jan 16, 2007	Jan	NEWA

METFORMIN HYDROCHLORIDE

TABLET; ORAL
METFORMIN HYDROCHLORIDE

>A>	AB		TORRENT PHARMS	500MG	N77711	001	Jan 24, 2007	Jan	NEWA
>A>	AB			850MG	N77711	002	Jan 24, 2007	Jan	NEWA
>A>	AB			1GM	N77711	003	Jan 24, 2007	Jan	NEWA

METRONIDAZOLE

GEL; VAGINAL
METROGEL-VAGINAL

>D>	AB	+	3M	0.75%	N20208	001	Aug 17, 1992	Jan	CAHN
>A>	AB	+	GRACEWAY	0.75%	N20208	001	Aug 17, 1992	Jan	CAHN

MITOMYCIN

INJECTABLE; INJECTION

>A>			MITOZYTREX						
>A>		+	SUPERGEN	5MG/VIAL	N50763	001	Nov 14, 2002	Jan	CTNA
>D>			MYTOZYTREX						
>D>		+	SUPERGEN	5MG/VIAL	N50763	001	Nov 14, 2002	Jan	CTNA

NESIRITIDE RECOMBINANT

FOR SOLUTION; INTRAVENOUS

			NATRECOR						
>A>		+	ALZA CORP	1.5MG/VIAL	N20920	001	Aug 10, 2001	Jan	CAHN
>D>		+	SCIOS	1.5MG/VIAL	N20920	001	Aug 10, 2001	Jan	CAHN

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

			MINITRAN						
>D>	AB1		3M	0.1MG/HR	N89771	001	Aug 30, 1996	Jan	CAHN
>D>	AB1			0.2MG/HR	N89772	001	Aug 30, 1996	Jan	CAHN
>D>	AB1			0.4MG/HR	N89773	001	Aug 30, 1996	Jan	CAHN
>D>	AB1			0.6MG/HR	N89774	001	Aug 30, 1996	Jan	CAHN
>A>	AB1		GRACEWAY	0.1MG/HR	N89771	001	Aug 30, 1996	Jan	CAHN
>A>	AB1			0.2MG/HR	N89772	001	Aug 30, 1996	Jan	CAHN
>A>	AB1			0.4MG/HR	N89773	001	Aug 30, 1996	Jan	CAHN
>A>	AB1			0.6MG/HR	N89774	001	Aug 30, 1996	Jan	CAHN

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

			ONDANSETRON HYDROCHLORIDE						
>A>	AP		HOSPIRA	EQ 2MG BASE/ML	N77840	001	Jan 19, 2007	Jan	NEWA
			ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER						
>A>	AP		HOSPIRA	EQ 0.64MG BASE/ML	N77348	001	Feb 01, 2007	Jan	NEWA
>A>			ZOFRAN AND DEXTROSE IN PLASTIC CONTAINER						
>A>	AP	+	GLAXOSMITHKLINE	EQ 0.64MG BASE/ML	N20403	001	Jan 31, 1995	Jan	CTNA
>D>			ZOFRAN IN PLASTIC CONTAINER						
>D>	AP	+	GLAXOSMITHKLINE	EQ 0.64MG BASE/ML	N20403	001	Jan 31, 1995	Jan	CTNA

ORPHENADRINE CITRATE

INJECTABLE; INJECTION

			NORFLEX						
>D>	AP	+	3M	30MG/ML	N13055	001		Jan	CAHN
>A>	AP	+	GRACEWAY	30MG/ML	N13055	001		Jan	CAHN

TABLET, EXTENDED RELEASE; ORAL

			NORFLEX						
>D>			@ 3M	100MG	N12157	001		Jan	CAHN
>A>			@ GRACEWAY	100MG	N12157	001		Jan	CAHN

OXYCODONE HYDROCHLORIDE

TABLET; ORAL

			OXYCODONE HYDROCHLORIDE						
>A>	AB		VINTAGE PHARMS	15MG	N77712	001	Jan 31, 2007	Jan	NEWA
>A>	AB			30MG	N77712	002	Jan 31, 2007	Jan	NEWA

PERGOLIDE MESYLATE

TABLET; ORAL

PERMAX

>D>	AB		VALEANT	EQ 0.05MG BASE	N19385	001	Dec 30, 1988	Jan	CAHN
>D>	AB	+		EQ 0.25MG BASE	N19385	002	Dec 30, 1988	Jan	CAHN
>D>	AB			EQ 1MG BASE	N19385	003	Dec 30, 1988	Jan	CAHN
>A>	AB		VALEANT PHARM INTL	EQ 0.05MG BASE	N19385	001	Dec 30, 1988	Jan	CAHN
>A>	AB	+		EQ 0.25MG BASE	N19385	002	Dec 30, 1988	Jan	CAHN
>A>	AB			EQ 1MG BASE	N19385	003	Dec 30, 1988	Jan	CAHN

PIRBUTEROL ACETATE

AEROSOL, METERED; INHALATION

MAXAIR

>D>			@ 3M	EQ 0.2MG BASE/INH	N19009	001	Dec 30, 1986	Jan	CAHN
>D>		+		EQ 0.2MG BASE/INH	N20014	001	Nov 30, 1992	Jan	CAHN
>A>			@ GRACEWAY	EQ 0.2MG BASE/INH	N19009	001	Dec 30, 1986	Jan	CAHN
>A>		+		EQ 0.2MG BASE/INH	N20014	001	Nov 30, 1992	Jan	CAHN

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL

POLYETHYLENE GLYCOL 3350

>A>	AA		ANABOLIC LABS	17GM/SCOOPFUL	N77706	001	Sep 27, 2006	Jan	CAHN
>D>	AA		YVR THERAP	17GM/SCOOPFUL	N77706	001	Sep 27, 2006	Jan	CAHN

PROCAINAMIDE HYDROCHLORIDE

>D>			CAPSULE; ORAL						
>D>			PROCAINAMIDE HYDROCHLORIDE						
>D>	AB		IVAX PHARMS	250MG	N84604	001		Jan	DISC
>A>			@	250MG	N84604	001		Jan	DISC
>D>	AB			375MG	N84595	001		Jan	DISC
>A>			@	375MG	N84595	001		Jan	DISC
>D>	AB			500MG	N84606	001		Jan	DISC
>A>			@	500MG	N84606	001		Jan	DISC
>D>	AB		WATSON LABS	250MG	N83287	001		Jan	DISC
>A>			@	250MG	N83287	001		Jan	DISC
>D>	AB			375MG	N84403	001		Jan	DISC
>A>			@	375MG	N84403	001		Jan	DISC
>D>	AB			500MG	N84280	001		Jan	DISC
>A>			@	500MG	N84280	001		Jan	DISC
>D>			PRONESTYL						
>D>	AB		APOTHECON	250MG	N07335	001		Jan	DISC
>A>			@	250MG	N07335	001		Jan	DISC
>D>	AB			375MG	N07335	004		Jan	DISC
>A>			@	375MG	N07335	004		Jan	DISC
>D>	AB	+		500MG	N07335	003		Jan	DISC
>A>			@	500MG	N07335	003		Jan	DISC
			TABLET, EXTENDED RELEASE; ORAL						
>D>			PRONESTYL-SR						
>D>	BC		APOTHECON	500MG	N87361	001		Jan	DISC
>A>			@	500MG	N87361	001		Jan	DISC

PROCHLORPERAZINE MALEATE

>D>		CAPSULE, EXTENDED RELEASE; ORAL							
>D>		COMPAZINE							
>D>	+	GLAXOSMITHKLINE	EQ 15MG BASE	N21019	002	Oct 06, 1999	Jan	DISC	
>A>		@	EQ 15MG BASE	N21019	002	Oct 06, 1999	Jan	DISC	

PROPRANOLOL HYDROCHLORIDE

		CAPSULE, EXTENDED RELEASE; ORAL							
		INDERAL LA							
>D>		WYETH PHARMS INC	60MG	N18553	004	Mar 18, 1987	Jan	CTEC	
>A>	AB		60MG	N18553	004	Mar 18, 1987	Jan	CTEC	
>D>	BX		80MG	N18553	002	Apr 19, 1983	Jan	CTEC	
>A>	AB		80MG	N18553	002	Apr 19, 1983	Jan	CTEC	
>D>	BX		120MG	N18553	003	Apr 19, 1983	Jan	CTEC	
>A>	AB		120MG	N18553	003	Apr 19, 1983	Jan	CTEC	
>D>	+		160MG	N18553	001	Apr 19, 1983	Jan	CTEC	
>A>	AB +		160MG	N18553	001	Apr 19, 1983	Jan	CTEC	
>A>		PROPRANOLOL HYDROCHLORIDE							
>A>	AB	PAR PHARM	60MG	N78065	001	Jan 26, 2007	Jan	NEWA	
>A>	AB		80MG	N78065	002	Jan 26, 2007	Jan	NEWA	
>A>	AB		120MG	N78065	003	Jan 26, 2007	Jan	NEWA	
>A>	AB		160MG	N78065	004	Jan 26, 2007	Jan	NEWA	
		TABLET; ORAL							
		INDERAL							
>D>	AB	WYETH PHARMS INC	10MG	N16418	001		Jan	DISC	
>A>		@	10MG	N16418	001		Jan	DISC	
>D>	AB		20MG	N16418	003		Jan	DISC	
>A>		@	20MG	N16418	003		Jan	DISC	

PYRIDOXINE HYDROCHLORIDE

		INJECTABLE; INJECTION							
		PYRIDOXINE HYDROCHLORIDE							
>D>	AP	ABRAXIS PHARM	100MG/ML	N80618	001		Jan	CRLD	
>A>	+		100MG/ML	N80618	001		Jan	CRLD	
>D>	AP +	WATSON LABS	100MG/ML	N80572	001		Jan	DISC	
>A>		@	100MG/ML	N80572	001		Jan	DISC	

RAMIPRIL

		CAPSULE; ORAL							
		ALTACE							
>D>	AB	KING PHARMS	1.25MG	N19901	001	Jan 28, 1991	Jan	CTEC	
>A>			1.25MG	N19901	001	Jan 28, 1991	Jan	CTEC	
>D>	AB		2.5MG	N19901	002	Jan 28, 1991	Jan	CTEC	
>A>			2.5MG	N19901	002	Jan 28, 1991	Jan	CTEC	
>D>	AB		5MG	N19901	003	Jan 28, 1991	Jan	CTEC	
>A>			5MG	N19901	003	Jan 28, 1991	Jan	CTEC	
>D>	AB +		10MG	N19901	004	Jan 28, 1991	Jan	CTEC	
>A>	+		10MG	N19901	004	Jan 28, 1991	Jan	CTEC	
>D>		RAMIPRIL							
>D>	AB	COBALT	1.25MG	N76549	001	Oct 24, 2005	Jan	DISC	
>A>		@	1.25MG	N76549	001	Oct 24, 2005	Jan	DISC	
>D>	AB		2.5MG	N76549	002	Oct 24, 2005	Jan	DISC	
>A>		@	2.5MG	N76549	002	Oct 24, 2005	Jan	DISC	
>D>	AB		5MG	N76549	003	Oct 24, 2005	Jan	DISC	
>A>		@	5MG	N76549	003	Oct 24, 2005	Jan	DISC	

CAPSULE; ORAL

>D>		RAMIPRIL						
>D>	AB	COBALT	10MG	N76549	004	Oct 24, 2005	Jan	DISC
>A>		@	10MG	N76549	004	Oct 24, 2005	Jan	DISC

SERTRALINE HYDROCHLORIDE

CONCENTRATE; ORAL

SERTRALINE HYDROCHLORIDE

>A>	AB	RANBAXY	EQ 20MG BASE/ML	N78053	001	Feb 05, 2007	Jan	NEWA

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

>A>	AB	ACTAVIS ELIZABETH	EQ 25MG BASE	N77345	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77345	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77345	003	Feb 06, 2007	Jan	NEWA
>A>	AB	APOTEX INC	EQ 25MG BASE	N76882	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N76882	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N76882	003	Feb 06, 2007	Jan	NEWA
>A>	AB	AUROBINDO PHARMA	EQ 25MG BASE	N77206	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77206	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77206	003	Feb 06, 2007	Jan	NEWA
>A>	AB	COBALT	EQ 25MG BASE	N77663	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77663	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77663	003	Feb 06, 2007	Jan	NEWA
>A>	AB	INVAGEN PHARMS	EQ 25MG BASE	N77397	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77397	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77397	003	Feb 06, 2007	Jan	NEWA
>A>	AB	LUPIN	EQ 25MG BASE	N77670	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77670	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77670	003	Feb 06, 2007	Jan	NEWA
>A>	AB	MUTUAL PHARM	EQ 25MG BASE	N77818	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77818	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77818	003	Feb 06, 2007	Jan	NEWA
>A>	AB	MYLAN	EQ 25MG BASE	N76671	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N76671	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N76671	003	Feb 06, 2007	Jan	NEWA
>A>	AB	PLIVA HRVATSKA DOO	EQ 25MG BASE	N77299	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77299	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77299	003	Feb 06, 2007	Jan	NEWA
>A>	AB	RANBAXY	EQ 25MG BASE	N77977	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77977	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77977	003	Feb 06, 2007	Jan	NEWA
>A>			EQ 150MG BASE	N77977	004	Feb 06, 2007	Jan	NEWA
>A>			EQ 200MG BASE	N77977	005	Feb 06, 2007	Jan	NEWA
>A>	AB	ROXANE	EQ 25MG BASE	N76881	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N76881	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N76881	003	Feb 06, 2007	Jan	NEWA
>A>	AB	SANDOZ	EQ 25MG BASE	N77713	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77713	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77713	003	Feb 06, 2007	Jan	NEWA
>A>	AB	SUN PHARM INDS (IN)	EQ 25MG BASE	N78108	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N78108	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N78108	003	Feb 06, 2007	Jan	NEWA
>A>	AB	TORRENT PHARMS	EQ 25MG BASE	N77765	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77765	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77765	003	Feb 06, 2007	Jan	NEWA
>A>	AB	WATSON LABS	EQ 25MG BASE	N77162	001	Feb 06, 2007	Jan	NEWA

TABLET; ORAL
SERTRALINE HYDROCHLORIDE

>A>	AB	WATSON LABS	EQ 50MG BASE	N77162	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77162	003	Feb 06, 2007	Jan	NEWA
>A>	AB	ZYDUS PHARMS USA	EQ 25MG BASE	N77106	001	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 50MG BASE	N77106	002	Feb 06, 2007	Jan	NEWA
>A>	AB		EQ 100MG BASE	N77106	003	Feb 06, 2007	Jan	NEWA

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION
SAIZEN

>A>	BX	SERONO	4MG/VIAL	N19764	005	Jan 16, 2007	Jan	NEWA

SOTALOL HYDROCHLORIDE

TABLET; ORAL
SOTALOL HYDROCHLORIDE

>A>	AB2	MYLAN	80MG	N77616	001	Feb 07, 2007	Jan	NEWA
>A>	AB2		120MG	N77616	002	Feb 07, 2007	Jan	NEWA
>A>	AB2		160MG	N77616	003	Feb 07, 2007	Jan	NEWA

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

>A>	AB	VINTAGE	200MG/5ML;40MG/5ML	N77785	001	Jan 24, 2007	Jan	NEWA

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

>A>	AB	VINTAGE	400MG;80MG	N78060	002	Jan 25, 2007	Jan	NEWA
>A>	AB		800MG;160MG	N78060	001	Jan 25, 2007	Jan	NEWA

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
>D> DRAXIMAGE MDP

>D>	AP +	DRAXIMAGE	N/A	N18035	001		Jan	CTNA

>A> DRAXIMAGE MDP-10

>A>	AP +	DRAXIMAGE	N/A	N18035	001		Jan	CTNA

DRAXIMAGE MDP-25

>A>	+	DRAXIMAGE	N/A	N18035	002	Feb 27, 2004	Jan	NEWA

THALIDOMIDE

CAPSULE; ORAL
THALOMID

>A>		CELGENE	150MG	N20785	004	Jan 10, 2007	Jan	NEWA

TOLCAPONE

TABLET; ORAL
TASMAR

>D>		VALEANT	100MG	N20697	001	Jan 29, 1998	Jan	CAHN
>D>	+		200MG	N20697	002	Jan 29, 1998	Jan	CAHN
>A>		VALEANT PHARM INTL	100MG	N20697	001	Jan 29, 1998	Jan	CAHN
>A>	+		200MG	N20697	002	Jan 29, 1998	Jan	CAHN

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL
>A> VALACYCLOVIR HYDROCHLORIDE

>A>	AB	RANBAXY	EQ 500MG BASE	N76588	001	Jan 31, 2007	Jan	NEWA

		TABLET; ORAL							
>A>		VALACYCLOVIR HYDROCHLORIDE							
>A>	AB	RANBAXY	EQ 1GM BASE	N76588	002	Jan 31, 2007	Jan	NEWA	
		VALTREX							
>D>		GLAXOSMITHKLINE	EQ 500MG BASE	N20487	001	Jun 23, 1995	Jan	CFTG	
>A>	AB		EQ 500MG BASE	N20487	001	Jun 23, 1995	Jan	CFTG	
>D>		+	EQ 1GM BASE	N20487	002	Jun 23, 1995	Jan	CFTG	
>A>	AB	+	EQ 1GM BASE	N20487	002	Jun 23, 1995	Jan	CFTG	

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SPONGE; TOPICAL

CHLORAPREP ONE-STEP

>A>	+	ENTURIA INC	2%;70% (26ML)	N20832	006	Nov 21, 2006	Jan	CAHN
>A>	+		2%;70% (3ML)	N20832	001	Jul 14, 2000	Jan	CAHN
>A>	+		2%;70% (10.5ML)	N20832	004	Aug 20, 2003	Jan	CAHN
>D>	+	MEDI FLEX INC	2%;70% (26ML)	N20832	006	Nov 21, 2006	Jan	CAHN
>D>	+		2%;70% (10.5ML)	N20832	004	Aug 20, 2003	Jan	CAHN
>D>	+		2%;70% (3ML)	N20832	001	Jul 14, 2000	Jan	CAHN

CHLORAPREP ONE-STEP FREPP

>A>	+	ENTURIA INC	2%;70% (1.5ML)	N20832	003	Apr 26, 2002	Jan	CAHN
>D>	+	MEDI FLEX INC	2%;70% (1.5ML)	N20832	003	Apr 26, 2002	Jan	CAHN

CHLORAPREP WITH TINT

>A>	+	ENTURIA INC	2%;70% (26ML)	N20832	002	May 03, 2005	Jan	CAHN
>A>	+		2%;70% (10.5ML)	N20832	005	Apr 03, 2006	Jan	CAHN
>D>	+	MEDI FLEX INC	2%;70% (10.5ML)	N20832	005	Apr 03, 2006	Jan	CAHN
>D>	+		2%;70% (26ML)	N20832	002	May 03, 2005	Jan	CAHN

SWAB; TOPICAL

CHLORAPREP ONE-STEP SEPP

>A>	+	ENTURIA INC	2%;70% (0.67ML)	N21555	001	Oct 07, 2002	Jan	CAHN
>D>	+	MEDI FLEX INC	2%;70% (0.67ML)	N21555	001	Oct 07, 2002	Jan	CAHN

CHLORAPREP SINGLE SWABSTICK

>A>	+	ENTURIA INC	2%;70% (1.75ML)	N21555	002	May 10, 2005	Jan	CAHN
>D>	+	MEDI FLEX INC	2%;70% (1.75ML)	N21555	002	May 10, 2005	Jan	CAHN

DOXYLAMINE SUCCINATE

TABLET; ORAL

UNISOM

>A>	+	MCNEIL CONS	25MG	N18066	001		Jan	CAHN
>D>	+	PFIZER	25MG	N18066	001		Jan	CAHN

>A> IBUPROFEN

>A> CAPSULE; ORAL

>A> ADVIL LIQUI-GELS

>A>	+	WYETH CONS	EQ 200MG FREE ACID AND POTASSIUM SALT	N20402	001	Apr 20, 1995	Jan	CAIN

>A> ADVIL MIGRAINE LIQUI-GELS

>A>	+	WYETH CONS	EQ 200MG FREE ACID AND POTASSIUM SALT	N20402	002	Mar 16, 2000	Jan	CAIN

>D> IBUPROFEN POTASSIUM

>D> CAPSULE; ORAL

>D> ADVIL LIQUI-GELS

>D>	+	WYETH CONS	200MG	N20402	001	Apr 20, 1995	Jan	CAIN

>D> ADVIL MIGRAINE LIQUI-GELS

>D>	+	WYETH CONS	200MG	N20402	002	Mar 16, 2000	Jan	CAIN

KETOTIFEN FUMARATE

SOLUTION/DROPS; OPHTHALMIC

ALAWAY

>D>	+	ALIMERA SCIENCES INC	EQ 0.025% BASE	N21996	001	Dec 01, 2006	Jan	CAHN
>A>	+	BAUSCH AND LOMB	EQ 0.025% BASE	N21996	001	Dec 01, 2006	Jan	CAHN

LOPERAMIDE HYDROCHLORIDE

TABLET, CHEWABLE; ORAL

>D>		IMODIUM A-D							
>D>	+	MCNEIL	2MG	N20448	001	Jul 24, 1997	Jan	CTNA	
>A>		IMODIUM A-D EZ CHEWS							
>A>	+	MCNEIL	2MG	N20448	001	Jul 24, 1997	Jan	CTNA	

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

		ZANTAC 150							
>A>	+	BOEHRINGER INGELHEIM	EQ 150MG BASE	N21698	001	Aug 31, 2004	Jan	CAHN	
>D>	+	MCNEIL CONS	EQ 150MG BASE	N21698	001	Aug 31, 2004	Jan	CAHN	
		ZANTAC 75							
>A>		BOEHRINGER INGELHEIM	EQ 75MG BASE	N20520	001	Dec 19, 1995	Jan	CAHN	
>D>		MCNEIL CONS	EQ 75MG BASE	N20520	001	Dec 19, 1995	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 2007

NO JANUARY 2007 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 2007 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

See report footnotes for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE		PATENT CODES		EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ALBUTEROL SULFATE - VENTOLIN HFA							
020983 001	**>A>** 6558651	Dec 19, 2016		DP			
	>A> 6743413	Jun 01, 2021		DP	U-716		
ANIDULAFUNGIN - ERAXIS							
021632 002	**>A>** 5965525	Oct 12, 2016	DS	DP	U-540		
	>A> 6384013	Mar 19, 2012	DS				
	>A> 6743777	Mar 19, 2012		DP	U-540		
	>A> 6960564	Apr 12, 2021		DP	U-540		
BALSALAZIDE DISODIUM - COLAZAL							
020610 001						**>A>** ODE	Dec 20, 2013
BUDESONIDE - PULMICORT RESPULES							
020929 001	**>A>** 6899099	Dec 23, 2018			U-645		
BUDESONIDE - PULMICORT RESPULES							
020929 002	**>A>** 6899099	Dec 23, 2018			U-645		
BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE							
077284 002						**>A>** PC	Jun 12, 2007
BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE							
077415 002						**>A>** PC	Jun 12, 2007
CELECOXIB - CELEBREX							
020998 004						**>A>** I-466	Jul 29, 2008
						>A> NPP	Dec 15, 2009
						>A> PED	Jun 15, 2010
						>A> PED	Jan 29, 2009
CICLESONIDE - OMNARIS							
022004 001	**>A>** 5482934	Jan 09, 2013	DS	DP	U-557		
	>A> 6767901	Oct 21, 2020		DP			
	>A> 6939559	Apr 21, 2019		DP			
COLESTIPOL HYDROCHLORIDE - COLESTIPOL HYDROCHLORIDE							
077510 001						**>A>** PC	Jun 12, 2007
DECITABINE - DACOGEN							
021790 001						**>A>** ODE	May 02, 2013
DICLOFENAC EPOLAMINE - FLECTOR							
021234 001						**>A>** NE	Jan 31, 2010
						>A> NDF	Jan 31, 2007
DROSPIRENONE; ETHINYL ESTRADIOL - YAZ							
021676 001						**>A>** I-522	Jan 26, 2010
EMTRICITABINE - EMTRIVA							
021500 001	**>A>** 5210085	May 11, 2010			U-257		
	>A> 5814639	Sep 29, 2015	DS	DP			
	>A> 5914331	Sep 29, 2015	DS				
EPLERENONE - INSPRA							
021437 001	**>A>** 7157101	Dec 08, 2019		DP	U-664		
EPLERENONE - INSPRA							
021437 002	**>A>** 7157101	Dec 08, 2019		DP	U-664		
EPLERENONE - INSPRA							
021437 003	**>A>** 7157101	Dec 08, 2019		DP	U-664		
ESTRADIOL; NORETHINDRONE ACETATE - ACTIVELLA							
020907 002						**>A>** D-104	Dec 28, 2009
FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX							
021520 002	**>A>** 5229382	Apr 23, 2011	DS	DP		**>A>** NC	Dec 24, 2006
	>A> 5229382*PED	Oct 23, 2011				**>A>** PED	Jun 24, 2007
	>A> 5945416	Mar 24, 2017	DS	DP			
FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX							
021520 003	**>A>** 5229382	Apr 23, 2011	DS	DP		**>A>** NC	Dec 24, 2006
	>A> 5229382*PED	Oct 23, 2011				**>A>** PED	Jun 24, 2007
	>A> 5945416	Mar 24, 2017	DS	DP			

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FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX					
021520 004	**>A>** 5229382	Apr 23, 2011	DS DP	**>A>** NC	Dec 24, 2006
	>A> 5229382*PED	Oct 23, 2011		**>A>** PED	Jun 24, 2007
	>A> 5945416	Mar 24, 2017	DS DP		
FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX					
021520 005	**>A>** 5229382	Apr 23, 2011	DS DP	**>A>** NC	Dec 24, 2006
	>A> 5229382*PED	Oct 23, 2011		**>A>** PED	Jun 24, 2007
	>A> 5945416	Mar 24, 2017	DS DP		
FORMOTEROL FUMARATE - FORADIL CERTIHALER					
021592 001	**>A>** 6182655	Dec 05, 2016	DP		
	>A> 6645466	Nov 10, 2019	DP		
GALANTAMINE HYDROBROMIDE - RAZADYNE ER					
021615 001	**>A>** 7160559	Dec 20, 2019	DP		
GALANTAMINE HYDROBROMIDE - RAZADYNE ER					
021615 002	**>A>** 7160559	Dec 20, 2019	DP		
GALANTAMINE HYDROBROMIDE - RAZADYNE ER					
021615 003	**>A>** 7160559	Dec 20, 2019	DP		
HYDROCHLOROTHIAZIDE; VALSARTAN - DIOVAN HCT					
020818 004	**>A>** 5399578	Mar 21, 2012	DS DP	U-3	
	>A> 6294197	Jun 18, 2017	DP	U-3	
HYDROCHLOROTHIAZIDE; VALSARTAN - DIOVAN HCT					
020818 005	**>A>** 5399578	Mar 21, 2012	DS DP	U-3	
	>A> 6294197	Jun 18, 2017	DP	U-3	
HYDROXOCOBALAMIN - CYANOKIT					
022041 002	**>A>** 5834448	Nov 14, 2016	DP	U-789 **>A>** ODE	Dec 15, 2013
IMATINIB MESYLATE - GLEEVEC					
021335 001	**>A>** 6958335	Dec 19, 2021		U-791	
	>A> 6958335*PED	Jun 19, 2022			
IMATINIB MESYLATE - GLEEVEC					
021335 002	**>A>** 6958335	Dec 19, 2021		U-791	
	>A> 6958335*PED	Jun 19, 2022			
IMATINIB MESYLATE - GLEEVEC					
021588 001	**>A>** 6958335	Dec 19, 2021		U-791	
	>A> 6958335*PED	Jun 19, 2022			
IMATINIB MESYLATE - GLEEVEC					
021588 002	**>A>** 6958335	Dec 19, 2021		U-791	
	>A> 6958335*PED	Jun 19, 2022			
LAMOTRIGINE - LAMICTAL					
020241 001	**>A>** 4602017	Jul 22, 2008		U-106 **>A>** I-516	Sep 22, 2009
	>A> 4602017*PED	Jan 22, 2009		**>A>** PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL					
020241 002	**>A>** 4602017	Jul 22, 2008		U-106 **>A>** I-516	Sep 22, 2009
	>A> 4602017*PED	Jan 22, 2009		**>A>** PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL					
020241 003	**>A>** 4602017	Jul 22, 2008		U-106 **>A>** I-516	Sep 22, 2009
	>A> 4602017*PED	Jan 22, 2009		**>A>** PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL					
020241 004	**>A>** 4602017	Jul 22, 2008		U-106 **>A>** I-516	Sep 22, 2009
	>A> 4602017*PED	Jan 22, 2009		**>A>** PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL					
020241 005	**>A>** 4602017	Jul 22, 2008		U-106 **>A>** I-516	Sep 22, 2009
	>A> 4602017*PED	Jan 22, 2009		**>A>** PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL					
020241 006	**>A>** 4602017	Jul 22, 2008		U-106 **>A>** I-516	Sep 22, 2009
	>A> 4602017*PED	Jan 22, 2009		**>A>** PED	Mar 22, 2010

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

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LAMOTRIGINE - LAMICTAL CD					
020764 001	**>A>** 4602017	Jul 22, 2008	U-106	**>A>** I-516	Sep 22, 2009
	>A> 4602017*PED	Jan 22, 2009		**>A>** PED	Mar 22, 2010
	>A> 5698226	Jan 29, 2012			
	>A> 5698226*PED	Jul 29, 2012			
LAMOTRIGINE - LAMICTAL CD					
020764 002	**>A>** 4602017	Jul 22, 2008	U-106	**>A>** I-516	Sep 22, 2009
	>A> 4602017*PED	Jan 22, 2009		**>A>** PED	Mar 22, 2010
	>A> 5698226	Jan 29, 2012			
	>A> 5698226*PED	Jul 29, 2012			
LAMOTRIGINE - LAMICTAL CD					
020764 003	**>A>** 4602017	Jul 22, 2008	U-106	**>A>** I-516	Sep 22, 2009
	>A> 4602017*PED	Jan 22, 2009		**>A>** PED	Mar 22, 2010
	>A> 5698226	Jan 29, 2012			
	>A> 5698226*PED	Jul 29, 2012			
LAMOTRIGINE - LAMICTAL CD					
020764 004	**>A>** 4602017	Jul 22, 2008	U-106	**>A>** I-516	Sep 22, 2009
	>A> 4602017*PED	Jan 22, 2009		**>A>** PED	Mar 22, 2010
	>A> 5698226	Jan 29, 2012			
	>A> 5698226*PED	Jul 29, 2012			
LATANOPROST - XALATAN					
020597 001	**>A>** 7163959	Jun 19, 2010	DS		
LOPERAMIDE HYDROCHLORIDE - IMODIUM A-D EZ CHEWS					
020448 001	**>A>** 5489436	Feb 06, 2013	DP		
	>A> 6814978	Aug 26, 2021	DP		
LOPINAVIR; RITONAVIR - KALETRA					
021251 001	**>A>** 5914332	Dec 13, 2015	U-351		
LOPINAVIR; RITONAVIR - KALETRA					
021906 001	**>A>** 7148359	Jul 19, 2019	DP		
MESALAMINE - LIALDA					
022000 001				**>A>** NP	Jan 16, 2010
METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET					
021410 001				**>A>** M-62	Jan 31, 2010
METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET					
021410 002				**>A>** M-62	Jan 31, 2010
METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET					
021410 003				**>A>** M-62	Jan 31, 2010
METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET					
021410 004				**>A>** M-62	Jan 31, 2010
METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET					
021410 005				**>A>** M-62	Jan 31, 2010
MOXIFLOXACIN HYDROCHLORIDE - VIGAMOX					
021598 001	**>A>** 6716830	Sep 29, 2019	DP		
OLANZAPINE - ZYPREXA					
020592 001	**>A>** 5229382	Apr 23, 2011	DS DP U-547	**>A>** I-417	Jan 14, 2007
	>A> 5229382	Apr 23, 2011	DS DP U-149	**>A>** PED	Jul 14, 2007
	>A> 5229382*PED	Oct 23, 2011			
OLANZAPINE - ZYPREXA					
020592 002	**>A>** 5229382	Apr 23, 2011	DS DP U-547	**>A>** I-417	Jan 14, 2007
	>A> 5229382	Apr 23, 2011	DS DP U-149	**>A>** PED	Jul 14, 2007
	>A> 5229382*PED	Oct 23, 2011			
OLANZAPINE - ZYPREXA					
020592 003	**>A>** 5229382	Apr 23, 2011	DS DP U-547	**>A>** I-417	Jan 14, 2007
	>A> 5229382	Apr 23, 2011	DS DP U-149	**>A>** PED	Jul 14, 2007
	>A> 5229382*PED	Oct 23, 2011			

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

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APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
OLANZAPINE - ZYPREXA					
020592 004	**>A>** 5229382	Apr 23, 2011	DS DP U-547	**>A>** I-417	Jan 14, 2007
	>A> 5229382	Apr 23, 2011	DS DP U-149	**>A>** PED	Jul 14, 2007
	>A> 5229382*PED	Oct 23, 2011			
OLANZAPINE - ZYPREXA					
020592 005	**>A>** 5229382	Apr 23, 2011	DS DP U-547	**>A>** I-417	Jan 14, 2007
	>A> 5229382	Apr 23, 2011	DS DP U-149	**>A>** PED	Jul 14, 2007
	>A> 5229382*PED	Oct 23, 2011			
OLANZAPINE - ZYPREXA					
020592 006	**>A>** 5229382	Apr 23, 2011	DS DP U-547	**>A>** I-417	Jan 14, 2007
	>A> 5229382	Apr 23, 2011	DS DP U-149	**>A>** PED	Jul 14, 2007
	>A> 5229382*PED	Oct 23, 2011			
OLANZAPINE - ZYPREXA					
021253 001	**>A>** 5229382	Apr 23, 2011	DS DP U-571	**>A>** NP	Mar 29, 2007
	>A> 5229382*PED	Oct 23, 2011		**>A>** NDF	Mar 29, 2007
				>A> PED	Sep 29, 2007
				>A> PED	Sep 29, 2007
OLANZAPINE - ZYPREXA ZYDIS					
021086 001	**>A>** 5229382	Apr 23, 2011	U-324	**>A>** I-400	Jul 10, 2006
	>A> 5229382*PED	Oct 23, 2011		**>A>** I-417	Jan 14, 2007
				>A> PED	Jan 10, 2007
				>A> PED	Jul 14, 2007
OLANZAPINE - ZYPREXA ZYDIS					
021086 002	**>A>** 5229382	Apr 23, 2011	U-324	**>A>** I-400	Jul 10, 2006
	>A> 5229382*PED	Oct 23, 2011		**>A>** I-417	Jan 14, 2007
				>A> PED	Jan 10, 2007
				>A> PED	Jul 14, 2007
OLANZAPINE - ZYPREXA ZYDIS					
021086 003	**>A>** 5229382	Apr 23, 2011	U-324	**>A>** I-400	Jul 10, 2006
	>A> 5229382*PED	Oct 23, 2011		**>A>** I-417	Jan 14, 2007
				>A> PED	Jan 10, 2007
				>A> PED	Jul 14, 2007
OLANZAPINE - ZYPREXA ZYDIS					
021086 004	**>A>** 5229382	Apr 23, 2011	U-324	**>A>** I-400	Jul 10, 2006
	>A> 5229382*PED	Oct 23, 2011		**>A>** I-417	Jan 14, 2007
				>A> PED	Jan 10, 2007
				>A> PED	Jul 14, 2007
ONDANSETRON - ONDANSETRON					
076506 001				**>A>** PC	Jun 24, 2007
ONDANSETRON - ONDANSETRON					
076506 002				**>A>** PC	Jun 24, 2007
ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE					
076183 001				**>A>** PC	Jun 24, 2007
ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE					
076183 002				**>A>** PC	Jun 24, 2007
ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE					
076183 003				**>A>** PC	Jun 24, 2007
OXALIPLATIN - ELOXATIN					
021492 001				**>A>** M-61	Jan 10, 2010
				>A> PED	Jul 10, 2010
OXALIPLATIN - ELOXATIN					
021492 002				**>A>** M-61	Jan 10, 2010
				>A> PED	Jul 10, 2010
OXALIPLATIN - ELOXATIN					
021759 001	**>A>** 5420319	Aug 09, 2016	DS		
	>A> 5420319*PED	Feb 09, 2017			
OXALIPLATIN - ELOXATIN					
021759 002	**>A>** 5420319	Aug 09, 2016	DS		
	>A> 5420319*PED	Feb 09, 2017			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY LIST

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APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
OXALIPLATIN - ELOXATIN					
021759 003	**>A>** 5290961	Jan 12, 2013	DS		
	>A> 5290961*PED	Jul 12, 2013			
	>A> 5338874	Apr 07, 2013	DS		
	>A> 5338874*PED	Oct 07, 2013			
	>A> 5420319	Aug 09, 2016	DS		
	>A> 5420319*PED	Feb 09, 2017			
	>A> 5716988	Aug 07, 2015	DP		
	>A> 5716988*PED	Feb 07, 2016			
PALIPERIDONE - INVEGA					
021999 001	**>A>** 5158952	Oct 27, 2009	DP U-90		
PALIPERIDONE - INVEGA					
021999 002	**>A>** 5158952	Oct 27, 2009	DP U-90		
PALIPERIDONE - INVEGA					
021999 003	**>A>** 5158952	Oct 27, 2009	DP U-90		
PALIPERIDONE - INVEGA					
021999 004	**>A>** 5158952	Oct 27, 2009	DP U-90		
PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE					
077395 001				**>A>** PC	Jun 10, 2007
PAROXETINE HYDROCHLORIDE - PAXIL CR					
020936 001	**>A>** 5789449	Jan 06, 2009	U-788		
	>A> 5789449*PED	Jul 06, 2009			
PAROXETINE HYDROCHLORIDE - PAXIL CR					
020936 002	**>A>** 5789449	Jan 06, 2009	U-788		
	>A> 5789449*PED	Jul 06, 2009			
PAROXETINE HYDROCHLORIDE - PAXIL CR					
020936 003	**>A>** 5789449	Jan 06, 2009	U-788		
	>A> 5789449*PED	Jul 06, 2009			
SELEGILINE - EMSAM					
021336 001	**>A>** 7150881	Jun 12, 2018	DS DP		
SELEGILINE - EMSAM					
021336 002	**>A>** 7150881	Jun 12, 2018	DS DP		
SELEGILINE - EMSAM					
021336 003	**>A>** 7150881	Jun 12, 2018	DS DP		
SOMATROPIN RECOMBINANT - SAIZEN					
019764 005				**>A>** I-440	Aug 26, 2007
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PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY LIST

See report footnotes for information regarding report content

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

Footnotes:

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 submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:
   DS = Drug Substance claim
   DP = Drug Product claim
   U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at http://www.fda.gov/cder/orange/patex.htm
3. 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.
4. *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.
5. *** U.S. Patent Nos. RE 36481 and RE 36520 were relisted for Zocor (NDA 19-766) pursuant to the decision and related order in Ranbaxy Labs. v.Leavitt, No. 05-1838 (D.D.C. April 30, 2006). The '481 and '520 patents remained listed in Approved Drug Products with Therapeutic Equivalence Evaluations until any applicable periods of exclusivity pursuant to section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act were triggered and run. For additional information on this matter, please refer to Docket Nos. 2005P-0008 and 2005P-0046. Patents were subsequently delisted in the December 2006 Orange Book update as the exclusivity periods have triggered and run to expiration.

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, 25th Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

The current complete list of patent terms is available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/pattermsall.cfm

The current complete list of exclusivity terms is available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/excltermsall.cfm