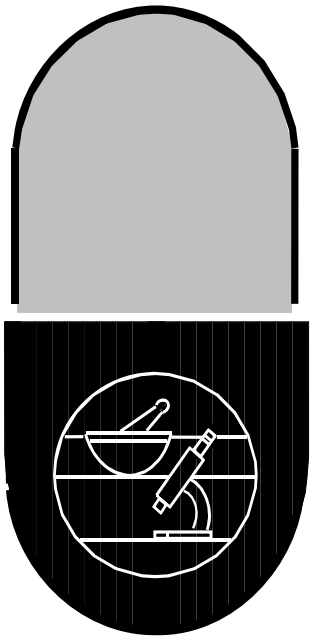
APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

FDA data supplied by DrugPatentWatch.com

CUMULATIVE SUPPLEMENT 02
February 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 02

February 2007

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27th EDITION

CUMULATIVE SUPPLEMENT 02
February 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at drugproducts@cder.fda.gov. Send Changes by FAX: 240-276-8974; mail to:

FDA/CDER Orange Book Staff
Office of Generic Drugs, HFD-610
7500 Standish Place
Rockville , MD 20855-2773

1.3 APPLICANT NAME CHANGES

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

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

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
BIONICHE PHARMA (BIONICHE PHARMA)	BIONICHE PHARMA USA LLC (BIONICHE PHARMA)
BIONICHE PHARMA (CANADA) LTD (BIONICHE (CANADA))	BIONICHE PHARMA USA LLC (BIONICHE PHARMA)
BIONICHE PHARMA USA INC (BIONICHE PHARMA USA)	BIONICHE PHARMA USA LLC (BIONICHE PHARMA)

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.

ABARELIX

INJECTABLE; INTRAMUSCULAR
PLENAXIS

>D>			@ PRAECIS	100MG/VIAL	N21320	001	Nov 25, 2003	Feb	CAHN
>A>			@ SPECIALITY EUROPEAN	100MG/VIAL	N21320	001	Nov 25, 2003	Feb	CAHN

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

TABLET; ORAL
ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

>D>	AB	+	MIKART	712.8MG;60MG;32MG	N40316	001	Apr 28, 1999	Feb	CTEC
>A>	AA	+		712.8MG;60MG;32MG	N40316	001	Apr 28, 1999	Feb	CTEC

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITATRATE

>D>	AB		WEST WARD	712.8MG;60MG;32MG	N40637	001	Sep 22, 2006	Feb	CTEC
>A>	AA			712.8MG;60MG;32MG	N40637	001	Sep 22, 2006	Feb	CTEC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>A>	AA		INTERPHARM	500MG;10MG	N40813	001	Feb 23, 2007	Feb	NEWA

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

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

TABLET, EXTENDED RELEASE; ORAL
ALBUTEROL SULFATE

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

VOSPIRE ER

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

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM

	AB		APOTEX INC	0.25MG	N77741	001	Jan 19, 2007	Jan	NEWA
	AB			0.5MG	N77741	002	Jan 19, 2007	Jan	NEWA
	AB			1MG	N77741	003	Jan 19, 2007	Jan	NEWA
	AB			2MG	N77741	004	Jan 19, 2007	Jan	NEWA
>D>			@ CLONMEL HLTHCARE	0.25MG	N74174	001	Oct 19, 1993	Feb	CAHN
>D>			@	0.5MG	N74174	002	Oct 19, 1993	Feb	CAHN
>D>			@	1MG	N74174	003	Oct 19, 1993	Feb	CAHN
>D>			@	2MG	N74174	004	Oct 19, 1993	Feb	CAHN
>A>			@ DAVA INTL INC	0.25MG	N74174	001	Oct 19, 1993	Feb	CAHN
>A>			@	0.5MG	N74174	002	Oct 19, 1993	Feb	CAHN
>A>			@	1MG	N74174	003	Oct 19, 1993	Feb	CAHN
>A>			@	2MG	N74174	004	Oct 19, 1993	Feb	CAHN

TABLET, EXTENDED RELEASE; ORAL
ALPRAZOLAM

	AB		ACTAVIS ELIZABETH	0.5MG	N78056	001	Feb 13, 2007	Jan	NEWA
	AB			1MG	N78056	002	Feb 13, 2007	Jan	NEWA
	AB			2MG	N78056	003	Feb 13, 2007	Jan	NEWA
	AB			3MG	N78056	004	Feb 13, 2007	Jan	NEWA

TABLET, EXTENDED RELEASE; ORAL
ALPRAZOLAM

	AB	COREPHARMA	0.5MG	N77996	001	Jan 31, 2007	Jan	NEWA
	AB		1MG	N77996	002	Jan 31, 2007	Jan	NEWA
	AB		2MG	N77996	003	Jan 31, 2007	Jan	NEWA
	AB		3MG	N77996	004	Jan 31, 2007	Jan	NEWA
>A>	AB	TEVA PHARMS	0.5MG	N77979	001	Feb 28, 2007	Feb	NEWA
>A>	AB		1MG	N77979	002	Feb 28, 2007	Feb	NEWA
>A>	AB		2MG	N77979	003	Feb 28, 2007	Feb	NEWA
>A>	AB		3MG	N77979	004	Feb 28, 2007	Feb	NEWA

TABLET, ORALLY DISINTEGRATING; ORAL
NIRAVAM

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

AMINO ACIDS

INJECTABLE; INJECTION
NOVAMINE 11.4%

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

NOVAMINE 15%

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

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

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

TABLET, FOR SUSPENSION; ORAL
AMOXICILLIN

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

DISPERMOX

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

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL
AMOXICILLIN AND CLAVULANATE POTASSIUM

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

ARIPIPRAZOLE

TABLET; ORAL
ABILIFY

>D>		+ OTSUKA	15MG	N21436	002	Nov 15, 2002	Feb	CRLD
>A>			15MG	N21436	002	Nov 15, 2002	Feb	CRLD
>D>		+	30MG	N21436	004	Nov 15, 2002	Feb	CRLD
>A>			30MG	N21436	004	Nov 15, 2002	Feb	CRLD

TABLET, ORALLY DISINTEGRATING; ORAL
ABILIFY

>D>		OTSUKA	10MG	N21729	002	Jun 07, 2006	Feb	CRLD
>A>		+	10MG	N21729	002	Jun 07, 2006	Feb	CRLD
>D>		+	30MG	N21729	005	Jun 07, 2006	Feb	CRLD
>A>			30MG	N21729	005	Jun 07, 2006	Feb	CRLD

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

NORGESIC

AB		GRACEWAY	385MG;30MG;25MG	N13416	003	Oct 27, 1982	Jan	CAHN

NORGESIC FORTE

AB	+	GRACEWAY	770MG;60MG;50MG	N13416	004	Oct 27, 1982	Jan	CAHN

AZITHROMYCIN

INJECTABLE; INJECTION

AZITHROMYCIN

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

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

>D> CORTISPORIN

>D> AT		MONARCH PHARMS	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N50416	002		Feb	DISC
>A>		@	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N50416	002		Feb	DISC

NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC AND HYDROCORTISONE

>D> AT	+	BAUSCH AND LOMB	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N64068	001	Oct 30, 1995	Feb	CTEC
>A>	+		400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N64068	001	Oct 30, 1995	Feb	CTEC

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

>D> NEOSPORIN

>D> AT		MONARCH PHARMS	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N50417	001		Feb	DISC
>A>		@	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N50417	001		Feb	DISC

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

>D> POLYSPORIN

>D> AT		MONARCH PHARMS	500 UNITS/GM;10,000 UNITS/GM	N61229	001		Feb	DISC
>A>		@	500 UNITS/GM;10,000 UNITS/GM	N61229	001		Feb	DISC

BUDESONIDE

POWDER, METERED; INHALATION

>D> BUDESONIDE

>D>		ASTRAZENECA	0.08MG/INH	N21949	001	Jul 12, 2006	Feb	CTNA
>D>	+		0.16MG/INH	N21949	002	Jul 12, 2006	Feb	CTNA

>A> PULMICORT FLEXHALER

>A>		ASTRAZENECA	0.08MG/INH	N21949	001	Jul 12, 2006	Feb	CTNA
>A>	+		0.16MG/INH	N21949	002	Jul 12, 2006	Feb	CTNA

BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE

SPRAY, METERED; INHALATION

SYMBICORT

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

CABERGOLINE

TABLET; ORAL
CABERGOLINE

>A>	AB	IVAX PHARMS INC	0.5MG	N77750	001	Mar 07, 2007	Feb	NEWA

CARBOPLATIN

INJECTABLE; IV (INFUSION)
CARBOPLATIN

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

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

>A>	AA	SUN PHARM INDS LTD	350MG	N40755	001	Feb 27, 2007	Feb	NEWA

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL
CEFADROXIL

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

CEFPROZIL

FOR SUSPENSION; ORAL
CEFPROZIL

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

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION
CEFIZOX

>D>	+	ASTELLAS	EQ 1GM BASE/VIAL	N50560	002	Sep 15, 1983	Feb	DISC
>A>		@	EQ 1GM BASE/VIAL	N50560	002	Sep 15, 1983	Feb	DISC
>D>			EQ 1GM BASE/VIAL	N63294	002	Mar 31, 1994	Feb	CRLD
>A>	+		EQ 1GM BASE/VIAL	N63294	002	Mar 31, 1994	Feb	CRLD

CEFTRIAXONE SODIUM

INJECTABLE; IM-IV
CEFTRIAXONE

>A>	AP	HANFORD GC	EQ 1GM BASE/VIAL	N65268	001	Feb 28, 2007	Feb	NEWA
>A>	AP		EQ 2GM BASE/VIAL	N65268	002	Feb 28, 2007	Feb	NEWA

INJECTABLE; INJECTION
CEFTRIAXONE

>A>	AP	HANFORD GC	EQ 10GM BASE/VIAL	N65269	001	Feb 28, 2007	Feb	NEWA

CELECOXIB

CAPSULE; ORAL
CELEBREX

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

CHLORAMPHENICOL SODIUM SUCCINATE

INJECTABLE; INJECTION

CHLORAMPHENICOL SODIUM SUCCINATE

>D>	AP	ABRAXIS PHARM	EQ 1GM BASE/VIAL	N62365	001	Aug 25, 1982	Feb	CRLD
>A>	+		EQ 1GM BASE/VIAL	N62365	001	Aug 25, 1982	Feb	CRLD

>D> CHLOROMYCETIN

>D>	AP	+ PARKEDALE	EQ 1GM BASE/VIAL	N50155	001		Feb	DISC
>A>		@	EQ 1GM BASE/VIAL	N50155	001		Feb	DISC

CHLOROTHIAZIDE

SUSPENSION; ORAL

DIURIL

>D>	+	MERCK	250MG/5ML	N11870	001		Feb	CAHN
>A>	+	SALIX PHARMS	250MG/5ML	N11870	001		Feb	CAHN

CITALOPRAM HYDROBROMIDE

>A> CAPSULE; ORAL

>A> CITALOPRAM HYDROBROMIDE

>A>		ALPHAPHARM	EQ 10MG BASE	N77668	001	Feb 28, 2007	Feb	NEWA
>A>			EQ 20MG BASE	N77668	002	Feb 28, 2007	Feb	NEWA
>A>	+		EQ 40MG BASE	N77668	003	Feb 28, 2007	Feb	NEWA

CLOBETASOL PROPIONATE

AEROSOL, FOAM; TOPICAL

OLUX E

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

SOLUTION; TOPICAL

CLOBETASOL PROPIONATE

>D>		@ ALTANA	0.05%	N75391	001	Feb 08, 1999	Feb	CMFD
>A>	AT		0.05%	N75391	001	Feb 08, 1999	Feb	CMFD

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HYDROCHLORIDE

>A>	AB	VINTAGE	0.1MG	N77901	001	Mar 09, 2007	Feb	NEWA
>A>	AB		0.2MG	N77901	002	Mar 09, 2007	Feb	NEWA
>A>	AB		0.3MG	N77901	003	Mar 09, 2007	Feb	NEWA

CYCLOBENZAPRINE HYDROCHLORIDE

>A> CAPSULE, EXTENDED RELEASE; ORAL

>A> AMRIX

>A>		ECR	15MG	N21777	001	Feb 01, 2007	Feb	NEWA
>A>	+		30MG	N21777	002	Feb 01, 2007	Feb	NEWA

TABLET; ORAL

CYCLOBENZAPRINE HYDROCHLORIDE

>A>	AB	VINTAGE PHARMS	5MG	N77797	001	Feb 28, 2007	Feb	NEWA
>A>	AB		10MG	N77797	002	Feb 28, 2007	Feb	NEWA

DEXMETHYLPHENIDATE HYDROCHLORIDE

TABLET; ORAL

DEXMETHYLPHENIDATE HYDROCHLORIDE

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

TABLET; ORAL
FOCALIN

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

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL
DEXEDRINE

>D>								
>D>	AA	GLAXOSMITHKLINE	5MG	N84935	001		Feb	DISC
>A>		@	5MG	N84935	001		Feb	DISC

DICLOFENAC EPOLAMINE

PATCH; TOPICAL
FLECTOR

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

DIDANOSINE

FOR SOLUTION; ORAL
DIDANOSINE

>A>								
>A>	AA	AUROBINDO PHARMA	10MG/ML	N78112	001	Mar 08, 2007	Feb	NEWA

VIDEX

>D>	+	BRISTOL MYERS SQUIBB	10MG/ML	N20156	001	Oct 09, 1991	Feb	CFTG
>A>	AA +		10MG/ML	N20156	001	Oct 09, 1991	Feb	CFTG

DIMYRISTOYL LECITHIN; PERFLEXANE

INJECTABLE; INTRAVENOUS
IMAGENT

>D>		@ IMCOR PH	0.92MG/VIAL;0.092MG/VIAL	N21191	001	May 31, 2002	Feb	CAHN
>A>		@ IMCOR PHARMS CO	0.92MG/VIAL;0.092MG/VIAL	N21191	001	May 31, 2002	Feb	CAHN

DIPYRIDAMOLE

TABLET; ORAL
DIPYRIDAMOLE

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

DOXYCYCLINE

CAPSULE; ORAL
DOXYCYCLINE

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

MONODOX

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

EDETATE CALCIUM DISODIUM

INJECTABLE; INJECTION
CALCIUM DISODIUM VERSENATE

	+	GRACEWAY	200MG/ML	N08922	001		Jan	CAHN

TABLET; ORAL
CALCIUM DISODIUM VERSENATE

		@ GRACEWAY	500MG	N08922	002		Jan	CAHN

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL
ERGOMAR
\+ ROSEDALE THERAPEUTIC 2MG N87693 001 Feb 24, 1983 Jan CAHN

ESTRADIOL

GEL, METERED; TRANSDERMAL
ELESTRIN
BX + BRADLEY PHARMS 0.06% N21813 001 Dec 15, 2006 Jan CAHN

TABLET; ORAL
ESTRADIOL
>A> @ HERITAGE PHARMS INC 0.5MG N40275 001 Dec 29, 1998 Feb CAHN
>A> @ 1MG N40275 002 Dec 29, 1998 Feb CAHN
>A> @ 2MG N40275 003 Dec 29, 1998 Feb CAHN
>D> @ RADIUS PHARMS 0.5MG N40275 001 Dec 29, 1998 Feb CAHN
>D> @ 1MG N40275 002 Dec 29, 1998 Feb CAHN
>D> @ 2MG N40275 003 Dec 29, 1998 Feb CAHN

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET, CHEWABLE; ORAL-28
OVCON-35 FE
\+ WARNER CHILCOTT 0.035MG;0.4MG N21490 001 Nov 14, 2003 Jan CTNA

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-21
MICROGESTIN 1.5/30
AB WATSON LABS 0.03MG;1.5MG N75548 002 Jul 30, 2003 Jan NEWA
MICROGESTIN 1/20
AB WATSON LABS 0.02MG;1MG N75647 002 Jul 30, 2003 Jan NEWA

FAMOTIDINE

FOR SUSPENSION; ORAL
PEPCID
>D> + MERCK 40MG/5ML N19527 001 Feb 02, 1987 Feb CAHN
>A> + SALIX PHARMS 40MG/5ML N19527 001 Feb 02, 1987 Feb CAHN

FENOFIBRATE

TABLET; ORAL
TRIGLIDE
SKYEPHARMA AG 50MG N21350 001 May 07, 2005 Jan CAHN
BX 160MG N21350 002 May 07, 2005 Jan CAHN

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION
FENOLDOPAM MESYLATE
>A> AP SICOR PHARMS EQ 10MG BASE/ML N77826 001 Mar 07, 2007 Feb NEWA

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL
DURAGESIC-12
AB ALZA 12.5UGM/HR N19813 005 Feb 04, 2005 Jan CFTG
FENTANYL-100
AB LAVIPHARM LABS 100UGM/HR N77051 004 Aug 04, 2006 Jan CTNA
AB MYLAN TECHNOLOGIES 100UGM/HR N76258 004 Jan 28, 2005 Jan CTNA

FILM, EXTENDED RELEASE; TRANSDERMAL

FENTANYL-12

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

FENTANYL-25

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

FENTANYL-50

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

FENTANYL-75

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

FINASTERIDE

TABLET; ORAL

FINASTERIDE

>A>	AB	DR REDDYS LABS LTD	5MG	N76437	001	Feb 28, 2007	Feb	NEWA

FLECAINIDE ACETATE

TABLET; ORAL

TAMBOCOR

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

FLUOXETINE HYDROCHLORIDE

SOLUTION; ORAL

FLUOXETINE HYDROCHLORIDE

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

FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION

FLUPHENAZINE DECANOATE

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

PROLIXIN DECANOATE

	@	BRISTOL MYERS SQUIBB	25MG/ML	N16727	001		Jan	DISC

FLUPHENAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

FLUPHENAZINE HYDROCHLORIDE

	+	ABRAXIS PHARM	2.5MG/ML	N89556	001	Apr 16, 1987	Jan	CRLD

PROLIXIN

	@	APOTHECON	2.5MG/ML	N11751	005		Jan	DISC

TABLET; ORAL

FLUPHENAZINE HYDROCHLORIDE

>D>	AB	MYLAN	10MG	N89804	001	Aug 12, 1988	Feb	CRLD
>A>	AB	+	10MG	N89804	001	Aug 12, 1988	Feb	CRLD

PROLIXIN

	@	APOTHECON	1MG	N11751	004		Jan	DISC
	@		2.5MG	N11751	001		Jan	DISC
	@		5MG	N11751	003		Jan	DISC
	@		10MG	N11751	002		Jan	DISC

FOLIC ACID

INJECTABLE; INJECTION

FOLIC ACID

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

FORMOTEROL FUMARATE

POWDER; INHALATION

FORADIL CERTIHALER

+		NOVARTIS	0.0085MG/INH	N21592	001	Dec 15, 2006	Jan	CRLD

GABAPENTIN

TABLET; ORAL

GABAPENTIN

>D>	AB		IVAX PHARMS	800MG	N76017	005	Apr 29, 2005	Feb	CRLD
>A>	AB	+		800MG	N76017	005	Apr 29, 2005	Feb	CRLD

NEURONTIN

>D>	AB	+	PFIZER PHARMS	800MG	N20882	002	Oct 09, 1998	Feb	CRLD
>A>	AB			800MG	N20882	002	Oct 09, 1998	Feb	CRLD

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM

>A>		@	WATSON LABS	1,000 UNITS/ML	N17064	002		Feb	CAHN
>A>		@		2,500 UNITS/ML	N17064	015		Feb	CAHN
>A>		@		3,000 UNITS/ML	N17064	016		Feb	CAHN
>A>		@		4,000 UNITS/ML	N17064	017		Feb	CAHN
>A>		@		5,000 UNITS/ML	N17064	003		Feb	CAHN
>A>		@		6,000 UNITS/ML	N17064	018		Feb	CAHN
>A>		@		7,500 UNITS/ML	N17064	019		Feb	CAHN
>A>		@		10,000 UNITS/ML	N17064	004		Feb	CAHN
>A>		@		20,000 UNITS/ML	N17064	005		Feb	CAHN
>A>		@		40,000 UNITS/ML	N17064	006		Feb	CAHN
>D>		@	WATSON PHARMS	1,000 UNITS/ML	N17064	002		Feb	CAHN
>D>		@		2,500 UNITS/ML	N17064	015		Feb	CAHN
>D>		@		3,000 UNITS/ML	N17064	016		Feb	CAHN
>D>		@		4,000 UNITS/ML	N17064	017		Feb	CAHN
>D>		@		5,000 UNITS/ML	N17064	003		Feb	CAHN
>D>		@		6,000 UNITS/ML	N17064	018		Feb	CAHN
>D>		@		7,500 UNITS/ML	N17064	019		Feb	CAHN
>D>		@		10,000 UNITS/ML	N17064	004		Feb	CAHN
>D>		@		20,000 UNITS/ML	N17064	005		Feb	CAHN
>D>		@		40,000 UNITS/ML	N17064	006		Feb	CAHN

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

>A>		@	HERITAGE PHARMS INC	25MG	N86243	001		Feb	CAHN
>A>		@		50MG	N86242	002		Feb	CAHN
>D>		@	RADIUS PHARMS	25MG	N86243	001		Feb	CAHN
>D>		@		50MG	N86242	002		Feb	CAHN

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

>A>	AB	ACTAVIS ELIZABETH	12.5MG	N40707	001	Feb 27, 2007	Feb	NEWA
>A>	AB	HERITAGE PHARMS INC	25MG	N85181	001		Feb	CAHN
>A>	AB		50MG	N85182	001		Feb	CAHN
>D>	AB	LEINER	25MG	N85181	001		Feb	CAHN
>D>	AB		50MG	N85182	001		Feb	CAHN
>D>		MYLAN	12.5MG	N40770	001	Jan 23, 2007	Feb	CTEC
>A>	AB		12.5MG	N40770	001	Jan 23, 2007	Feb	CTEC
			12.5MG	N40770	001	Jan 23, 2007	Jan	NEWA
	AB		25MG	N40735	002	Jan 23, 2007	Jan	NEWA
	AB		50MG	N40735	003	Jan 23, 2007	Jan	NEWA

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL

>A> MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>A>	AB	TEVA	12.5MG;7.5MG	N76980	001	Mar 07, 2007	Feb	NEWA
>A>	AB		12.5MG;15MG	N76980	003	Mar 07, 2007	Feb	NEWA
>A>	AB		25MG;15MG	N76980	002	Mar 07, 2007	Feb	NEWA

UNIRETIC

>D>		SCHWARZ PHARMA	12.5MG;7.5MG	N20729	001	Jun 27, 1997	Feb	CFTG
>A>	AB		12.5MG;7.5MG	N20729	001	Jun 27, 1997	Feb	CFTG
>D>			12.5MG;15MG	N20729	003	Feb 14, 2002	Feb	CFTG
>A>	AB		12.5MG;15MG	N20729	003	Feb 14, 2002	Feb	CFTG
>D>	+		25MG;15MG	N20729	002	Jun 27, 1997	Feb	CFTG
>A>	AB +		25MG;15MG	N20729	002	Jun 27, 1997	Feb	CFTG

HYDROCORTISONE

TABLET; ORAL

CORTEF

>D>		@ PHARMACIA AND UPJOHN	10MG	N08697	001		Feb	CMFD
>A>			10MG	N08697	001		Feb	CMFD

HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROMORPHONE HYDROCHLORIDE

>D>	AP	WATSON LABS	10MG/ML	N74317	001	Aug 23, 1995	Feb	DISC
>A>		@	10MG/ML	N74317	001	Aug 23, 1995	Feb	DISC

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HYDROCHLORIDE

>D>	AP	HOSPIRA	25MG/ML	N87416	001		Feb	DISC
>A>		@	25MG/ML	N87416	001		Feb	DISC
>D>	AP		50MG/ML	N87546	001		Feb	DISC
>A>		@	50MG/ML	N87546	001		Feb	DISC
>D>	AP	WATSON LABS	50MG/ML	N85779	001		Feb	DISC
>A>		@	50MG/ML	N85779	001		Feb	DISC

ILOPROST

SOLUTION; INHALATION

VENTAVIS

>D>	+	ACTELION	10UGM/ML (10UGM/ML)	N21779	002	Dec 08, 2005	Feb	CAHN

SOLUTION; INHALATION
VENTAVIS

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

IMIQUIMOD

CREAM; TOPICAL
ALDARA

	+	GRACEWAY	5%	N20723	001	Feb 27, 1997	Jan	CAHN

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

>A>		@ HERITAGE PHARMS INC	25MG	N18851	001	May 18, 1984	Feb	CAHN
>A>		@	50MG	N18851	002	May 18, 1984	Feb	CAHN
>D>		MYLAN	25MG	N18858	001	Apr 20, 1984	Feb	CTEC
>A>	AB		25MG	N18858	001	Apr 20, 1984	Feb	CTEC
>D>		@ RADIUS PHARMS	25MG	N18851	001	May 18, 1984	Feb	CAHN
>D>		@	50MG	N18851	002	May 18, 1984	Feb	CAHN
>D>		@ SANDOZ	25MG	N70673	001	Apr 29, 1987	Feb	CMFD
>A>	AB		25MG	N70673	001	Apr 29, 1987	Feb	CMFD
>D>		@	50MG	N70674	001	Apr 29, 1987	Feb	CMFD
>A>	AB		50MG	N70674	001	Apr 29, 1987	Feb	CMFD

IRON SUCROSE

INJECTABLE; INTRAVENOUS
VENOFER

>D>		LUITPOLD	EQ 50MG BASE/2.5ML(EQ 20MG BASE/ML)	N21135	002	Mar 20, 2005	Feb	DISC
>A>		@	EQ 50MG BASE/2.5ML(EQ 20MG BASE/ML)	N21135	002	Mar 20, 2005	Feb	DISC
>D>			EQ 75MG BASE/3.75ML(EQ 20MG BASE/ML)	N21135	003	Mar 29, 2005	Feb	DISC
>A>		@	EQ 75MG BASE/3.75ML(EQ 20MG BASE/ML)	N21135	003	Mar 29, 2005	Feb	DISC
>A>			EQ 200MG BASE/10ML(EQ 20MG BASE/ML)	N21135	004	Feb 09, 2007	Feb	NEWA

ISOSORBIDE DINITRATE

TABLET; ORAL
ISOSORBIDE DINITRATE

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

KETOPROFEN

CAPSULE; ORAL
KETOPROFEN

>A>	AB	HERITAGE PHARMS INC	25MG	N74014	001	Jan 29, 1993	Feb	CAHN
>A>	AB		50MG	N74014	002	Jan 29, 1993	Feb	CAHN
>A>	AB		75MG	N74014	003	Jan 29, 1993	Feb	CAHN
>D>	AB	RADIUS PHARMS	25MG	N74014	001	Jan 29, 1993	Feb	CAHN
>D>	AB		50MG	N74014	002	Jan 29, 1993	Feb	CAHN
>D>	AB		75MG	N74014	003	Jan 29, 1993	Feb	CAHN

LEUCOVORIN CALCIUM

TABLET; ORAL
LEUCOVORIN CALCIUM

		@ PHARMACHEMIE	EQ 5MG BASE	N73099	001	Mar 28, 1997	Jan	DISC
		@	EQ 25MG BASE	N73101	001	Mar 28, 1997	Jan	DISC

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS
ELIGARD

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

LIDOCAINE

PATCH; TOPICAL
LIDOCAINE

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

LIDOCAINE HYDROCHLORIDE

SOLUTION; ORAL
LIDOCAINE HYDROCHLORIDE VISCOUS

>A>	AT	VINTAGE	2%	N40708	001	Feb 27, 2007	Feb	NEWA

SOLUTION; TOPICAL
LIDOCAINE HYDROCLORIDE

>A>	AT	VINTAGE	4%	N40710	001	Feb 27, 2007	Feb	NEWA

>A> LISDEXAMFETAMINE DIMESYLATE

CAPSULE; ORAL
VYVANSE

>A>		NEW RIVER	30MG	N21977	001	Feb 23, 2007	Feb	NEWA
>A>			50MG	N21977	002	Feb 23, 2007	Feb	NEWA
>A>	+		70MG	N21977	003	Feb 23, 2007	Feb	NEWA

LOVASTATIN

TABLET; ORAL
LOVASTATIN

>A>	AB	APOTEX INC	10MG	N77748	001	Feb 28, 2007	Feb	NEWA
>A>	AB		20MG	N77748	002	Feb 28, 2007	Feb	NEWA
>A>	AB		40MG	N77748	003	Feb 28, 2007	Feb	NEWA

TABLET, EXTENDED RELEASE; ORAL
ALTOPREV

>D>		ANDRX LABS LLC	10MG	N21316	001	Jun 26, 2002	Feb	DISC
>A>		@	10MG	N21316	001	Jun 26, 2002	Feb	DISC

MAGNESIUM SULFATE

INJECTABLE; INJECTION
MAGNESIUM SULFATE IN PLASTIC CONTAINER

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

MESALAMINE

TABLET, DELAYED RELEASE; ORAL
LIALDA

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

METFORMIN HYDROCHLORIDE

TABLET; ORAL
METFORMIN HYDROCHLORIDE

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

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
CONCERTA

>D>			ALZA	18MG	N21121	001	Aug 01, 2000	Feb	CAHN
>D>				27MG	N21121	004	Apr 01, 2002	Feb	CAHN
>D>				36MG	N21121	002	Aug 01, 2000	Feb	CAHN
>D>		+		54MG	N21121	003	Dec 08, 2000	Feb	CAHN
>A>			JOHNSON AND JOHNSON	18MG	N21121	001	Aug 01, 2000	Feb	CAHN
>A>				27MG	N21121	004	Apr 01, 2002	Feb	CAHN
>A>				36MG	N21121	002	Aug 01, 2000	Feb	CAHN
>A>		+		54MG	N21121	003	Dec 08, 2000	Feb	CAHN

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE SODIUM SUCCINATE

>A>	AP		BEDFORD LABS	EQ 40MG BASE/VIAL	N40662	001	Feb 21, 2007	Feb	NEWA
>A>	AP			EQ 125MG BASE/VIAL	N40641	002	Feb 21, 2007	Feb	NEWA
>A>	AP			EQ 500MG BASE/VIAL	N40641	003	Feb 21, 2007	Feb	NEWA
>A>	AP			EQ 500MG BASE/VIAL	N40709	001	Feb 21, 2007	Feb	NEWA
>A>	AP			EQ 1GM BASE/VIAL	N40641	004	Feb 21, 2007	Feb	NEWA
>A>	AP			EQ 1GM BASE/VIAL	N40709	002	Feb 21, 2007	Feb	NEWA

METRONIDAZOLE

GEL; VAGINAL
METROGEL-VAGINAL

	AB	+	GRACEWAY	0.75%	N20208	001	Aug 17, 1992	Jan	CAHN

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION
MIDAZOLAM HYDROCHLORIDE

>D>									
>D>	AP	+	HOSPIRA	EQ 1MG BASE/ML	N75857	001	Jul 22, 2002	Feb	CTNA
>D>	AP	+		EQ 5MG BASE/ML	N75857	002	Jul 22, 2002	Feb	CTNA
>A>	AP		TAYLOR	EQ 1MG BASE/ML	N75494	001	Jun 30, 2000	Feb	CAHN
>A>	AP			EQ 5MG BASE/ML	N75494	002	Jun 30, 2000	Feb	CAHN
>D>	AP		TAYLOR PHARMA	EQ 1MG BASE/ML	N75494	001	Jun 30, 2000	Feb	CAHN
>D>	AP			EQ 5MG BASE/ML	N75494	002	Jun 30, 2000	Feb	CAHN
>A>			MIDAZOLAM HYDROCHLORIDE PRESERVATIVE FREE						
>A>	AP	+	HOSPIRA	EQ 1MG BASE/ML	N75857	001	Jul 22, 2002	Feb	CTNA
>A>	AP	+		EQ 5MG BASE/ML	N75857	002	Jul 22, 2002	Feb	CTNA

MITOMYCIN

INJECTABLE; INJECTION

MITOZYTREX

		+	SUPERGEN	5MG/VIAL	N50763	001	Nov 14, 2002	Jan	CTNA

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

KADIAN

>A>			ALPHARMA US PHARMS	200MG	N20616	007	Feb 27, 2007	Feb	NEWA

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE HYDROCHLORIDE

>D>	AP		HOSPIRA	10MG/ML	N70914	001	Feb 03, 1989	Feb	CRLD
>A>	AP	+		10MG/ML	N70914	001	Feb 03, 1989	Feb	CRLD
>D>	AP			10MG/ML	N70915	001	Feb 03, 1989	Feb	CRLD
>A>	AP	+		10MG/ML	N70915	001	Feb 03, 1989	Feb	CRLD
>D>	AP			20MG/ML	N70916	001	Feb 03, 1989	Feb	CRLD
>A>	AP	+		20MG/ML	N70916	001	Feb 03, 1989	Feb	CRLD
>D>	AP			20MG/ML	N70918	001	Feb 03, 1989	Feb	CRLD
>A>	AP	+		20MG/ML	N70918	001	Feb 03, 1989	Feb	CRLD

>D> NUBAIN

>D>	AP	+	ENDO PHARMS	10MG/ML	N18024	001		Feb	DISC
>A>		@		10MG/ML	N18024	001		Feb	DISC
>D>	AP	+		20MG/ML	N18024	002	May 27, 1982	Feb	DISC
>A>		@		20MG/ML	N18024	002	May 27, 1982	Feb	DISC

NESIRITIDE RECOMBINANT

FOR SOLUTION; INTRAVENOUS

NATRECOR

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

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

MINITRAN

	AB1		GRACEWAY	0.1MG/HR	N89771	001	Aug 30, 1996	Jan	CAHN
	AB1			0.2MG/HR	N89772	001	Aug 30, 1996	Jan	CAHN
	AB1			0.4MG/HR	N89773	001	Aug 30, 1996	Jan	CAHN
	AB1			0.6MG/HR	N89774	001	Aug 30, 1996	Jan	CAHN

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

	AP		HOSPIRA	EQ 2MG BASE/ML	N77840	001	Jan 19, 2007	Jan	NEWA

ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER

	AP		HOSPIRA	EQ 0.64MG BASE/ML	N77348	001	Feb 01, 2007	Jan	NEWA
>A>	AP		MAYNE PHARMA USA	EQ 0.64MG BASE/ML	N76978	001	Feb 26, 2007	Feb	NEWA

ZOFRAN AND DEXTROSE IN PLASTIC CONTAINER

	AP	+	GLAXOSMITHKLINE	EQ 0.64MG BASE/ML	N20403	001	Jan 31, 1995	Jan	CTNA

ORPHENADRINE CITRATE

INJECTABLE; INJECTION
NORFLEX

	AP	+	GRACEWAY	30MG/ML	N13055	001		Jan	CAHN

TABLET, EXTENDED RELEASE; ORAL
NORFLEX

		@	GRACEWAY	100MG	N12157	001		Jan	CAHN

OXYCODONE HYDROCHLORIDE

TABLET; ORAL
OXYCODONE HYDROCHLORIDE

	AB		VINTAGE PHARMS	15MG	N77712	001	Jan 31, 2007	Jan	NEWA
	AB			30MG	N77712	002	Jan 31, 2007	Jan	NEWA

ROXICODONE

>D>	AB	+	XANODYNE PHARM	15MG	N21011	001	Aug 31, 2000	Feb	CAHN
>D>	AB			30MG	N21011	002	Aug 31, 2000	Feb	CAHN
>A>	AB	+	XANODYNE PHARMS INC	15MG	N21011	001	Aug 31, 2000	Feb	CAHN
>A>	AB			30MG	N21011	002	Aug 31, 2000	Feb	CAHN

PAROXETINE HYDROCHLORIDE

TABLET; ORAL
PAROXETINE HYDROCHLORIDE

>A>	AB		ZYDUS PHARMS USA	EQ 10MG BASE	N77584	001	Mar 07, 2007	Feb	NEWA
>A>	AB			EQ 20MG BASE	N77584	002	Mar 07, 2007	Feb	NEWA
>A>	AB			EQ 30MG BASE	N77584	003	Mar 07, 2007	Feb	NEWA
>A>	AB			EQ 40MG BASE	N77584	004	Mar 07, 2007	Feb	NEWA

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL
PENTOXIFYLLINE

>A>	AB		HERITAGE PHARMS INC	400MG	N74877	001	Jul 08, 1997	Feb	CAHN
>D>	AB		RADIUS PHARMS	400MG	N74877	001	Jul 08, 1997	Feb	CAHN

PERGOLIDE MESYLATE

TABLET; ORAL
PERMAX

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

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
PHENTERMINE HYDROCHLORIDE

>D>	AA		AMBI PHARMS	30MG	N40083	001	Mar 07, 1997	Feb	CAHN
>D>	AA		SANDOZ	30MG	N87190	001		Feb	CRLD
>A>	AA	+		30MG	N87190	001		Feb	CRLD
>A>	AA		TG UNITED INC	30MG	N40083	001	Mar 07, 1997	Feb	CAHN

PILOCARPINE HYDROCHLORIDE

TABLET; ORAL
PILOCARPINE HYDROCHLORIDE

>A>	AB		ROXANE	7.5MG	N76963	002	Feb 27, 2007	Feb	NEWA

PIPERACILLIN SODIUM

INJECTABLE; INJECTION
PIPERACILLIN

>D>		+	ABRAXIS PHARM	EQ 2GM BASE/VIAL	N65114	001	Nov 14, 2003	Feb	CAHN
>D>		+		EQ 3GM BASE/VIAL	N65114	002	Nov 14, 2003	Feb	CAHN
>D>		+		EQ 4GM BASE/VIAL	N65114	003	Nov 14, 2003	Feb	CAHN
>D>		+		EQ 40GM BASE/VIAL	N65157	001	Jul 12, 2004	Feb	CAHN
>A>		+	ISTITUTO BIOCHIMICO	EQ 2GM BASE/VIAL	N65114	001	Nov 14, 2003	Feb	CAHN
>A>		+		EQ 3GM BASE/VIAL	N65114	002	Nov 14, 2003	Feb	CAHN
>A>		+		EQ 4GM BASE/VIAL	N65114	003	Nov 14, 2003	Feb	CAHN
>A>		+		EQ 40GM BASE/VIAL	N65157	001	Jul 12, 2004	Feb	CAHN

PIRBUTEROL ACETATE

AEROSOL, METERED; INHALATION
MAXAIR

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

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL
POLYETHYLENE GLYCOL 3350

	AA		ANABOLIC LABS	17GM/SCOOPFUL	N77706	001	Sep 27, 2006	Jan	CAHN

PREDNICARBATE

OINTMENT; TOPICAL
DERMATOP

>D>		+	SANOFI AVENTIS US	0.1%	N19568	001	Sep 23, 1991	Feb	CFTG
>A>	AB	+		0.1%	N19568	001	Sep 23, 1991	Feb	CFTG
>A>			PREDNICARBATE						
>A>	AB		ALTANA	0.1%	N77236	001	Mar 09, 2007	Feb	NEWA

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL
PROCAINAMIDE HYDROCHLORIDE

		@	IVAX PHARMS	250MG	N84604	001		Jan	DISC
		@		375MG	N84595	001		Jan	DISC
		@		500MG	N84606	001		Jan	DISC
		@	WATSON LABS	250MG	N83287	001		Jan	DISC
		@		375MG	N84403	001		Jan	DISC
		@		500MG	N84280	001		Jan	DISC

PRONESTYL

		@	APOTHECON	250MG	N07335	001		Jan	DISC
		@		375MG	N07335	004		Jan	DISC
		@		500MG	N07335	003		Jan	DISC

TABLET, EXTENDED RELEASE; ORAL
PRONESTYL-SR

		@	APOTHECON	500MG	N87361	001		Jan	DISC

PROCHLORPERAZINE

SUPPOSITORY; RECTAL
COMPAZINE

>D>									
>D>	AB	+	GLAXOSMITHKLINE	25MG	N11127	002		Feb	DISC
>A>		@		25MG	N11127	002		Feb	DISC

SUPPOSITORY; RECTAL
PROCHLORPERAZINE

>D>	AB		G AND W LABS	25MG	N40058	001	Nov 24, 1993	Feb	CRLD
>A>	AB	+		25MG	N40058	001	Nov 24, 1993	Feb	CRLD

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION
>D> COMPAZINE

>D>	AP	+	GLAXOSMITHKLINE	EQ 5MG BASE/ML	N10742	002		Feb	DISC
>A>		@		EQ 5MG BASE/ML	N10742	002		Feb	DISC

>D> PROCHLORPERAZINE

>D>	AP		BAXTER HLTHCARE	EQ 5MG BASE/ML	N87759	001	Oct 01, 1982	Feb	DISC
>A>		@		EQ 5MG BASE/ML	N87759	001	Oct 01, 1982	Feb	DISC

PROCHLORPERAZINE EDISYLATE

>D>	AP		BAXTER HLTHCARE	EQ 5MG BASE/ML	N89903	001	Aug 29, 1989	Feb	CRLD
>A>	AP	+		EQ 5MG BASE/ML	N89903	001	Aug 29, 1989	Feb	CRLD
>D>	AP		HOSPIRA	EQ 5MG BASE/ML	N89703	001	Apr 07, 1988	Feb	DISC
>A>		@		EQ 5MG BASE/ML	N89703	001	Apr 07, 1988	Feb	DISC
>D>	AP		WATSON LABS	EQ 5MG BASE/ML	N89530	001	Jul 08, 1987	Feb	DISC
>A>		@		EQ 5MG BASE/ML	N89530	001	Jul 08, 1987	Feb	DISC

PROCHLORPERAZINE MALEATE

CAPSULE, EXTENDED RELEASE; ORAL
COMPAZINE

			@ GLAXOSMITHKLINE	EQ 15MG BASE	N21019	002	Oct 06, 1999	Jan	DISC

TABLET; ORAL
>D> COMPAZINE

>D>	AB		GLAXOSMITHKLINE	EQ 5MG BASE	N10571	001		Feb	DISC
>A>		@		EQ 5MG BASE	N10571	001		Feb	DISC
>D>	AB			EQ 10MG BASE	N10571	002		Feb	DISC
>A>		@		EQ 10MG BASE	N10571	002		Feb	DISC
>D>	AB	+		EQ 25MG BASE	N10571	003		Feb	DISC
>A>		@		EQ 25MG BASE	N10571	003		Feb	DISC

PROCHLORPERAZINE MALEATE

>D>	AB		SANDOZ	EQ 10MG BASE	N40101	002	Jul 19, 1996	Feb	CRLD
>A>	AB	+		EQ 10MG BASE	N40101	002	Jul 19, 1996	Feb	CRLD
>D>	AB			EQ 25MG BASE	N40101	003	Jul 19, 1996	Feb	DISC
>A>		@		EQ 25MG BASE	N40101	003	Jul 19, 1996	Feb	DISC

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
DOLENE

>A>			@ HERITAGE PHARMS INC	65MG	N80530	001		Feb	CAHN
>D>			@ RADIUS PHARMS	65MG	N80530	001		Feb	CAHN

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
INDERAL LA

	AB		WYETH PHARMS INC	60MG	N18553	004	Mar 18, 1987	Jan	CTEC
	AB			80MG	N18553	002	Apr 19, 1983	Jan	CTEC
	AB			120MG	N18553	003	Apr 19, 1983	Jan	CTEC
	AB	+		160MG	N18553	001	Apr 19, 1983	Jan	CTEC

PROPRANOLOL HYDROCHLORIDE

>A>	AB		MYLAN	60MG	N78022	001	Feb 15, 2007	Feb	NEWA
>A>	AB			80MG	N78022	002	Feb 15, 2007	Feb	NEWA
>A>	AB			120MG	N78022	003	Feb 15, 2007	Feb	NEWA

CAPSULE, EXTENDED RELEASE; ORAL
PROPRANOLOL HYDROCHLORIDE

>A>	AB	MYLAN	160MG	N78022	004	Feb 15, 2007	Feb	NEWA
	AB	PAR PHARM	60MG	N78065	001	Jan 26, 2007	Jan	NEWA
	AB		80MG	N78065	002	Jan 26, 2007	Jan	NEWA
	AB		120MG	N78065	003	Jan 26, 2007	Jan	NEWA
	AB		160MG	N78065	004	Jan 26, 2007	Jan	NEWA

TABLET; ORAL
INDERAL

		@ WYETH PHARMS INC	10MG	N16418	001		Jan	DISC
		@	20MG	N16418	003		Jan	DISC

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HYDROCHLORIDE

	+	ABRAXIS PHARM	100MG/ML	N80618	001		Jan	CRLD
		@ WATSON LABS	100MG/ML	N80572	001		Jan	DISC

RABEPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL
ACIPHEX

>D>	+	EISAI MEDCL RES	20MG	N20973	002	Aug 19, 1999	Feb	CFTG
>A>	AB +		20MG	N20973	002	Aug 19, 1999	Feb	CFTG

>A> RABEPRAZOLE SODIUM

>A>	AB	TEVA	20MG	N76822	001	Feb 21, 2007	Feb	NEWA

RAMIPRIL

CAPSULE; ORAL
ALTACE

		KING PHARMS	1.25MG	N19901	001	Jan 28, 1991	Jan	CTEC
			2.5MG	N19901	002	Jan 28, 1991	Jan	CTEC
			5MG	N19901	003	Jan 28, 1991	Jan	CTEC
	+		10MG	N19901	004	Jan 28, 1991	Jan	CTEC

RAMIPRIL

		@ COBALT	1.25MG	N76549	001	Oct 24, 2005	Jan	DISC
		@	2.5MG	N76549	002	Oct 24, 2005	Jan	DISC
		@	5MG	N76549	003	Oct 24, 2005	Jan	DISC
		@	10MG	N76549	004	Oct 24, 2005	Jan	DISC

>A> TABLET; ORAL
>A> ALTACE

>A>		COBALT	1.25MG	N22021	001	Feb 27, 2007	Feb	NEWA
>A>			2.5MG	N22021	002	Feb 27, 2007	Feb	NEWA
>A>			5MG	N22021	003	Feb 27, 2007	Feb	NEWA
>A>	+		10MG	N22021	004	Feb 27, 2007	Feb	NEWA

RANITIDINE HYDROCHLORIDE

SYRUP; ORAL
>A> RANITIDINE HYDROCHLORIDE

>A>	AA	ALPHARMA US PHARMS	EQ 15MG BASE/ML	N76124	001	Feb 21, 2007	Feb	NEWA

ZANTAC

>D>	+	GLAXOSMITHKLINE	EQ 15MG BASE/ML	N19675	001	Dec 30, 1988	Feb	CFTG
>A>	AA +		EQ 15MG BASE/ML	N19675	001	Dec 30, 1988	Feb	CFTG

SERMORELIN ACETATE

INJECTABLE; INJECTION

GEREF

>A>		+	EMD SERONO	EQ 0.05MG BASE/AMP	N19863	001	Dec 28, 1990	Feb	CAHN
>A>		@		EQ 0.5MG BASE/VIAL	N20443	001	Sep 26, 1997	Feb	CAHN
>A>		@		EQ 1MG BASE/VIAL	N20443	002	Sep 26, 1997	Feb	CAHN
>D>		+	SERONO	EQ 0.05MG BASE/AMP	N19863	001	Dec 28, 1990	Feb	CAHN
>D>		@		EQ 0.5MG BASE/VIAL	N20443	001	Sep 26, 1997	Feb	CAHN
>D>		@		EQ 1MG BASE/VIAL	N20443	002	Sep 26, 1997	Feb	CAHN

SERTRALINE HYDROCHLORIDE

CONCENTRATE; ORAL

SERTRALINE HYDROCHLORIDE

>D>	AB		RANBAXY	EQ 20MG BASE/ML	N78053	001	Feb 05, 2007	Feb	CTEC
>A>	AA			EQ 20MG BASE/ML	N78053	001	Feb 05, 2007	Feb	CTEC
	AB			EQ 20MG BASE/ML	N78053	001	Feb 05, 2007	Jan	NEWA
>D>	AB		ROXANE	EQ 20MG BASE/ML	N76934	001	Jun 30, 2006	Feb	CTEC
>A>	AA			EQ 20MG BASE/ML	N76934	001	Jun 30, 2006	Feb	CTEC

ZOLOFT

>D>	AB	+	PFIZER	EQ 20MG BASE/ML	N20990	001	Dec 07, 1999	Feb	CTEC
>A>	AA	+		EQ 20MG BASE/ML	N20990	001	Dec 07, 1999	Feb	CTEC

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

	AB		ACTAVIS ELIZABETH	EQ 25MG BASE	N77345	001	Feb 06, 2007	Jan	NEWA
	AB			EQ 50MG BASE	N77345	002	Feb 06, 2007	Jan	NEWA
	AB			EQ 100MG BASE	N77345	003	Feb 06, 2007	Jan	NEWA
	AB		APOTEX INC	EQ 25MG BASE	N76882	001	Feb 06, 2007	Jan	NEWA
	AB			EQ 50MG BASE	N76882	002	Feb 06, 2007	Jan	NEWA
	AB			EQ 100MG BASE	N76882	003	Feb 06, 2007	Jan	NEWA
	AB		AUROBINDO PHARMA	EQ 25MG BASE	N77206	001	Feb 06, 2007	Jan	NEWA
	AB			EQ 50MG BASE	N77206	002	Feb 06, 2007	Jan	NEWA
	AB			EQ 100MG BASE	N77206	003	Feb 06, 2007	Jan	NEWA
	AB		COBALT	EQ 25MG BASE	N77663	001	Feb 06, 2007	Jan	NEWA
	AB			EQ 50MG BASE	N77663	002	Feb 06, 2007	Jan	NEWA
	AB			EQ 100MG BASE	N77663	003	Feb 06, 2007	Jan	NEWA
	AB		INVAGEN PHARMS	EQ 25MG BASE	N77397	001	Feb 06, 2007	Jan	NEWA
	AB			EQ 50MG BASE	N77397	002	Feb 06, 2007	Jan	NEWA
	AB			EQ 100MG BASE	N77397	003	Feb 06, 2007	Jan	NEWA
	AB		LUPIN	EQ 25MG BASE	N77670	001	Feb 06, 2007	Jan	NEWA
	AB			EQ 50MG BASE	N77670	002	Feb 06, 2007	Jan	NEWA
	AB			EQ 100MG BASE	N77670	003	Feb 06, 2007	Jan	NEWA
	AB		MUTUAL PHARM	EQ 25MG BASE	N77818	001	Feb 06, 2007	Jan	NEWA
	AB			EQ 50MG BASE	N77818	002	Feb 06, 2007	Jan	NEWA
	AB			EQ 100MG BASE	N77818	003	Feb 06, 2007	Jan	NEWA
	AB		MYLAN	EQ 25MG BASE	N76671	001	Feb 06, 2007	Jan	NEWA
	AB			EQ 50MG BASE	N76671	002	Feb 06, 2007	Jan	NEWA
	AB			EQ 100MG BASE	N76671	003	Feb 06, 2007	Jan	NEWA
	AB		PLIVA HRVATSKA DOO	EQ 25MG BASE	N77299	001	Feb 06, 2007	Jan	NEWA
	AB			EQ 50MG BASE	N77299	002	Feb 06, 2007	Jan	NEWA
	AB			EQ 100MG BASE	N77299	003	Feb 06, 2007	Jan	NEWA
	AB		RANBAXY	EQ 25MG BASE	N77977	001	Feb 06, 2007	Jan	NEWA
	AB			EQ 50MG BASE	N77977	002	Feb 06, 2007	Jan	NEWA
	AB			EQ 100MG BASE	N77977	003	Feb 06, 2007	Jan	NEWA
				EQ 150MG BASE	N77977	004	Feb 06, 2007	Jan	NEWA
				EQ 200MG BASE	N77977	005	Feb 06, 2007	Jan	NEWA

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

AB	ROXANE	EQ 25MG BASE	N76881	001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N76881	002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N76881	003	Feb 06, 2007	Jan	NEWA
AB	SANDOZ	EQ 25MG BASE	N77713	001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77713	002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77713	003	Feb 06, 2007	Jan	NEWA
AB	SUN PHARM INDS (IN)	EQ 25MG BASE	N78108	001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N78108	002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N78108	003	Feb 06, 2007	Jan	NEWA
AB	TORRENT PHARMS	EQ 25MG BASE	N77765	001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77765	002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77765	003	Feb 06, 2007	Jan	NEWA
AB	WATSON LABS	EQ 25MG BASE	N77162	001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77162	002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77162	003	Feb 06, 2007	Jan	NEWA
AB	ZYDUS PHARMS USA	EQ 25MG BASE	N77106	001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77106	002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77106	003	Feb 06, 2007	Jan	NEWA

SODIUM LACTATE

INJECTABLE; INJECTION

SODIUM LACTATE IN PLASTIC CONTAINER

>D>		HOSPIRA	5MEQ/ML	N18947	001	Sep 05, 1984	Feb	CRLD
>A>	+		5MEQ/ML	N18947	001	Sep 05, 1984	Feb	CRLD

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION

SAIZEN

>A>	BX	EMD SERONO	4MG/VIAL	N19764	005	Jan 16, 2007	Feb	CAHN
>A>	BX		5MG/VIAL	N19764	002	Oct 08, 1996	Feb	CAHN
>A>	@		6MG/VIAL	N19764	001	Oct 08, 1996	Feb	CAHN
>A>	+		8.8MG/VIAL	N19764	003	Aug 29, 2000	Feb	CAHN
>D>	BX	SERONO	4MG/VIAL	N19764	005	Jan 16, 2007	Feb	CAHN
	BX		4MG/VIAL	N19764	005	Jan 16, 2007	Jan	NEWA
>D>	BX		5MG/VIAL	N19764	002	Oct 08, 1996	Feb	CAHN
>D>	@		6MG/VIAL	N19764	001	Oct 08, 1996	Feb	CAHN
>D>	+		8.8MG/VIAL	N19764	003	Aug 29, 2000	Feb	CAHN

SEROSTIM

>A>	BX	EMD SERONO	4MG/VIAL	N20604	003	Jul 25, 1997	Feb	CAHN
>A>	BX		5MG/VIAL	N20604	002	Aug 23, 1996	Feb	CAHN
>A>	BX		6MG/VIAL	N20604	001	Aug 23, 1996	Feb	CAHN
>A>	@		8.8MG/VIAL	N20604	004	Sep 06, 2001	Feb	CAHN
>D>	BX	SERONO	4MG/VIAL	N20604	003	Jul 25, 1997	Feb	CAHN
>D>	BX		5MG/VIAL	N20604	002	Aug 23, 1996	Feb	CAHN
>D>	BX		6MG/VIAL	N20604	001	Aug 23, 1996	Feb	CAHN
>D>	@		8.8MG/VIAL	N20604	004	Sep 06, 2001	Feb	CAHN

INJECTABLE; SUBCUTANEOUS

SEROSTIM LQ

>A>	@ EMD SERONO	6MG/0.5ML	N20604	005	Feb 11, 2005	Feb	CAHN
>D>	@ SERONO	6MG/0.5ML	N20604	005	Feb 11, 2005	Feb	CAHN

SOTALOL HYDROCHLORIDE

TABLET; ORAL
SOTALOL HYDROCHLORIDE

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

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
BACTRIM

>D>								
>D>	AP	+ MUTUAL PHARM	80MG/ML;16MG/ML	N18374	001		Feb	DISC
>A>		@	80MG/ML;16MG/ML	N18374	001		Feb	DISC

SUSPENSION; ORAL
BACTRIM PEDIATRIC

>D>	AB	MUTUAL PHARM	200MG/5ML;40MG/5ML	N17560	002		Feb	DISC
>A>		@	200MG/5ML;40MG/5ML	N17560	002		Feb	DISC

SEPTRA

>D>	AB	+ MONARCH PHARMS	200MG/5ML;40MG/5ML	N17598	001		Feb	DISC
>A>		@	200MG/5ML;40MG/5ML	N17598	001		Feb	DISC

SEPTRA GRAPE

>D>	AB	MONARCH PHARMS	200MG/5ML;40MG/5ML	N17598	002	Feb 12, 1986	Feb	DISC
>A>		@	200MG/5ML;40MG/5ML	N17598	002	Feb 12, 1986	Feb	DISC

SULFAMETHOXAZOLE AND TRIMETHOPRIM

>D>	AB	TEVA	200MG/5ML;40MG/5ML	N18812	001	Jan 28, 1983	Feb	DISC
>D>	AB		200MG/5ML;40MG/5ML	N18812	002	Jun 10, 1983	Feb	DISC
>A>		@	200MG/5ML;40MG/5ML	N18812	002	Jun 10, 1983	Feb	DISC
>A>		@	200MG/5ML;40MG/5ML	N18812	001	Jan 28, 1983	Feb	DISC
>D>	AB	TEVA PHARMS	200MG/5ML;40MG/5ML	N77612	001	Nov 13, 2006	Feb	CRLD
>A>	AB	+	200MG/5ML;40MG/5ML	N77612	001	Nov 13, 2006	Feb	CRLD
	AB	VINTAGE	200MG/5ML;40MG/5ML	N77785	001	Jan 24, 2007	Jan	NEWA

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

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

SULFASALAZINE

TABLET; ORAL
SULFASALAZINE

>A>		@ HERITAGE PHARMS INC	500MG	N80197	001		Feb	CAHN
>D>		@ RADIUS PHARMS	500MG	N80197	001		Feb	CAHN

SULINDAC

TABLET; ORAL
SULINDAC

>A>		@ HERITAGE PHARMS INC	150MG	N73262	002	Sep 06, 1991	Feb	CAHN
>A>		@	200MG	N73262	001	Sep 06, 1991	Feb	CAHN
>D>		@ RADIUS PHARMS	150MG	N73262	002	Sep 06, 1991	Feb	CAHN
>D>		@	200MG	N73262	001	Sep 06, 1991	Feb	CAHN

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
DRAXIMAGE MDP-10

	AP	+ DRAXIMAGE	N/A	N18035	001		Jan	CTNA

INJECTABLE; INJECTION
DRAXIMAGE MDP-25
\+ DRAXIMAGE N/A N18035 002 Feb 27, 2004 Jan NEWA

TERCONAZOLE

SUPPOSITORY; VAGINAL
TERCONAZOLE
>A> AB TARO 80MG N77553 001 Mar 09, 2007 Feb NEWA

THALIDOMIDE

CAPSULE; ORAL
THALOMID
CELGENE 150MG N20785 004 Jan 10, 2007 Jan NEWA

THEOPHYLLINE

TABLET; ORAL
>D> QUIBRON-T
>D> \+ MONARCH PHARMS 300MG N88656 001 Aug 22, 1985 Feb DISC
>A> @ 300MG N88656 001 Aug 22, 1985 Feb DISC

TABLET, EXTENDED RELEASE; ORAL
>D> QUIBRON-T/SR
>D> BC MONARCH PHARMS 300MG N87563 001 Jun 21, 1983 Feb DISC
>A> @ 300MG N87563 001 Jun 21, 1983 Feb DISC

TOLCAPONE

TABLET; ORAL
TASMAR
VALEANT PHARM INTL 100MG N20697 001 Jan 29, 1998 Jan CAHN
\+ 200MG N20697 002 Jan 29, 1998 Jan CAHN

TRAMADOL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
>D> TRAMADOL HYDROCHLORIDE
>D> BIOVAIL LABS INTL 100MG N21692 001 Sep 08, 2005 Feb CTNA
>D> 200MG N21692 002 Sep 08, 2005 Feb CTNA
>D> \+ 300MG N21692 003 Sep 08, 2005 Feb CTNA
>A> ULTRAM ER
>A> BIOVAIL LABS INTL 100MG N21692 001 Sep 08, 2005 Feb CTNA
>A> 200MG N21692 002 Sep 08, 2005 Feb CTNA
>A> \+ 300MG N21692 003 Sep 08, 2005 Feb CTNA

VALACYCLOVIR HYDROCHLORIDE

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

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION
>D> ISOPTIN
>D> AP \+ FSC 2.5MG/ML N18485 001 Feb DISC
>A> @ 2.5MG/ML N18485 001 Feb DISC

INJECTABLE; INJECTION

VERAPAMIL HYDROCHLORIDE

>D>	AP		LUITPOLD	2.5MG/ML	N70225	001	Nov 12, 1985	Feb	DISC
>A>			@	2.5MG/ML	N70225	001	Nov 12, 1985	Feb	DISC
>D>	AP			2.5MG/ML	N70617	001	Nov 12, 1985	Feb	CRLD
>A>	AP	+		2.5MG/ML	N70617	001	Nov 12, 1985	Feb	CRLD

TABLET; ORAL

CALAN

>D>	AB		GD SEARLE LLC	120MG	N18817	002	Sep 10, 1984	Feb	CRLD
>A>	AB	+		120MG	N18817	002	Sep 10, 1984	Feb	CRLD

>D> ISOPTIN

>D>	AB		FSC	40MG	N18593	003	Nov 23, 1987	Feb	DISC
>A>			@	40MG	N18593	003	Nov 23, 1987	Feb	DISC
>D>	AB			80MG	N18593	001	Mar 08, 1982	Feb	DISC
>A>			@	80MG	N18593	001	Mar 08, 1982	Feb	DISC
>D>	AB	+		120MG	N18593	002	Mar 08, 1982	Feb	DISC
>A>			@	120MG	N18593	002	Mar 08, 1982	Feb	DISC

VERAPAMIL HYDROCHLORIDE

>A>			@ HERITAGE PHARMS INC	80MG	N71880	001	Apr 05, 1988	Feb	CAHN
>A>			@	120MG	N71881	001	Apr 05, 1988	Feb	CAHN
>D>			@ RADIUS PHARMS	80MG	N71880	001	Apr 05, 1988	Feb	CAHN
>D>			@	120MG	N71881	001	Apr 05, 1988	Feb	CAHN

ZONISAMIDE

CAPSULE; ORAL

ZONISAMIDE

>A>	AB		COREPHARMA	25MG	N77876	001	Feb 21, 2007	Feb	NEWA
>A>	AB			50MG	N77876	002	Feb 21, 2007	Feb	NEWA
>A>	AB			100MG	N77876	003	Feb 21, 2007	Feb	NEWA

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

	SPONGE; TOPICAL							
	CHLORAPREP ONE-STEP							
+	ENTURIA INC	2%;70% (3ML)	N20832	001	Jul 14, 2000	Jan	CAHN
+		2%;70% (10.5ML)	N20832	004	Aug 20, 2003	Jan	CAHN
+		2%;70% (26ML)	N20832	006	Nov 21, 2006	Jan	CAHN
	CHLORAPREP ONE-STEP FREPP							
+	ENTURIA INC	2%;70% (1.5ML)	N20832	003	Apr 26, 2002	Jan	CAHN
	CHLORAPREP WITH TINT							
>A> +	ENTURIA INC	2%;70% (3ML)	N20832	007	Oct 10, 2006	Feb	NEWA
+		2%;70% (26ML)	N20832	002	May 03, 2005	Jan	CAHN
+		2%;70% (10.5ML)	N20832	005	Apr 03, 2006	Jan	CAHN
	SWAB; TOPICAL							
	CHLORAPREP ONE-STEP SEPP							
+	ENTURIA INC	2%;70% (0.67ML)	N21555	001	Oct 07, 2002	Jan	CAHN
	CHLORAPREP SINGLE SWABSTICK							
+	ENTURIA INC	2%;70% (1.75ML)	N21555	002	May 10, 2005	Jan	CAHN

DOXYLAMINE SUCCINATE

	TABLET; ORAL							
	UNISOM							
>A> +	CHATTEM	25MG	N18066	001		Feb	CAHN
>D> +	MCNEIL CONS	25MG	N18066	001		Feb	CAHN
+		25MG	N18066	001		Jan	CAHN

IBUPROFEN

	CAPSULE; ORAL							
	ADVIL LIQUI-GELS							
+	WYETH CONS	EQ 200MG FREE ACID AND POTASSIUM SALT	N20402	001	Apr 20, 1995	Jan	CAIN
	ADVIL MIGRAINE LIQUI-GELS							
+	WYETH CONS	EQ 200MG FREE ACID AND POTASSIUM SALT	N20402	002	Mar 16, 2000	Jan	CAIN

KETOTIFEN FUMARATE

	SOLUTION/DROPS; OPHTHALMIC							
	ALAWAY							
+	BAUSCH AND LOMB	EQ 0.025% BASE	N21996	001	Dec 01, 2006	Jan	CAHN

LOPERAMIDE HYDROCHLORIDE

	TABLET, CHEWABLE; ORAL							
	IMODIUM A-D EZ CHEWS							
+	MCNEIL	2MG	N20448	001	Jul 24, 1997	Jan	CTNA

NONOXYNOL-9

	SPONGE; VAGINAL							
	TODAY							
>D>	@ ALLENDALE PHARMS	1GM	N18683	001	Apr 01, 1983	Feb	CMFD
>A> +		1GM	N18683	001	Apr 01, 1983	Feb	CMFD

ORLISTAT

	CAPSULE; ORAL							
>A>	ALLI							
>A> +	GLAXOSMITHKLINE CONS	60MG	N21887	001	Feb 07, 2007	Feb	NEWA

RANITIDINE HYDROCHLORIDE

TABLET, EFFERVESCENT; ORAL

ZANTAC 75

>A>	@ BOEHRINGER INGELHEIM	EQ 75MG BASE	N20745	001	Feb 26, 1998	Feb	CAHN
>D>	@ MCNEIL CONS	EQ 75MG BASE	N20745	001	Feb 26, 1998	Feb	CAHN

TABLET; ORAL

ZANTAC 150

+	BOEHRINGER INGELHEIM	EQ 150MG BASE	N21698	001	Aug 31, 2004	Jan	CAHN

ZANTAC 75

	BOEHRINGER INGELHEIM	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 02 FEBRUARY 2007

NO FEBRUARY 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 FEBRUARY 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		6558651	Dec 19, 2016		DP			
		6743413	Jun 01, 2021		DP	U-716		
ANIDULAFUNGIN - ERAXIS								
021632 002		5965525	Oct 12, 2016	DS	DP	U-540		
		6384013	Mar 19, 2012	DS				
		6743777	Mar 19, 2012		DP	U-540		
		6960564	Apr 12, 2021		DP	U-540		
ARFORMOTEROL TARTRATE - BROVANA								
021912 001	>A>	5795564	Apr 03, 2012			U-793		
	>A>	6068833	Apr 03, 2012			U-793		
	>A>	6589508	Apr 03, 2012			U-793		
	>A>	6866839	Apr 03, 2012			U-793		
ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE - MOVIPREP								
021881 001	>A>	7169381	Sep 01, 2024	DS	DP			
ATORVASTATIN CALCIUM - LIPITOR								
020702 001							>A> I-523	Mar 02, 2010
ATORVASTATIN CALCIUM - LIPITOR								
020702 002							>A> I-523	Mar 02, 2010
ATORVASTATIN CALCIUM - LIPITOR								
020702 003							>A> I-523	Mar 02, 2010
ATORVASTATIN CALCIUM - LIPITOR								
020702 004							>A> I-523	Mar 02, 2010
AVOBENZONE; ECAMSULE; OCTOCRYLENE - CAPITAL SOLEIL 15								
021501 001							>A> NC	Jul 21, 2009
							>A> NP	Oct 02, 2009
AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE - ANTHELIOS 20								
021471 001							>A> NC	Oct 05, 2009
BALSALAZIDE DISODIUM - COLAZAL								
020610 001							ODE	Dec 20, 2013
BOSENTAN - TRACLEER								
021290 001							>A> M-64	Feb 15, 2010
BOSENTAN - TRACLEER								
021290 002							>A> M-64	Feb 15, 2010
BUDESONIDE - PULMICORT RESPULES								
020929 001		6899099	Dec 23, 2018			U-645		
BUDESONIDE - PULMICORT RESPULES								
020929 002		6899099	Dec 23, 2018			U-645		
BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE								
077284 002							PC	Jun 12, 2007
BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE								
077415 002							PC	Jun 12, 2007
CELECOXIB - CELEBREX								
020998 004	>A>	5466823	Nov 30, 2013	DS			I-466	Jul 29, 2008
	>A>	5466823*PED	May 30, 2014				NPP	Dec 15, 2009
	>A>	5563165	Nov 30, 2013		DP		PED	Jun 15, 2010
	>A>	5563165*PED	May 30, 2014				PED	Jan 29, 2009
	>A>	5760068	Jun 02, 2015			U-672		
	>A>	5760068*PED	Dec 02, 2015					
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - CHLORAPREP ONE-STEP								
020832 006	>A>	6991394	Jan 31, 2024		DP			
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - CHLORAPREP WITH TINT								
020832 002	>A>	6991394	Jan 31, 2024		DP			

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
CICLESONIDE - OMNARIS								
022004 001		5482934	Jan 09, 2013	DS	DP	U-557		
		6767901	Oct 21, 2020		DP			
		6939559	Apr 21, 2019		DP			
CLOBETASOL PROPIONATE - OLUX E								
022013 001	>A>	6730288	Sep 08, 2019		DP		>A> NP	Jan 12, 2010
	>A>	7029659	Sep 08, 2019		DP			
COLESTIPOL HYDROCHLORIDE - COLESTIPOL HYDROCHLORIDE								
077510 001							PC	Jun 12, 2007
CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX								
021777 001							>A> NDF	Feb 01, 2010
CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX								
021777 002							>A> NDF	Feb 01, 2010
DASATINIB - SPRYCEL								
021986 001	>A>	7153856	Apr 28, 2020			U-780		
DASATINIB - SPRYCEL								
021986 002	>A>	7153856	Apr 28, 2020			U-780		
DASATINIB - SPRYCEL								
021986 003	>A>	7153856	Apr 28, 2020			U-780		
DECITABINE - DACOGEN								
021790 001							ODE	May 02, 2013
DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR								
021802 004	>A>	5837284	Dec 04, 2015		DP			
	>A>	5908850	Dec 04, 2015			U-678		
	>A>	6228398	Nov 01, 2019		DP	U-676		
	>A>	6528530	Dec 04, 2015		DP			
	>A>	6635284	Dec 04, 2015		DP	U-677		
	>A>	6730325	Nov 01, 2019		DP	U-676		
DICLOFENAC EPOLAMINE - FLECTOR								
021234 001	>A>	4948805	Nov 09, 2007	DS			NE	Jan 31, 2010
	>A>	5607690	Apr 13, 2014		DP		>A> NDF	Jan 31, 2010
DROSPIRENONE; ETHINYL ESTRADIOL - YAZ								
021676 001	>A>	7163931	Dec 20, 2021			U-1	I-522	Jan 26, 2010
DULOXETINE HYDROCHLORIDE - CYMBALTA								
021427 001							>A> I-524	Feb 23, 2010
DULOXETINE HYDROCHLORIDE - CYMBALTA								
021427 002							>A> I-524	Feb 23, 2010
DULOXETINE HYDROCHLORIDE - CYMBALTA								
021427 004							>A> I-524	Feb 23, 2010
EMTRICITABINE - EMTRIVA								
021500 001		5210085	May 11, 2010			U-257		
		5814639	Sep 29, 2015	DS	DP			
		5914331	Sep 29, 2015	DS				
EPLERENONE - INSPRA								
021437 001		7157101	Dec 08, 2019		DP	U-664		
EPLERENONE - INSPRA								
021437 002		7157101	Dec 08, 2019		DP	U-664		
EPLERENONE - INSPRA								
021437 003		7157101	Dec 08, 2019		DP	U-664		
ESTRADIOL; NORETHINDRONE ACETATE - ACTIVELLA								
020907 002							D-104	Dec 28, 2009
							>A> I-525	Dec 29, 2009
FENTANYL CITRATE - ACTIQ								
020747 001							>A> M-63	Feb 06, 2010

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
FENTANYL CITRATE - ACTIQ								
020747 002							**>A>** M-63	Feb 06, 2010
FENTANYL CITRATE - ACTIQ								
020747 003							**>A>** M-63	Feb 06, 2010
FENTANYL CITRATE - ACTIQ								
020747 004							**>A>** M-63	Feb 06, 2010
FENTANYL CITRATE - ACTIQ								
020747 005							**>A>** M-63	Feb 06, 2010
FENTANYL CITRATE - ACTIQ								
020747 006							**>A>** M-63	Feb 06, 2010
FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX								
021520 002		5229382	Apr 23, 2011	DS	DP		NC	Dec 24, 2006
		5229382*PED	Oct 23, 2011				PED	Jun 24, 2007
		5945416	Mar 24, 2017	DS	DP			
FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX								
021520 003		5229382	Apr 23, 2011	DS	DP		NC	Dec 24, 2006
		5229382*PED	Oct 23, 2011				PED	Jun 24, 2007
		5945416	Mar 24, 2017	DS	DP			
FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX								
021520 004		5229382	Apr 23, 2011	DS	DP		NC	Dec 24, 2006
		5229382*PED	Oct 23, 2011				PED	Jun 24, 2007
		5945416	Mar 24, 2017	DS	DP			
FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX								
021520 005		5229382	Apr 23, 2011	DS	DP		NC	Dec 24, 2006
		5229382*PED	Oct 23, 2011				PED	Jun 24, 2007
		5945416	Mar 24, 2017	DS	DP			
FORMOTEROL FUMARATE - FORADIL CERTIHALER								
021592 001		6182655	Dec 05, 2016		DP		**>A>** NP	Dec 15, 2009
		6645466	Nov 10, 2019		DP			
GALANTAMINE HYDROBROMIDE - RAZADYNE ER								
021615 001		7160559	Dec 20, 2019		DP			
GALANTAMINE HYDROBROMIDE - RAZADYNE ER								
021615 002		7160559	Dec 20, 2019		DP			
GALANTAMINE HYDROBROMIDE - RAZADYNE ER								
021615 003		7160559	Dec 20, 2019		DP			
HYDROCHLOROTHIAZIDE; VALSARTAN - DIOVAN HCT								
020818 004		5399578	Mar 21, 2012	DS	DP	U-3		
		6294197	Jun 18, 2017		DP	U-3		
HYDROCHLOROTHIAZIDE; VALSARTAN - DIOVAN HCT								
020818 005		5399578	Mar 21, 2012	DS	DP	U-3		
		6294197	Jun 18, 2017		DP	U-3		
HYDROXOCOBALAMIN - CYANOKIT								
022041 002		5834448	Nov 14, 2016		DP	U-789	ODE	Dec 15, 2013
IBUPROFEN LYSINE - NEOPROFEN								
021903 001	**>A>**	6342530	Nov 14, 2020	DS	DP	U-794		
	>A>	6344479	Mar 20, 2021	DS	DP	U-794		
IMATINIB MESYLATE - GLEEVEC								
021335 001		6958335	Dec 19, 2021			U-791		
		6958335*PED	Jun 19, 2022					
IMATINIB MESYLATE - GLEEVEC								
021335 002		6958335	Dec 19, 2021			U-791		
		6958335*PED	Jun 19, 2022					
IMATINIB MESYLATE - GLEEVEC								
021588 001		6958335	Dec 19, 2021			U-791		
		6958335*PED	Jun 19, 2022					

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
IMATINIB MESYLATE - GLEEVEC					
021588 002	6958335	Dec 19, 2021	U-791		
	6958335*PED	Jun 19, 2022			
KETOCONAZOLE - XOLEGEL					
021946 001	**>A>** 7179475	Dec 04, 2018	DP U-792		
LAMOTRIGINE - LAMICTAL					
020241 001	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL					
020241 002	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL					
020241 003	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL					
020241 004	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL					
020241 005	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL					
020241 006	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
LAMOTRIGINE - LAMICTAL CD					
020764 001	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
LAMOTRIGINE - LAMICTAL CD					
020764 002	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
LAMOTRIGINE - LAMICTAL CD					
020764 003	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
LAMOTRIGINE - LAMICTAL CD					
020764 004	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
LATANOPROST - XALATAN					
020597 001	7163959	Jun 19, 2010	DS		
LISDEXAMFETAMINE DIMESYLATE - VYVANSE					
021977 001				**>A>** NCE	Feb 23, 2012
LISDEXAMFETAMINE DIMESYLATE - VYVANSE					
021977 002				**>A>** NCE	Feb 23, 2012
LISDEXAMFETAMINE DIMESYLATE - VYVANSE					
021977 003				**>A>** NCE	Feb 23, 2012
LOPERAMIDE HYDROCHLORIDE - IMODIUM A-D EZ CHEWS					
020448 001	5489436	Feb 06, 2013	DP		
	6814978	Aug 26, 2021	DP		

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APPL/PROD NO		PATENT NO	PATENT EXPIRATON DATE		PATENT CODES			EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
LOPINAVIR; RITONAVIR - KALETRA									
021251 001		5914332	Dec 13, 2015				U-351		
LOPINAVIR; RITONAVIR - KALETRA									
021906 001		7148359	Jul 19, 2019		DP				
MESALAMINE - LIALDA									
022000 001	**>A>**	6773720	Jun 08, 2020		DP			NP	Jan 16, 2010
METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET									
021410 001								M-62	Jan 31, 2010
METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET									
021410 002								M-62	Jan 31, 2010
METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET									
021410 003								M-62	Jan 31, 2010
METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET									
021410 004								M-62	Jan 31, 2010
METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET									
021410 005								M-62	Jan 31, 2010
MOXIFLOXACIN HYDROCHLORIDE - VIGAMOX									
021598 001		6716830	Sep 29, 2019		DP				
OLANZAPINE - ZYPREXA									
020592 001		5229382	Apr 23, 2011	DS	DP		U-547	I-417	Jan 14, 2007
		5229382	Apr 23, 2011	DS	DP		U-149	PED	Jul 14, 2007
		5229382*PED	Oct 23, 2011						
OLANZAPINE - ZYPREXA									
020592 002		5229382	Apr 23, 2011	DS	DP		U-547	I-417	Jan 14, 2007
		5229382	Apr 23, 2011	DS	DP		U-149	PED	Jul 14, 2007
		5229382*PED	Oct 23, 2011						
OLANZAPINE - ZYPREXA									
020592 003		5229382	Apr 23, 2011	DS	DP		U-547	I-417	Jan 14, 2007
		5229382	Apr 23, 2011	DS	DP		U-149	PED	Jul 14, 2007
		5229382*PED	Oct 23, 2011						
OLANZAPINE - ZYPREXA									
020592 004		5229382	Apr 23, 2011	DS	DP		U-547	I-417	Jan 14, 2007
		5229382	Apr 23, 2011	DS	DP		U-149	PED	Jul 14, 2007
		5229382*PED	Oct 23, 2011						
OLANZAPINE - ZYPREXA									
020592 005		5229382	Apr 23, 2011	DS	DP		U-547	I-417	Jan 14, 2007
		5229382	Apr 23, 2011	DS	DP		U-149	PED	Jul 14, 2007
		5229382*PED	Oct 23, 2011						
OLANZAPINE - ZYPREXA									
020592 006		5229382	Apr 23, 2011	DS	DP		U-547	I-417	Jan 14, 2007
		5229382	Apr 23, 2011	DS	DP		U-149	PED	Jul 14, 2007
		5229382*PED	Oct 23, 2011						
OLANZAPINE - ZYPREXA									
021253 001		5229382	Apr 23, 2011	DS	DP		U-571	NP	Mar 29, 2007
		5229382*PED	Oct 23, 2011					NDF	Mar 29, 2007
								PED	Sep 29, 2007
								PED	Sep 29, 2007
OLANZAPINE - ZYPREXA ZYDIS									
021086 001		5229382	Apr 23, 2011				U-324	I-400	Jul 10, 2006
		5229382*PED	Oct 23, 2011					I-417	Jan 14, 2007
								PED	Jan 10, 2007
								PED	Jul 14, 2007
OLANZAPINE - ZYPREXA ZYDIS									
021086 002		5229382	Apr 23, 2011				U-324	I-400	Jul 10, 2006
		5229382*PED	Oct 23, 2011					I-417	Jan 14, 2007
								PED	Jan 10, 2007
								PED	Jul 14, 2007

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OLANZAPINE - ZYPREXA ZYDIS					
021086 003	5229382	Apr 23, 2011	U-324	I-400	Jul 10, 2006
	5229382*PED	Oct 23, 2011		I-417	Jan 14, 2007
				PED	Jan 10, 2007
				PED	Jul 14, 2007
OLANZAPINE - ZYPREXA ZYDIS					
021086 004	5229382	Apr 23, 2011	U-324	I-400	Jul 10, 2006
	5229382*PED	Oct 23, 2011		I-417	Jan 14, 2007
				PED	Jan 10, 2007
				PED	Jul 14, 2007
ONDANSETRON - ONDANSETRON					
076506 001				PC	Jun 24, 2007
ONDANSETRON - ONDANSETRON					
076506 002				PC	Jun 24, 2007
ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE					
076183 001				PC	Jun 24, 2007
ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE					
076183 002				PC	Jun 24, 2007
ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE					
076183 003				PC	Jun 24, 2007
OXALIPLATIN - ELOXATIN					
021492 001				M-61	Jan 10, 2010
				PED	Jul 10, 2010
OXALIPLATIN - ELOXATIN					
021492 002				M-61	Jan 10, 2010
				PED	Jul 10, 2010
OXALIPLATIN - ELOXATIN					
021759 001	5420319	Aug 09, 2016	DS		
	5420319*PED	Feb 09, 2017			
OXALIPLATIN - ELOXATIN					
021759 002	5420319	Aug 09, 2016	DS		
	5420319*PED	Feb 09, 2017			
OXALIPLATIN - ELOXATIN					
021759 003	5290961	Jan 12, 2013	DS		
	5290961*PED	Jul 12, 2013			
	5338874	Apr 07, 2013	DS		
	5338874*PED	Oct 07, 2013			
	5420319	Aug 09, 2016	DS		
	5420319*PED	Feb 09, 2017			
	5716988	Aug 07, 2015	DP		
	5716988*PED	Feb 07, 2016			
OXCARBAZEPINE - TRILEPTAL					
021014 001	**>A>** 7037525	Feb 12, 2018	U-724		
	>A> 7037525*PED	Aug 12, 2018			
OXCARBAZEPINE - TRILEPTAL					
021014 002	**>A>** 7037525	Feb 12, 2018	U-724		
	>A> 7037525*PED	Aug 12, 2018			
OXCARBAZEPINE - TRILEPTAL					
021014 003	**>A>** 7037525	Feb 12, 2018	U-724		
	>A> 7037525*PED	Aug 12, 2018			
OXYBUTYNIN - OXYTROL					
021351 002	**>A>** 7179483	Apr 26, 2020	DS U-318		
PALIPERIDONE - INVEGA					
021999 001	5158952	Oct 27, 2009	DP U-90		
PALIPERIDONE - INVEGA					
021999 002	5158952	Oct 27, 2009	DP U-90		

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PALIPERIDONE - INVEGA					
021999 003	5158952	Oct 27, 2009	DP U-90		
PALIPERIDONE - INVEGA					
021999 004	5158952	Oct 27, 2009	DP U-90		
PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE					
077395 001				PC	Jun 10, 2007
PAROXETINE HYDROCHLORIDE - PAXIL CR					
020936 001	5789449	Jan 06, 2009	U-788		
	5789449*PED	Jul 06, 2009			
PAROXETINE HYDROCHLORIDE - PAXIL CR					
020936 002	5789449	Jan 06, 2009	U-788		
	5789449*PED	Jul 06, 2009			
PAROXETINE HYDROCHLORIDE - PAXIL CR					
020936 003	5789449	Jan 06, 2009	U-788		
	5789449*PED	Jul 06, 2009			
RISPERIDONE - RISPERDAL					
020272 001	**>A>** 4804663	Dec 29, 2007	U-90	**>A>** I-509	Oct 06, 2009
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-413	Dec 04, 2006
				>A> I-412	Dec 04, 2006
				>A> PED	Jun 04, 2007
				>A> PED	Jun 04, 2007
				>A> PED	Apr 06, 2010
RISPERIDONE - RISPERDAL					
020272 002	**>A>** 4804663	Dec 29, 2007	U-90	**>A>** I-509	Oct 06, 2009
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-413	Dec 04, 2006
				>A> I-412	Dec 04, 2006
				>A> PED	Jun 04, 2007
				>A> PED	Jun 04, 2007
				>A> PED	Apr 06, 2010
RISPERIDONE - RISPERDAL					
020272 003	**>A>** 4804663	Dec 29, 2007	U-90	**>A>** I-509	Oct 06, 2009
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-413	Dec 04, 2006
				>A> I-412	Dec 04, 2006
				>A> PED	Jun 04, 2007
				>A> PED	Jun 04, 2007
				>A> PED	Apr 06, 2010
RISPERIDONE - RISPERDAL					
020272 004	**>A>** 4804663	Dec 29, 2007	U-90	**>A>** I-509	Oct 06, 2009
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-413	Dec 04, 2006
				>A> I-412	Dec 04, 2006
				>A> PED	Jun 04, 2007
				>A> PED	Jun 04, 2007
				>A> PED	Apr 06, 2010
RISPERIDONE - RISPERDAL					
020272 005	**>A>** 4804663	Dec 29, 2007	U-90	**>A>** I-413	Dec 04, 2006
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-412	Dec 04, 2006
				>A> PED	Jun 04, 2007
				>A> PED	Jun 04, 2007
RISPERIDONE - RISPERDAL					
020272 007	**>A>** 4804663	Dec 29, 2007	U-90	**>A>** I-509	Oct 06, 2009
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-413	Dec 04, 2006
				>A> I-412	Dec 04, 2006
				>A> PED	Jun 04, 2007
				>A> PED	Jun 04, 2007
				>A> PED	Apr 06, 2010
RISPERIDONE - RISPERDAL					
020272 008	**>A>** 4804663	Dec 29, 2007	U-90	**>A>** I-509	Oct 06, 2009
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-413	Dec 04, 2006
				>A> I-412	Dec 04, 2006
				>A> PED	Jun 04, 2007
				>A> PED	Jun 04, 2007
				>A> PED	Apr 06, 2010

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RISPERIDONE - RISPERDAL					
020588 001	**>A>** 4804663	Dec 29, 2007	U-90	**>A>** I-509	Oct 06, 2009
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-413	Dec 04, 2006
	>A> 5453425	Jul 11, 2014		**>A>** I-412	Dec 04, 2006
	>A> 5453425*PED	Jan 11, 2015		**>A>** PED	Apr 06, 2010
	>A> 5616587	Jul 11, 2014		**>A>** PED	Jun 04, 2007
	>A> 5616587*PED	Jan 11, 2015		**>A>** PED	Jun 04, 2007
	>A> RE39181	Jul 11, 2014	DP		
	>A> RE39181*PED	Jan 11, 2015			
RISPERIDONE - RISPERDAL					
021444 001	**>A>** 4804663	Dec 29, 2007	DS DP U-516	**>A>** I-509	Oct 06, 2009
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-413	Dec 04, 2006
	>A> 5648093	Jul 15, 2014	DP	**>A>** I-412	Dec 04, 2006
	>A> 5648093*PED	Jan 15, 2015		**>A>** PED	Jun 04, 2007
	>A> 6224905	Jun 10, 2017	DP	**>A>** PED	Jun 04, 2007
	>A> 6244905*PED	Dec 10, 2017		**>A>** PED	Apr 06, 2010
RISPERIDONE - RISPERDAL					
021444 002	**>A>** 4804663	Dec 29, 2007	DS DP U-516	**>A>** I-509	Oct 06, 2009
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-413	Dec 04, 2006
	>A> 5648093	Jul 15, 2014	DP	**>A>** I-412	Dec 04, 2006
	>A> 5648093*PED	Jan 15, 2015		**>A>** PED	Jun 04, 2007
	>A> 6224905	Jun 10, 2017	DP	**>A>** PED	Jun 04, 2007
	>A> 6244905*PED	Dec 10, 2017		**>A>** PED	Apr 06, 2010
RISPERIDONE - RISPERDAL					
021444 003	**>A>** 4804663	Dec 29, 2007	DS DP U-516	**>A>** I-509	Oct 06, 2009
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-413	Dec 04, 2006
	>A> 5648093	Jul 15, 2014	DP	**>A>** I-412	Dec 04, 2006
	>A> 5648093*PED	Jan 15, 2015		**>A>** PED	Apr 06, 2010
	>A> 6224905	Jun 10, 2017	DP	**>A>** PED	Jun 04, 2007
	>A> 6244905*PED	Dec 10, 2017		**>A>** PED	Jun 04, 2007
RISPERIDONE - RISPERDAL					
021444 004	**>A>** 4804663	Dec 29, 2007	DS DP U-516	**>A>** I-509	Oct 06, 2009
	>A> 4804663	Dec 29, 2007	DS DP U-543	**>A>** I-413	Dec 04, 2006
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-412	Dec 04, 2006
	>A> 5648093	Jul 15, 2014	DP	**>A>** PED	Jun 04, 2007
	>A> 5648093*PED	Jan 15, 2015		**>A>** PED	Jun 04, 2007
	>A> 6224905	Jun 10, 2017	DP	**>A>** PED	Apr 06, 2010
	>A> 6244905*PED	Dec 10, 2017			
RISPERIDONE - RISPERDAL					
021444 005	**>A>** 4804663	Dec 29, 2007	DS DP U-516	**>A>** I-509	Oct 06, 2009
	>A> 4804663	Dec 29, 2007	DS DP U-543	**>A>** I-413	Dec 04, 2006
	>A> 4804663*PED	Jun 29, 2008		**>A>** I-412	Dec 04, 2006
	>A> 5648093	Jul 15, 2014	DP	**>A>** PED	Jun 04, 2007
	>A> 5648093*PED	Jan 15, 2015		**>A>** PED	Jun 04, 2007
	>A> 6224905	Jun 10, 2017	DP	**>A>** PED	Apr 06, 2010
	>A> 6244905*PED	Dec 10, 2017			

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RISPERIDONE - RISPERDAL CONSTA					
021346 001	**>A>** 4804663	Dec 29, 2007		**>A>** NDF	Oct 29, 2006
	>A> 4804663*PED	Jun 29, 2008		**>A>** PED	Apr 29, 2007
	>A> 5688801	Nov 18, 2014			
	>A> 5688801*PED	May 18, 2015			
	>A> 5770231	Nov 19, 2013			
	>A> 5770231*PED	May 19, 2014			
	>A> 5792477	May 02, 2017			
	>A> 5792477*PED	Nov 02, 2017			
	>A> 5916598	May 02, 2017			
	>A> 5916598*PED	Nov 02, 2017			
	>A> 5965168	Nov 19, 2013			
	>A> 5965168*PED	May 19, 2014			
	>A> 6110503	May 02, 2017			
	>A> 6110503*PED	Nov 02, 2017			
	>A> 6110921	Nov 19, 2013			
	>A> 6110921*PED	May 19, 2014			
	>A> 6194006	Dec 30, 2018			
	>A> 6194006*PED	Jun 30, 2019			
	>A> 6264987	May 19, 2020			
	>A> 6264987*PED	Nov 19, 2020			
	>A> 6368632	Nov 19, 2013	U-543		
	>A> 6368632*PED	May 19, 2014			
	>A> 6379703	Dec 30, 2018	DP		
	>A> 6379703*PED	Jun 30, 2019			
	>A> 6379704	May 19, 2020	DP		
	>A> 6379704*PED	Nov 19, 2020			
	>A> 6403114	May 02, 2017			
	>A> 6403114*PED	Nov 02, 2017			
	>A> 6534092	May 19, 2020	DP		
	>A> 6534092*PED	Nov 19, 2020			
	>A> 6596316	Dec 30, 2008	DP		
	>A> 6596316*PED	Jun 30, 2009			

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RISPERIDONE - RISPERDAL CONSTA					
021346 002	**>A>** 4804663	Dec 29, 2007		**>A>** NDF	Oct 29, 2006
	>A> 4804663*PED	Jun 29, 2008		**>A>** PED	Apr 29, 2007
	>A> 5688801	Nov 18, 2014			
	>A> 5688801*PED	May 18, 2015			
	>A> 5770231	Nov 19, 2013			
	>A> 5770231*PED	May 19, 2014			
	>A> 5792477	May 02, 2017			
	>A> 5792477*PED	Nov 02, 2017			
	>A> 5916598	May 02, 2017			
	>A> 5916598*PED	Nov 02, 2017			
	>A> 5965168	Nov 19, 2013			
	>A> 5965168*PED	May 19, 2014			
	>A> 6110503	May 02, 2017			
	>A> 6110503*PED	Nov 02, 2017			
	>A> 6110921	Nov 19, 2013			
	>A> 6110921*PED	May 19, 2014			
	>A> 6194006	Dec 30, 2018			
	>A> 6194006*PED	Jun 30, 2019			
	>A> 6264987	May 19, 2020			
	>A> 6264987*PED	Nov 19, 2020			
	>A> 6368632	Nov 19, 2013	U-543		
	>A> 6368632*PED	May 19, 2014			
	>A> 6379703	Dec 30, 2018	DP		
	>A> 6379703*PED	Jun 30, 2019			
	>A> 6379704	May 19, 2020	DP		
	>A> 6379704*PED	Nov 19, 2020			
	>A> 6403114	May 02, 2017			
	>A> 6403114*PED	Nov 02, 2017			
	>A> 6534092	May 19, 2020	DP		
	>A> 6534092*PED	Nov 19, 2020			
	>A> 6596316	Dec 30, 2008	DP		
	>A> 6596316*PED	Jun 30, 2009			

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RISPERIDONE - RISPERDAL CONSTA								
021346 003	>A>	4804663	Dec	29, 2007			>A> NDF	Oct 29, 2006
	>A>	4804663*PED	Jun	29, 2008			>A> PED	Apr 29, 2007
	>A>	5688801	Nov	18, 2014				
	>A>	5688801*PED	May	18, 2015				
	>A>	5770231	Nov	19, 2013				
	>A>	5770231*PED	May	19, 2014				
	>A>	5792477	May	02, 2017				
	>A>	5792477*PED	Nov	02, 2017				
	>A>	5916598	May	02, 2017				
	>A>	5916598*PED	Nov	02, 2017				
	>A>	5965168	Nov	19, 2013				
	>A>	5965168*PED	May	19, 2014				
	>A>	6110503	May	02, 2017				
	>A>	6110503*PED	Nov	02, 2017				
	>A>	6110921	Nov	19, 2013				
	>A>	6110921*PED	May	19, 2014				
	>A>	6194006	Dec	30, 2018				
	>A>	6194006*PED	Jun	30, 2019				
	>A>	6264987	May	19, 2020				
	>A>	6264987*PED	Nov	19, 2020				
	>A>	6368632	Nov	19, 2013		U-543		
	>A>	6368632*PED	May	19, 2014				
	>A>	6379703	Dec	30, 2018	DP			
	>A>	6379703*PED	Jun	30, 2019				
	>A>	6379704	May	19, 2020	DP			
	>A>	6379704*PED	Nov	19, 2020				
	>A>	6403114	May	02, 2017				
	>A>	6403114*PED	Nov	02, 2017				
	>A>	6534092	May	19, 2020	DP			
	>A>	6534092*PED	Nov	19, 2020				
	>A>	6596316	Dec	30, 2008	DP			
	>A>	6596316*PED	Jun	30, 2009				
SELEGILINE - EMSAM								
021336 001		7150881	Jun	12, 2018	DS	DP		
SELEGILINE - EMSAM								
021336 002		7150881	Jun	12, 2018	DS	DP		
SELEGILINE - EMSAM								
021336 003		7150881	Jun	12, 2018	DS	DP		
SOMATROPIN RECOMBINANT - SAIZEN								
019764 005							I-440	Aug 26, 2007
TERIPARATIDE RECOMBINANT HUMAN - FORTEO								
021318 001		7163684	Aug	19, 2019		U-790		
THALIDOMIDE - THALOMID								
020785 004	>A>	5629327	May	13, 2014		U-731	>A> ODE	May 23, 2013
	>A>	6045501	Aug	28, 2018		U-731		
	>A>	6235756	Mar	01, 2013		U-731		
	>A>	6315720	Oct	23, 2020		U-731		
	>A>	6561976	Aug	28, 2018		U-731		
	>A>	6561977	Oct	23, 2020		U-731		
	>A>	6755784	Oct	23, 2020		U-731		
	>A>	6869399	Oct	23, 2020		U-731		
	>A>	6908432	Aug	28, 2018		U-731		
	>A>	7141018	Oct	23, 2020		U-731		
TIMOLOL MALEATE - TIMOLOL MALEATE								
020963 001	>A>	6174524	Mar	26, 2019				
	>A>	6174524*PED	Sep	26, 2019				

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TIMOLOL MALEATE - TIMOLOL MALEATE					
020963 002	**>A>** 6174524	Mar 26, 2019			
	>A> 6174524*PED	Sep 26, 2019			
ZIPRASIDONE HYDROCHLORIDE - GEODON					
021483 001	**>A>** 7175855	May 18, 2020	DP		

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