

APPROVED DRUG PRODUCTS

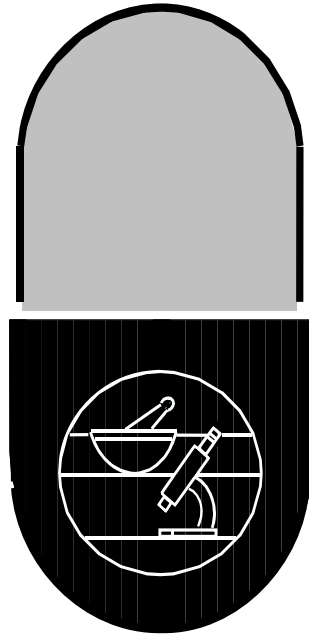
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**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

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

27th EDITION

Cumulative Supplement 01

January 2007

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27th EDITION

**CUMULATIVE SUPPLEMENT 01
January 2007**

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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

<u>CATEGORIES COUNTED</u>	<u>DEC 2006</u>	<u>MAR 2007</u>	<u>JUN 2007</u>	<u>SEPT 2007</u>
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

¹Amino 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 preceded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

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

PRESCRIPTION DRUG PRODUCT LIST - 27TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLMENT 1 - January 2007

1-1

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							
>A>		ALBUTEROL SULFATE					
>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

>A> 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
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CLOBETASOL PROPIONATE

AEROSOL, FOAM; TOPICAL

OLUX E

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

DEXMETHYLPHENIDATE HYDROCHLORIDE

TABLET; ORAL

DEXMETHYLPHENIDATE HYDROCHLORIDE

>A>							
>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

DICLOFENAC EPOLAMINE

PATCH; TOPICAL

FLECTOR

>A>							
>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
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INJECTABLE; INJECTIONCALCIUM DISODIUM VERSENATE

>A>	+	GRACEWAY	200MG/ML	N08922 001		Jan	CAHN
<u>TABLET; ORAL</u>							
<u>CALCIUM DISODIUM VERSENATE</u>							
>D>		@ 3M	500MG	N08922 002		Jan	CAHN
>A>		@ GRACEWAY	500MG	N08922 002		Jan	CAHN

ERGOTAMINE TARTRATETABLET; SUBLINGUALERGOMAR

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

ESTRADIOLGEL, METERED; TRANSDERMALELESTRIN

>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; NORETHINDRONETABLET, 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 ACETATETABLET; 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

FENOFIBRATETABLET; ORALTRIGLIDE

>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

FENTANYLFILM, EXTENDED RELEASE; TRANSDERMALDURAGESIC-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

>D>		FENTANYL							
>D>	AB	MYLAN TECHNOLOGIES	100UGM/HR	N76258	004	Jan 28, 2005	Jan	CTNA	
>A>		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	
>A>		FENTANYL-12							
>A>	AB	MYLAN TECHNOLOGIES	12.5UGM/HR	N76258	005	Jan 23, 2007	Jan	NEWA	
>A>		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	
>A>		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	
>A>		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 ACETATETABLET; 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	
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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	
>D>		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	
>D>		PROLIXIN							
>D>	AP	+	APOTHECON	2.5MG/ML	N11751	005		Jan	DISC
>A>		@	2.5MG/ML	N11751	005			Jan	DISC

TABLET; ORAL

PROLIXIN

>D>		PROLIXIN							
>D>	AB	APOTHECON	1MG	N11751	004			Jan	DISC

TABLET; ORAL

>D>		PROLIXIN						
>A>		@ 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
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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

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>		ZOFRAAN AND DEXTROSE IN PLASTIC CONTAINER						
>A>	AP	+	GLAXOSMITHKLINE	EQ 0.64MG BASE/ML	N20403	001	Jan 31, 1995	Jan
>D>		ZOFRAAN IN PLASTIC CONTAINER						
>D>	AP	+	GLAXOSMITHKLINE	EQ 0.64MG BASE/ML	N20403	001	Jan 31, 1995	Jan

ORPHENADRINE CITRATE

INJECTABLE; INJECTION

NORFLEX

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

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/SC00PFUL	N77706 001	Sep 27, 2006	Jan	CAHN
>D>	AA	YVR THERAP	17GM/SC00PFUL	N77706 001	Sep 27, 2006	Jan	CAHN

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

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

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
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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 D00	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
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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
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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

DRAXIMAGE MDP

>D>							
>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
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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

VALACYCLOVIR HYDROCHLORIDE

>A>							
>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	

OTC DRUG PRODUCT LIST - 27TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2007

2-1

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

CAPSULE; ORAL

ADVIL LIQUI-GELS

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

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

CAPSULE; ORAL

ADVIL LIQUI-GELS

>D>	+	WYETH CONS	200MG	N20402 001	Apr 20, 1995	Jan	CAIN
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ADVIL MIGRAINE LIQUI-GELS

>D>	+	WYETH CONS	200MG	N20402 002	Mar 16, 2000	Jan	CAIN
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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 EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ALBUTEROL SULFATE - VENTOLIN HFA</u>					
020983 001	>A> 6558651	Dec 19, 2016	DP		
	>A> 6743413	Jun 01, 2021	DP	U-716	
<u>ANIDULAFUNGIN - ERAXIS</u>					
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
<u>BALSALAZIDE DISODIUM - COLAZAL</u>					
020610 001				>A> ODE	Dec 20, 2013
<u>BUDESONIDE - PULMICORT RESPULES</u>					
020929 001	>A> 6899099	Dec 23, 2018		U-645	
<u>BUDESONIDE - PULMICORT RESPULES</u>					
020929 002	>A> 6899099	Dec 23, 2018		U-645	
<u>BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE</u>					
077284 002				>A> PC	Jun 12, 2007
<u>BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE</u>					
077415 002				>A> PC	Jun 12, 2007
<u>CELECOXIB - CELEBREX</u>					
020998 004				>A> I-466	Jul 29, 2008
				>A> NPP	Dec 15, 2009
				>A> PED	Jun 15, 2010
				>A> PED	Jan 29, 2009
<u>CICLESONIDE - OMNARIS</u>					
022004 001	>A> 5482934	Jan 09, 2013	DS	DP	U-557
	>A> 6767901	Oct 21, 2020		DP	
	>A> 6939559	Apr 21, 2019		DP	
<u>COLESTIPOL HYDROCHLORIDE - COLESTIPOL HYDROCHLORIDE</u>					
077510 001				>A> PC	Jun 12, 2007
<u>DECITABINE - DACOGEN</u>					
021790 001				>A> ODE	May 02, 2013
<u>DICLOFENAC EPOLAMINE - FLECTOR</u>					
021234 001				>A> NE	Jan 31, 2010
				>A> NDF	Jan 31, 2007
<u>DROSPIRENONE; ETHINYL ESTRADIOL - YAZ</u>					
021676 001				>A> I-522	Jan 26, 2010
<u>EMTRICITABINE - EMTRIVA</u>					
021500 001	>A> 5210085	May 11, 2010			U-257
	>A> 5814639	Sep 29, 2015	DS	DP	
	>A> 5914331	Sep 29, 2015	DS		
<u>EPLERENONE - INSPRA</u>					
021437 001	>A> 7157101	Dec 08, 2019		DP	U-664
<u>EPLERENONE - INSPRA</u>					
021437 002	>A> 7157101	Dec 08, 2019		DP	U-664
<u>EPLERENONE - INSPRA</u>					
021437 003	>A> 7157101	Dec 08, 2019		DP	U-664
<u>ESTRADIOL; NORETHINDRONE ACETATE - ACTIVELLA</u>					
020907 002				>A> D-104	Dec 28, 2009
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 002	>A> 5229382	Apr 23, 2011	DS	DP	
	>A> 5229382*PED	Oct 23, 2011			>A> NC
	>A> 5945416	Mar 24, 2017	DS	DP	>A> PED
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 003	>A> 5229382	Apr 23, 2011	DS	DP	
	>A> 5229382*PED	Oct 23, 2011			>A> NC
	>A> 5945416	Mar 24, 2017	DS	DP	>A> PED

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

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

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>LAMOTRIGINE - LAMICTAL CD</u>					
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			
<u>LAMOTRIGINE - LAMICTAL CD</u>					
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			
<u>LAMOTRIGINE - LAMICTAL CD</u>					
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			
<u>LAMOTRIGINE - LAMICTAL CD</u>					
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			
<u>LATANOPROST - XALATAN</u>					
020597 001	>A> 7163959	Jun 19, 2010	DS		
<u>LOPERAMIDE HYDROCHLORIDE - IMODIUM A-D EZ CHEWS</u>					
020448 001	>A> 5489436	Feb 06, 2013	DP		
	>A> 6814978	Aug 26, 2021	DP		
<u>LOPINAVIR; RITONAVIR - KALETRA</u>					
021251 001	>A> 5914332	Dec 13, 2015	U-351		
<u>LOPINAVIR; RITONAVIR - KALETRA</u>					
021906 001	>A> 7148359	Jul 19, 2019	DP		
<u>MESALAMINE - LIALDA</u>					
022000 001				>A> NP	Jan 16, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 001				>A> M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 002				>A> M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 003				>A> M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 004				>A> M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 005				>A> M-62	Jan 31, 2010
<u>MOXIFLOXACIN HYDROCHLORIDE - VIGAMOX</u>					
021598 001	>A> 6716830	Sep 29, 2019	DP		
<u>OLANZAPINE - ZYPREXA</u>					
020592 001	>A> 5229382	Apr 23, 2011	DS	DP U-547	Jan 14, 2007
	>A> 5229382	Apr 23, 2011	DS	DP U-149	Jul 14, 2007
	>A> 5229382*PED	Oct 23, 2011			
<u>OLANZAPINE - ZYPREXA</u>					
020592 002	>A> 5229382	Apr 23, 2011	DS	DP U-547	Jan 14, 2007
	>A> 5229382	Apr 23, 2011	DS	DP U-149	Jul 14, 2007
	>A> 5229382*PED	Oct 23, 2011			
<u>OLANZAPINE - ZYPREXA</u>					
020592 003	>A> 5229382	Apr 23, 2011	DS	DP U-547	Jan 14, 2007
	>A> 5229382	Apr 23, 2011	DS	DP U-149	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 EXPIRATION 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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<u>OXALIPLATIN - ELOXATIN</u>					
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			
<u>PALIPERIDONE - INVEGA</u>					
021999 001	>A> 5158952	Oct 27, 2009	DP	U-90	
<u>PALIPERIDONE - INVEGA</u>					
021999 002	>A> 5158952	Oct 27, 2009	DP	U-90	
<u>PALIPERIDONE - INVEGA</u>					
021999 003	>A> 5158952	Oct 27, 2009	DP	U-90	
<u>PALIPERIDONE - INVEGA</u>					
021999 004	>A> 5158952	Oct 27, 2009	DP	U-90	
<u>PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE</u>					
077395 001				>A> PC	Jun 10, 2007
<u>PAROXETINE HYDROCHLORIDE - PAXIL CR</u>					
020936 001	>A> 5789449	Jan 06, 2009	U-788		
	>A> 5789449*PED	Jul 06, 2009			
<u>PAROXETINE HYDROCHLORIDE - PAXIL CR</u>					
020936 002	>A> 5789449	Jan 06, 2009	U-788		
	>A> 5789449*PED	Jul 06, 2009			
<u>PAROXETINE HYDROCHLORIDE - PAXIL CR</u>					
020936 003	>A> 5789449	Jan 06, 2009	U-788		
	>A> 5789449*PED	Jul 06, 2009			
<u>SELEGILINE - EMSAM</u>					
021336 001	>A> 7150881	Jun 12, 2018	DS	DP	
<u>SELEGILINE - EMSAM</u>					
021336 002	>A> 7150881	Jun 12, 2018	DS	DP	
<u>SELEGILINE - EMSAM</u>					
021336 003	>A> 7150881	Jun 12, 2018	DS	DP	
<u>SOMATROPIN RECOMBINANT - SAIZEN</u>					
019764 005				>A> I-440	Aug 26, 2007
<u>TERIPARATIDE RECOMBINANT HUMAN - FORTEO</u>					
021318 001	>A> 7163684	Aug 19, 2019	U-790		

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

See report footnotes for information regarding report content

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