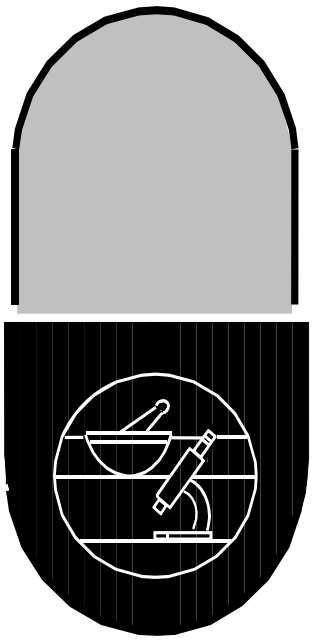
CUMULATIVE SUPPLEMENT 02
February 2009



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

29th EDITION

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

2009

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

APPROVED DRUG PRODUCTS
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Cumulative Supplement 2

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1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 28th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to mark to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement. Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 29th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 30th Edition. The current edition

Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >**A**>. The Patent and Exclusivity List new additions are indicated by the symbol **>A>** to the left of Patent Number or Exclusivity Code. The **>A>** symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol **>D>** (DELETE) to the left of the line. The information line with the **>D>** symbol is dropped in subsequent Cumulative Supplements for that item.

The Patent and Exclusivity List is arranged in alphabetical order by active ingredient name(s) and trade name. The trade name will follow the active ingredient name separated by a dash symbol. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Drug substance and drug product patents are indicated as such with DS or DP in the Patent codes column. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms, Section B, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Refer to Section 1.3 for internet access to the most current list of Patent and Exclusivity terms.

1.2 CUMULATIVE SUPPLEMENT CONTENT

Since February 2005, we have been providing daily Electronic Orange Book (EOB) product information for new generic drug approvals. Daily generic updates provide the consumer with the current list of approved generic products which is important for substitution purposes. Previously, a first-time-generic product approved early in the month would not be published in the Cumulative Supplement (CS) for several weeks.

The CS monthly update publish goal is by the end of the following month’s second work week (e.g., November’s supplement will be updated by the end of the second full work week in December).

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.
- All product changes received and processed as of the date of publication.
  - o Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
  - o Discontinued products will be processed as of the date of publication. There will be circumstances where a product is discontinued in one month, however, it will be reported in a different month's CS. For example, the Orange Book Staff received a letter November 7 that the product has been discontinued from manufacturing and marketing. The Orange Book subsequently publishes the October CS on November 14. The product will show in the October CS that it is discontinued even though the date of discontinuance is the day that the Orange Book Staff receives notification (November 7).

- New Drug Application (NDA) approvals (20,000 and 50,000 series) appear in the CS month they were approved.

- Patent information, also updated daily in the EOB, is current to the date of publication.
- Exclusivity information is updated monthly and current to the date of publication.

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at drugproducts@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)
DABUR ONCOLOGY PLC (DABUR ONCOLOGY PLC)	FRESENIUS KABI ONCOLOGY PLC (FRESENIUS KABI ONCOL)

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://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 2008	MAR 2009	JUN 2009	SEPT 2009
DRUG PRODUCTS LISTED	12751			
SINGLE SOURCE	2433 (19.1%)			
MULTISOURCE	10229 (80.2%)			
THERAPEUTICALLY EQUIVALENT	10072 (79.0%)			
NOT THERAPEUTICALLY EQUIVALENT	157 (1.2%)			
EXCEPTIONS[1]	89 (0.7%)			
NEW MOLECULAR ENTITIES APPROVED	15			
NUMBER OF APPLICANTS	719			

[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.

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

>D>		HYDROCET						
>D>		@ MALLINCKRODT	500MG;5MG	N89006	001	Aug 09, 1985	Feb	CTNA
>A>		HYDROCODONE BITARTRATE AND ACETAMINOPHEN						
>A>		@ MALLINCKRODT	500MG;5MG	N89006	001	Aug 09, 1985	Feb	CTNA

ALBUTEROL

AEROSOL, METERED; INHALATION

		ALBUTEROL						
		@ ARMSTRONG PHARMS	0.09MG/INH	N72273	001	Aug 14, 1996	Jan	DISC

ALBUTEROL SULFATE

SOLUTION; INHALATION

		ALBUTEROL SULFATE						
AN		HOLOPACK INTL	EQ 0.083% BASE	N77839	001	Dec 16, 2008	Jan	CAHN

AMILORIDE HYDROCHLORIDE

TABLET; ORAL

		AMILORIDE HYDROCHLORIDE						
AB	+	PAR PHARM	5MG	N70346	001	Jan 22, 1986	Jan	CTEC
AB		SIGMAPHARM LABS LLC	5MG	N79133	001	Jan 30, 2009	Jan	NEWA

AMINOCAPROIC ACID

TABLET; ORAL

		AMICAR						
		XANODYNE PHARM	1GM	N15197	002	Jun 24, 2004	Jan	NEWA

AMLODIPINE BESYLATE

TABLET; ORAL

		AMLODIPINE BESYLATE						
AB		SYNTHON PHARMS	EQ 2.5MG BASE	N77080	001	Jun 27, 2007	Jan	CAHN
AB			EQ 5MG BASE	N77080	002	Jun 27, 2007	Jan	CAHN
AB			EQ 10MG BASE	N77080	003	Jun 27, 2007	Jan	CAHN

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL

		AMOXICILLIN AND CLAVULANATE POTASSIUM						
>A>	AB	APOTEX	250MG;EQ 125MG BASE	N65333	001	Feb 24, 2009	Feb	NEWA
>A>	AB		500MG;EQ 125MG BASE	N65333	002	Feb 24, 2009	Feb	NEWA

APRACLONIDINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

>A>		APRACLONIDINE HYDROCHLORIDE						
>A>	AT	AKORN INC	EQ 0.5% BASE	N77764	001	Mar 12, 2009	Feb	NEWA
		IOPIDINE						
>D>	+	ALCON	EQ 0.5% BASE	N20258	001	Jul 30, 1993	Feb	CFTG
>A>	AT	+	EQ 0.5% BASE	N20258	001	Jul 30, 1993	Feb	CFTG

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

		ORPHENGESIC						
		@ SOLCO HLTHCARE	385MG;30MG;25MG	N75141	001	May 29, 1998	Jan	CAHN

TABLET; ORAL
ORPHENGESIC FORTE
@ SOLCO HLTHCARE 770MG;60MG;50MG N75141 002 May 29, 1998 Jan CAHN

ATRACURIUM BESYLATE

INJECTABLE; INJECTION
ATRACURIUM BESYLATE
@ HOSPIRA 10MG/ML N74740 001 Mar 28, 1997 Jan DISC
ATRACURIUM BESYLATE PRESERVATIVE FREE
@ HOSPIRA 10MG/ML N74741 001 Mar 28, 1997 Jan DISC

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL
BUSPAR
>D> AB BRISTOL MYERS SQUIBB 15MG N18731 003 Apr 22, 1996 Feb CRLD
>A> AB + 15MG N18731 003 Apr 22, 1996 Feb CRLD
>D> AB + 30MG N18731 004 Apr 22, 1996 Feb DISC
>A> @ 30MG N18731 004 Apr 22, 1996 Feb DISC
BUSPIRONE HYDROCHLORIDE
>A> AB DR REDDYS LABS LTD 5MG N78246 001 Feb 27, 2009 Feb NEWA
>A> AB 10MG N78246 002 Feb 27, 2009 Feb NEWA
>A> AB 15MG N78246 003 Feb 27, 2009 Feb NEWA
>A> AB 30MG N78246 004 Feb 27, 2009 Feb NEWA

CALCITRIOL

OINTMENT; TOPICAL
VECTICAL
+ GALDERMA LABS LP 3UGM/GM N22087 001 Jan 23, 2009 Jan NEWA

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL
CARBAMAZEPINE
AB TORRENT PHARMS 100MG N75712 001 Jul 05, 2001 Jan CAHN

CARBOPLATIN

INJECTABLE; IV (INFUSION)
CARBOPLATIN
>A> AP PHARMACHEMIE BV EQ 50MG/5ML (10MG/ML) N77679 001 Feb 25, 2009 Feb NEWA
>A> AP EQ 450MG/45ML (10MG/ML) N77679 003 Feb 25, 2009 Feb NEWA
>A> AP EQ 150MG/15ML (10MG/ML) N77679 002 Feb 25, 2009 Feb NEWA

CHOLINE FENOFIBRATE

CAPSULE, DELAYED RELEASE; ORAL
TRILIPIX
ABBOTT LABS EQ 45MG FENOFIBRIC ACID N22224 001 Dec 15, 2008 Jan CTNA
+ EQ 135MG FENOFIBRIC ACID N22224 002 Dec 15, 2008 Jan CTNA

CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL
CIPROFLOXACIN HYDROCHLORIDE
@ TEVA EQ 250MG BASE N76136 001 Jun 09, 2004 Jan DISC
@ EQ 500MG BASE N76136 002 Jun 09, 2004 Jan DISC
@ EQ 750MG BASE N76136 003 Jun 09, 2004 Jan DISC

CITALOPRAM HYDROBROMIDE

TABLET; ORAL

CITALOPRAM HYDROBROMIDE

>D>	AB	AKYMA PHARMS	EQ 10MG BASE	N77045	003	Apr 29, 2005	Feb	CAHN
>D>	AB		EQ 20MG BASE	N77045	002	Apr 29, 2005	Feb	CAHN
>D>	AB		EQ 40MG BASE	N77045	001	Apr 29, 2005	Feb	CAHN
>A>	AB	AMNEAL PHARMS	EQ 10MG BASE	N77045	003	Apr 29, 2005	Feb	CAHN
>A>	AB		EQ 20MG BASE	N77045	002	Apr 29, 2005	Feb	CAHN
>A>	AB		EQ 40MG BASE	N77045	001	Apr 29, 2005	Feb	CAHN
>A>	AB	GLENMARK GENERICS	EQ 10MG BASE	N77654	001	Feb 27, 2009	Feb	NEWA
>A>	AB		EQ 20MG BASE	N77654	002	Feb 27, 2009	Feb	NEWA
>A>	AB		EQ 40MG BASE	N77654	003	Feb 27, 2009	Feb	NEWA

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

CYTOXAN

>A>		@ BAXTER HLTHCARE	100MG/VIAL	N12142	001		Feb	CAHN
>A>		@	200MG/VIAL	N12142	002		Feb	CAHN
>A>		@	500MG/VIAL	N12142	003		Feb	CAHN
>A>		@	1GM/VIAL	N12142	004	Aug 30, 1982	Feb	CAHN
>A>		@	2GM/VIAL	N12142	005	Aug 30, 1982	Feb	CAHN
>D>		@ BRISTOL MYERS SQUIBB	100MG/VIAL	N12142	001		Feb	CAHN
>D>		@	200MG/VIAL	N12142	002		Feb	CAHN
>D>		@	500MG/VIAL	N12142	003		Feb	CAHN
>D>		@	1GM/VIAL	N12142	004	Aug 30, 1982	Feb	CAHN
>D>		@	2GM/VIAL	N12142	005	Aug 30, 1982	Feb	CAHN

LYOPHILIZED CYTOXAN

>A>	+	BAXTER HLTHCARE	100MG/VIAL	N12142	006	Dec 05, 1985	Feb	CAHN
>A>	+		200MG/VIAL	N12142	007	Dec 10, 1985	Feb	CAHN
>A>	AP +		500MG/VIAL	N12142	008	Jan 04, 1984	Feb	CAHN
>A>	AP +		1GM/VIAL	N12142	010	Sep 24, 1985	Feb	CAHN
>A>	AP +		2GM/VIAL	N12142	009	Dec 10, 1984	Feb	CAHN
>D>	+	BRISTOL MYERS SQUIBB	100MG/VIAL	N12142	006	Dec 05, 1985	Feb	CAHN
>D>	+		200MG/VIAL	N12142	007	Dec 10, 1985	Feb	CAHN
>D>	AP +		500MG/VIAL	N12142	008	Jan 04, 1984	Feb	CAHN
>D>	AP +		1GM/VIAL	N12142	010	Sep 24, 1985	Feb	CAHN
>D>	AP +		2GM/VIAL	N12142	009	Dec 10, 1984	Feb	CAHN

TABLET; ORAL

CYTOXAN

>A>		@ BAXTER HLTHCARE	25MG	N12141	002		Feb	CAHN
>A>		@	50MG	N12141	001		Feb	CAHN
>D>		@ BRISTOL MYERS SQUIBB	25MG	N12141	002		Feb	CAHN
>D>		@	50MG	N12141	001		Feb	CAHN

DESOGESTREL; ETHINYL ESTRADIOL

>D> TABLET; ORAL-21

>D> DESOGESTREL AND ETHINYL ESTRADIOL

>D>		DURAMED PHARMS BARR	0.15MG;0.03MG	N75256	001	Aug 12, 1999	Feb	DISC
>A>		@	0.15MG;0.03MG	N75256	001	Aug 12, 1999	Feb	DISC

DEXAMETHASONE; TOBRAMYCIN

SUSPENSION/DROPS; OPHTHALMIC

>A> TOBRADEX ST

>A>	+	ALCON	0.05%;0.3%	N50818	001	Feb 13, 2009	Feb	NEWA

DEXLANSOPRAZOLE

CAPSULE, DELAYED RELEASE; ORAL

KAPIDEX

			TAKEDA PHARMS	30MG	N22287	001	Jan 30, 2009	Jan	NEWA
		+		60MG	N22287	002	Jan 30, 2009	Jan	NEWA

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HYDROCHLORIDE

>D>	AB		COREPHARMA	25MG	N40828	001	Nov 05, 2008	Feb	CTEC
>A>	AA			25MG	N40828	001	Nov 05, 2008	Feb	CTEC

TENUATE

>D>	AB	+	WATSON PHARMS	25MG	N11722	002		Feb	CTEC
>A>	AA	+		25MG	N11722	002		Feb	CTEC

DIVALPROEX SODIUM

CAPSULE, DELAYED REL PELLETS; ORAL

DEPAKOTE

	AB	+	ABBOTT	EQ 125MG VALPROIC ACID	N19680	001	Sep 12, 1989	Jan	CFTG

DIVALPROEX SODIUM

	AB		DR REDDYS LABS LTD	EQ 125MG VALPROIC ACID	N78979	001	Jan 23, 2009	Jan	NEWA
	AB		ZYDUS PHARMS USA INC	EQ 125MG VALPROIC ACID	N78919	001	Jan 27, 2009	Jan	NEWA

TABLET, DELAYED RELEASE; ORAL

DIVALPROEX SODIUM

>A>	AB		ZYDUS PHARMS USA INC	EQ 125MG VALPROIC ACID	N77100	001	Mar 05, 2009	Feb	NEWA
>A>	AB			EQ 250MG VALPROIC ACID	N77100	002	Mar 05, 2009	Feb	NEWA
>A>	AB			EQ 500MG VALPROIC ACID	N77100	003	Mar 05, 2009	Feb	NEWA

TABLET, EXTENDED RELEASE; ORAL

DEPAKOTE ER

	AB		ABBOTT	EQ 250MG VALPROIC ACID	N21168	002	May 31, 2002	Jan	CFTG
	AB	+		EQ 500MG VALPROIC ACID	N21168	001	Aug 04, 2000	Jan	CFTG

DIVALPROEX SODIUM

>A>	AB		ANCHEN PHARMS	EQ 250MG VALPROIC ACID	N78445	001	Feb 26, 2009	Feb	NEWA
	AB		MYLAN	EQ 250MG VALPROIC ACID	N77567	001	Jan 29, 2009	Jan	NEWA
	AB			EQ 500MG VALPROIC ACID	N77567	002	Jan 29, 2009	Jan	NEWA
	AB		WOCKHARDT	EQ 250MG VALPROIC ACID	N78705	002	Feb 10, 2009	Jan	NEWA
>A>	AB		ZYDUS PHARMS USA INC	EQ 250MG VALPROIC ACID	N78239	001	Feb 27, 2009	Feb	NEWA

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

		+	PAR PHARM	EQ 150MG BASE	N65055	003	Jul 15, 2005	Jan	CRLD

ENALAPRILAT

INJECTABLE; INJECTION

ENALAPRILAT

>D>	AP		HOSPIRA	1.25MG/ML	N75458	001	Aug 22, 2000	Feb	CRLD
>A>	AP	+		1.25MG/ML	N75458	001	Aug 22, 2000	Feb	CRLD
>D>			VASOTEC						
>D>	AP	+	BIOVAIL LABS INTL	1.25MG/ML	N19309	001	Feb 09, 1988	Feb	DISC
>A>			@	1.25MG/ML	N19309	001	Feb 09, 1988	Feb	DISC

ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYL

GRANULE; ORAL

			ERYZOLE						
			@ ALRA	EQ 200MG BASE/5ML;EQ 600MG BASE/5ML	N62758	001	Jun 15, 1988	Jan	DISC
			PEDIAZOLE						
			@ ROSS LABS	EQ 200MG BASE/5ML;EQ 600MG BASE/5ML	N50529	001		Jan	DISC

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION

			ERYTHROCIN						
>D>	AP	+	HOSPIRA	EQ 1GM BASE/VIAL	N50182	003		Feb	DISC
>A>			@	EQ 1GM BASE/VIAL	N50182	003		Feb	DISC
>D>	AP			EQ 1GM BASE/VIAL	N62638	002	Oct 31, 1986	Feb	CRLD
>A>	AP	+		EQ 1GM BASE/VIAL	N62638	002	Oct 31, 1986	Feb	CRLD

ETOPOSIDE

CAPSULE; ORAL

			ETOPOSIDE						
>D>	AB		GENPHARM	50MG	N75635	001	Sep 19, 2001	Feb	CRLD
>A>		+		50MG	N75635	001	Sep 19, 2001	Feb	CRLD
>D>			VEPESID						
>D>	AB	+	BRISTOL MYERS SQUIBB	50MG	N19557	001	Dec 30, 1986	Feb	DISC
>A>			@	50MG	N19557	001	Dec 30, 1986	Feb	DISC

>A> FEBUXOSTAT

>A> TABLET; ORAL

>A>			ULORIC						
>A>			TAKEDA PHARMS	40MG	N21856	001	Feb 13, 2009	Feb	NEWA
>A>		+		80MG	N21856	002	Feb 13, 2009	Feb	NEWA

FENOPROFEN CALCIUM

CAPSULE; ORAL

			NALFON						
>D>		+	PEDINOL	EQ 300MG BASE	N17604	002		Feb	DISC
>A>			@	EQ 300MG BASE	N17604	002		Feb	DISC
			NALFON 200						
>D>			PEDINOL	EQ 200MG BASE	N17604	003		Feb	CRLD
>A>		+		EQ 200MG BASE	N17604	003		Feb	CRLD

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION

			FLUDARABINE PHOSPHATE						
>A>	AP		ACTAVIS TOTOWA	50MG/VIAL	N78610	001	Feb 11, 2009	Feb	NEWA

FLUOCINOLONE ACETONIDE

OIL; TOPICAL

			DERMA-SMOOTHE/FS						
>A>		+	HILL DERMAC	0.01%	N19452	002	Nov 09, 2005	Feb	NEWA

FLUOROURACIL

SOLUTION; TOPICAL

			FLUOROPLEX						
>D>			@ ALLERGAN HERBERT	1%	N16765	001		Feb	CAHN

SOLUTION; TOPICAL
FLUOROPLEX
>A> @ ELORAC 1% N16765 001 Feb CAHN

FOSINOPRIL SODIUM; HYDROCHLOROTHIAZIDE

TABLET; ORAL
>D> MONOPRIL-HCT
>D> AB BRISTOL MYERS SQUIBB 10MG;12.5MG N20286 002 Nov 30, 1994 Feb DISC
>A> @ 10MG;12.5MG N20286 002 Nov 30, 1994 Feb DISC
>D> AB + 20MG;12.5MG N20286 001 Nov 30, 1994 Feb DISC
>A> @ 20MG;12.5MG N20286 001 Nov 30, 1994 Feb DISC

GALANTAMINE HYDROBROMIDE

SOLUTION; ORAL
GALANTAMINE HYDROBROMIDE
AA ROXANE 4MG/ML N78185 001 Jan 30, 2009 Jan NEWA
RAZADYNE
AA + ORTHO MCNEIL JANSSEN 4MG/ML N21224 001 Jun 22, 2001 Jan CFTG

TABLET; ORAL
GALANTAMINE HYDROBROMIDE
AB PAR PHARM EQ 4MG BASE N77604 001 Feb 06, 2009 Jan NEWA
AB EQ 8MG BASE N77604 002 Feb 06, 2009 Jan NEWA
AB EQ 12MG BASE N77604 003 Feb 06, 2009 Jan NEWA
AB ROXANE EQ 4MG BASE N77608 001 Feb 11, 2009 Jan NEWA
AB EQ 8MG BASE N77608 002 Feb 11, 2009 Jan NEWA
AB EQ 12MG BASE N77608 003 Feb 11, 2009 Jan NEWA

GLYCOPYRROLATE

TABLET; ORAL
GLYCOPYRROLATE
>A> AA WEST WARD 1MG N40836 001 Mar 05, 2009 Feb NEWA
>A> AA 2MG N40836 002 Mar 05, 2009 Feb NEWA

GRANISETRON HYDROCHLORIDE

TABLET; ORAL
GRANISETRON HYDROCHLORIDE
>A> AB DR REDDYS LABS LTD EQ 1MG BASE N78846 001 Feb 27, 2009 Feb NEWA

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL
>D> HYCODAN
>D> AA + ENDO PHARMS 1.5MG/5ML;5MG/5ML N05213 002 Jul 26, 1988 Feb DISC
>A> @ 1.5MG/5ML;5MG/5ML N05213 002 Jul 26, 1988 Feb DISC
HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE
>D> AA HI TECH PHARMA 1.5MG/5ML;5MG/5ML N40613 001 Feb 08, 2008 Feb CRLD
>A> AA + 1.5MG/5ML;5MG/5ML N40613 001 Feb 08, 2008 Feb CRLD

TABLET; ORAL
>D> HYCODAN
>D> AA + ENDO PHARMS 1.5MG;5MG N05213 001 Jul 26, 1988 Feb DISC
>A> @ 1.5MG;5MG N05213 001 Jul 26, 1988 Feb DISC
TUSSIGON
>D> AA KING PHARMS 1.5MG;5MG N88508 001 Jul 30, 1985 Feb CRLD
>A> AA + 1.5MG;5MG N88508 001 Jul 30, 1985 Feb CRLD

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

TABLET; ORAL
QUINAPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>A>	AB	RANBAXY	12.5MG;EQ 10MG BASE	N78211	001	Mar 04, 2009	Feb	NEWA
>A>	AB		12.5MG;EQ 20MG BASE	N78211	002	Mar 04, 2009	Feb	NEWA
>A>	AB		25MG;EQ 20MG BASE	N78211	003	Mar 04, 2009	Feb	NEWA

>D> HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE

>D> SUSPENSION; OPHTHALMIC
>D> TERRA-CORTRIL

>A>		@ PFIZER	1.5%;EQ 5MG BASE/ML	N61016	001		Feb	DISC

>D> SUSPENSION/DROPS; OPHTHALMIC
>D> TERRA-CORTRIL

>D>		+ PFIZER	1.5%;EQ 5MG BASE/ML	N61016	001		Feb	DISC

HYDROXYUREA

CAPSULE; ORAL
HYDROXYUREA

>D>		@ BARR	500MG	N75143	001	Oct 16, 1998	Feb	CMFD
>A>	AB		500MG	N75143	001	Oct 16, 1998	Feb	CMFD

IBUPROFEN

TABLET; ORAL
IBUPROFEN

>D>	AB	DR REDDYS LA	800MG	N75682	003	Nov 14, 2001	Feb	CRLD
>A>	AB	+	800MG	N75682	003	Nov 14, 2001	Feb	CRLD
	AB	SHASUN USA	400MG	N78329	001	Feb 05, 2009	Jan	NEWA
	AB		600MG	N78329	002	Feb 05, 2009	Jan	NEWA
	AB		800MG	N78329	003	Feb 05, 2009	Jan	NEWA
>D>		MOTRIN						
>A>		@ MCNEIL CONS	400MG	N17463	002		Feb	DISC
>A>		@	600MG	N17463	004		Feb	DISC
>A>		@	800MG	N17463	005	May 22, 1985	Feb	DISC
>D>	AB	MCNEIL CONSUMER	400MG	N17463	002		Feb	DISC
>D>	AB		600MG	N17463	004		Feb	DISC
>D>	AB	+	800MG	N17463	005	May 22, 1985	Feb	DISC

IFOSFAMIDE

INJECTABLE; INJECTION
IFEX

>A>		@ BAXTER HLTHCARE	1GM/VIAL	N19763	001	Dec 30, 1988	Feb	CAHN
>A>		@	3GM/VIAL	N19763	002	Dec 30, 1988	Feb	CAHN
>D>		@ BRISTOL MYERS SQUIBB	1GM/VIAL	N19763	001	Dec 30, 1988	Feb	CAHN
>D>		@	3GM/VIAL	N19763	002	Dec 30, 1988	Feb	CAHN

IFOSFAMIDE; MESNA

INJECTABLE; INJECTION
IFEX/MESNEX KIT

>A>		+ BAXTER HLTHCARE	1GM/VIAL;100MG/ML	N19763	003	Oct 10, 1992	Feb	CAHN
>A>		+	3GM/VIAL;100MG/ML	N19763	004	Oct 10, 1992	Feb	CAHN
>D>		+ BRISTOL MYERS SQUIBB	1GM/VIAL;100MG/ML	N19763	003	Oct 10, 1992	Feb	CAHN
>D>		+	3GM/VIAL;100MG/ML	N19763	004	Oct 10, 1992	Feb	CAHN

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

INDOCIN SR

>D>		+	SANDOZ	75MG	N74464	001	May 28, 1998	Feb	CTEC
>A>	AB	+		75MG	N74464	001	May 28, 1998	Feb	CTEC

INDOMETHACIN

>A>	AB		AVANTHI INC	75MG	N79175	001	Mar 06, 2009	Feb	NEWA

INSULIN GLULISINE RECOMBINANT

INJECTABLE; SUBCUTANEOUS

APIDRA SOLOSTAR

>A>			SANOFI AVENTIS US	300 UNITS/3ML	N21629	003	Feb 24, 2009	Feb	NEWA

IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION

IRINOTECAN HYDROCHLORIDE

	AP		PHARMAFORCE	40MG/2ML(20MG/ML)	N90016	001	Jan 28, 2009	Jan	NEWA
	AP			100MG/5ML(20MG/ML)	N90016	002	Jan 28, 2009	Jan	NEWA

KETOCONAZOLE

GEL; TOPICAL

XOLEGEL

		+	STIEFEL LABS INC	2%	N21946	001	Jul 28, 2006	Jan	CAHN

LAMOTRIGINE

TABLET; ORAL

LAMOTRIGINE

	AB		APOTEX INC	25MG	N78625	001	Jan 27, 2009	Jan	NEWA
	AB			100MG	N78625	002	Jan 27, 2009	Jan	NEWA
	AB			150MG	N78625	003	Jan 27, 2009	Jan	NEWA
	AB			200MG	N78625	004	Jan 27, 2009	Jan	NEWA
	AB		AUROBINDO PHARMA	25MG	N78956	001	Jan 27, 2009	Jan	NEWA
	AB			100MG	N78956	002	Jan 27, 2009	Jan	NEWA
	AB			150MG	N78956	003	Jan 27, 2009	Jan	NEWA
	AB			200MG	N78956	004	Jan 27, 2009	Jan	NEWA
	AB		CADISTA PHARMS	25MG	N79132	001	Jan 27, 2009	Jan	NEWA
	AB			100MG	N79132	002	Jan 27, 2009	Jan	NEWA
	AB			150MG	N79132	003	Jan 27, 2009	Jan	NEWA
	AB			200MG	N79132	004	Jan 27, 2009	Jan	NEWA
	AB		DR REDDYS LABS LTD	25MG	N76708	001	Jan 27, 2009	Jan	NEWA
	AB			100MG	N76708	002	Jan 27, 2009	Jan	NEWA
	AB			150MG	N76708	003	Jan 27, 2009	Jan	NEWA
	AB			200MG	N76708	004	Jan 27, 2009	Jan	NEWA
	AB		GENPHARM ULC	25MG	N77428	001	Jan 27, 2009	Jan	NEWA
	AB			100MG	N77428	002	Jan 27, 2009	Jan	NEWA
	AB			150MG	N77428	003	Jan 27, 2009	Jan	NEWA
	AB			200MG	N77428	004	Jan 27, 2009	Jan	NEWA
	AB		MATRIX LABS LTD	25MG	N78443	001	Feb 11, 2009	Jan	NEWA
	AB			100MG	N78443	002	Feb 11, 2009	Jan	NEWA
	AB			150MG	N78443	003	Feb 11, 2009	Jan	NEWA
	AB			200MG	N78443	004	Feb 11, 2009	Jan	NEWA
	AB		MYLAN	25MG	N77420	001	Jan 27, 2009	Jan	NEWA
	AB			100MG	N77420	002	Jan 27, 2009	Jan	NEWA
	AB			150MG	N77420	003	Jan 27, 2009	Jan	NEWA
	AB			200MG	N77420	004	Jan 27, 2009	Jan	NEWA

TABLET; ORAL
LAMOTRIGINE

AB	ROXANE	25MG	N77392	001	Jan 27, 2009	Jan	NEWA
AB		100MG	N77392	002	Jan 27, 2009	Jan	NEWA
AB		150MG	N77392	003	Jan 27, 2009	Jan	NEWA
AB		200MG	N77392	004	Jan 27, 2009	Jan	NEWA
AB	SANDOZ	25MG	N78645	001	Jan 27, 2009	Jan	NEWA
AB		100MG	N78645	002	Jan 27, 2009	Jan	NEWA
AB		150MG	N78645	003	Jan 27, 2009	Jan	NEWA
AB		200MG	N78645	004	Jan 27, 2009	Jan	NEWA
AB	TARO PHARM INDS	25MG	N78525	001	Jan 27, 2009	Jan	NEWA
AB		100MG	N78525	002	Jan 27, 2009	Jan	NEWA
AB		150MG	N78525	003	Jan 27, 2009	Jan	NEWA
AB		200MG	N78525	004	Jan 27, 2009	Jan	NEWA
AB	TORRENT PHARMS	25MG	N78947	001	Jan 27, 2009	Jan	NEWA
AB		100MG	N78947	002	Jan 27, 2009	Jan	NEWA
AB		150MG	N78947	003	Jan 27, 2009	Jan	NEWA
AB		200MG	N78947	004	Jan 27, 2009	Jan	NEWA
AB	UPSHER SMITH	25MG	N78310	001	Feb 04, 2009	Jan	NEWA
AB		100MG	N78310	002	Feb 04, 2009	Jan	NEWA
AB		150MG	N78310	003	Feb 04, 2009	Jan	NEWA
AB		200MG	N78310	004	Feb 04, 2009	Jan	NEWA
AB	WOCKHARDT	25MG	N78982	001	Jan 27, 2009	Jan	NEWA
AB		100MG	N78982	002	Jan 27, 2009	Jan	NEWA
AB		150MG	N78982	003	Jan 27, 2009	Jan	NEWA
AB		200MG	N78982	004	Jan 27, 2009	Jan	NEWA
AB	ZYDUS PHARMS USA	25MG	N77633	001	Jan 27, 2009	Jan	NEWA
		50MG	N77633	002	Jan 27, 2009	Jan	NEWA
AB		100MG	N77633	003	Jan 27, 2009	Jan	NEWA
AB		150MG	N77633	004	Jan 27, 2009	Jan	NEWA
AB		200MG	N77633	005	Jan 27, 2009	Jan	NEWA
		250MG	N77633	006	Jan 27, 2009	Jan	NEWA

TABLET, CHEWABLE; ORAL
LAMOTRIGINE

>A> AB	GLENMARK GENERICS	5MG	N79099	001	Feb 19, 2009	Feb	NEWA
>A> AB		25MG	N79099	002	Feb 19, 2009	Feb	NEWA
AB	TARO	5MG	N79204	001	Feb 04, 2009	Jan	NEWA
AB		25MG	N79204	002	Feb 04, 2009	Jan	NEWA

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LEUPROLIDE ACETATE

>A> AP	SUN PHARMA GLOBAL	1MG/0.2ML	N78885	001	Mar 09, 2009	Feb	NEWA

LEVETIRACETAM

SOLUTION; ORAL
LEVETIRACETAM

AA	TARO	100MG/ML	N78774	001	Feb 10, 2009	Jan	NEWA

TABLET; ORAL
LEVETIRACETAM

AB	GENPHARM ULC	250MG	N78731	001	Feb 10, 2009	Jan	NEWA
AB		500MG	N78731	002	Feb 10, 2009	Jan	NEWA
AB		750MG	N78731	003	Feb 10, 2009	Jan	NEWA
AB		1GM	N78731	004	Feb 10, 2009	Jan	NEWA
AB	SOLCO HLTHCARE	250MG	N78106	001	Feb 10, 2009	Jan	NEWA
AB		500MG	N78106	002	Feb 10, 2009	Jan	NEWA

TABLET; ORAL
LEVETIRACETAM

AB		SOLCO HLTHCARE	750MG	N78106	003	Feb 10, 2009	Jan	NEWA
AB			1GM	N78106	004	Feb 10, 2009	Jan	NEWA
>A> AB		WATSON LABS FLORIDA	250MG	N77408	001	Mar 02, 2009	Feb	NEWA
>A> AB			500MG	N77408	002	Mar 02, 2009	Feb	NEWA
>A> AB			750MG	N77408	003	Mar 02, 2009	Feb	NEWA

TABLET, EXTENDED RELEASE; ORAL
KEPPRA XR

>D>	+	UCB INC	500MG	N22285	001	Sep 12, 2008	Feb	CRLD
>A>			500MG	N22285	001	Sep 12, 2008	Feb	CRLD
>A>	+		750MG	N22285	002	Feb 12, 2009	Feb	NEWA

LINDANE

SHAMPOO; TOPICAL
LINDANE

AT	+	OLTA PHARMS	1%	N87266	001		Jan	CAHN

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE

AB		GLENMARK GENERICS	150MG	N79139	001	Feb 03, 2009	Jan	NEWA
AB			300MG	N79139	002	Feb 03, 2009	Jan	NEWA
AB			600MG	N79139	003	Feb 03, 2009	Jan	NEWA

MALATHION

LOTION; TOPICAL
>A> MALATHION

>A> AT		SYNERX PHARMA	0.5%	N78743	001	Mar 06, 2009	Feb	NEWA

OVIDE

>D>	+	TARO PHARMS NORTH	0.5%	N18613	001	Aug 02, 1982	Feb	CFTG
>A> AT	+		0.5%	N18613	001	Aug 02, 1982	Feb	CFTG

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
ANTIVERT

AA	+	PFIZER	12.5MG	N10721	006		Jan	CAHN
AA	+		25MG	N10721	004		Jan	CAHN
AA	+		50MG	N10721	001	Jan 20, 1982	Jan	CAHN

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE

>A> AA		ALEMBIC LTD	200MG	N90122	001	Feb 18, 2009	Feb	NEWA
>A> AA			400MG	N90122	002	Feb 18, 2009	Feb	NEWA

MEQUINOL; TRETINOIN

SOLUTION; TOPICAL
SOLAGE

	+	STIEFEL LABS INC	2%;0.01%	N20922	001	Dec 10, 1999	Jan	CAHN

METAPROTERENOL SULFATE

SOLUTION; INHALATION
>D> ALUPENT

>D> AN	+	BOEHRINGER INGELHEIM	0.4%	N18761	002	Oct 10, 1986	Feb	DISC
>A>		@	0.4%	N18761	002	Oct 10, 1986	Feb	DISC

SOLUTION; INHALATION

>D>			ALUPENT						
>D>	AN	+	BOEHRINGER INGELHEIM	0.6%	N18761	001	Jun 30, 1983	Feb	DISC
>A>			@	0.6%	N18761	001	Jun 30, 1983	Feb	DISC

METFORMIN HYDROCHLORIDE

TABLET; ORAL

			METFORMIN HYDROCHLORIDE						
	AB		ALVOGEN	500MG	N76033	001	Jan 24, 2002	Jan	CAHN
	AB			850MG	N76033	002	Jan 24, 2002	Jan	CAHN
	AB			1GM	N76033	003	Jan 24, 2002	Jan	CAHN

METHOCARBAMOL

TABLET; ORAL

			METHOCARBAMOL						
			@ SOLCO HLTHCARE	500MG	N86989	001		Jan	CAHN
			@	750MG	N86988	001		Jan	CAHN

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

			METHYLPREDNISOLONE ACETATE						
	AB		SANDOZ	40MG/ML	N40719	001	Jan 29, 2009	Jan	NEWA
>A>	AB			40MG/ML	N40794	001	Mar 05, 2009	Feb	NEWA
	AB			80MG/ML	N40719	002	Jan 29, 2009	Jan	NEWA
>A>	AB			80MG/ML	N40794	002	Mar 05, 2009	Feb	NEWA

METOPROLOL TARTRATE

TABLET; ORAL

			METOPROLOL TARTRATE						
			@ SOLCO HLTHCARE	50MG	N74453	001	Apr 27, 1995	Jan	CAHN
			@	100MG	N74453	002	Apr 27, 1995	Jan	CAHN

MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE

OINTMENT; TOPICAL

			VUSION						
		+	STIEFEL LABS INC	0.25%;81.35%;15%	N21026	001	Feb 16, 2006	Jan	CAHN

MILNACIPRAN HYDROCHLORIDE

TABLET; ORAL

			SAVELLA						
			CYPRESS BIOSCIENCE	12.5MG	N22256	001	Jan 14, 2009	Jan	NEWA
				25MG	N22256	002	Jan 14, 2009	Jan	NEWA
				50MG	N22256	003	Jan 14, 2009	Jan	NEWA
		+		100MG	N22256	004	Jan 14, 2009	Jan	NEWA

MINOCYCLINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

			MINOCYCLINE HYDROCHLORIDE						
	AB		IMPAX LABS INC	EQ 45MG BASE	N90024	001	Feb 03, 2009	Jan	NEWA
	AB			EQ 90MG BASE	N90024	002	Feb 03, 2009	Jan	NEWA
	AB			EQ 135MG BASE	N90024	003	Feb 03, 2009	Jan	NEWA
			SOLODYN						
	AB		MEDICIS	EQ 45MG BASE	N50808	001	May 08, 2006	Jan	CFTG
	AB			EQ 90MG BASE	N50808	002	May 08, 2006	Jan	CFTG
	AB	+		EQ 135MG BASE	N50808	003	May 08, 2006	Jan	CFTG

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL
KADIAN

>D>			ACTAVIS ELIZABETH	10MG	N20616	008	Apr 20, 2007	Feb	CRLD
>A>		+		10MG	N20616	008	Apr 20, 2007	Feb	CRLD
>D>				80MG	N20616	006	Oct 27, 2006	Feb	CRLD
>A>		+		80MG	N20616	006	Oct 27, 2006	Feb	CRLD

NABUMETONE

TABLET; ORAL
NABUMETONE

>A>	AB		ACTAVIS ELIZABETH	500MG	N79093	001	Feb 27, 2009	Feb	NEWA
>A>	AB			750MG	N79093	002	Feb 27, 2009	Feb	NEWA

NIMODIPINE

CAPSULE; ORAL
NIMOTOP

>D>									
>D>	AB	+	BAYER PHARMS	30MG	N18869	001	Dec 28, 1988	Feb	DISC
>A>			@	30MG	N18869	001	Dec 28, 1988	Feb	DISC

OFLOXACIN

SOLUTION/DROPS; OPHTHALMIC
OFLOXACIN

>A>	AT		FDC LTD	0.3%	N78559	001	Feb 25, 2009	Feb	NEWA

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL
OMEPRAZOLE

	AB		KREMERS URBAN DEV	40MG	N75410	003	Jan 23, 2009	Jan	NEWA

OXYBUTYNIN CHLORIDE

GEL; TRANSDERMAL
OXYBUTYNIN CHLORIDE

		+	WATSON LABS	10%(100MG/PACKET)	N22204	001	Jan 27, 2009	Jan	NEWA

TABLET, EXTENDED RELEASE; ORAL
OXYBUTYIN CHLORIDE

	AB		OSMOTICA PHARM	5MG	N78503	001	Feb 04, 2009	Jan	NEWA
	AB			10MG	N78503	002	Feb 04, 2009	Jan	NEWA
	AB			15MG	N78503	003	Feb 04, 2009	Jan	NEWA

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION
PAMIDRONATE DISODIUM

>A>	AP		GENERAMEDIX	30MG/VIAL	N78300	001	Mar 10, 2009	Feb	NEWA
>A>	AP			90MG/VIAL	N78300	002	Mar 10, 2009	Feb	NEWA

PHENYTOIN SODIUM

CAPSULE; ORAL
PROMPT PHENYTOIN SODIUM

			@ IVAX PHARMS	100MG PROMPT	N80259	001		Jan	DISC

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL
POLYETHYLENE GLYCOL 3350

	AA		GAVIS PHARMS	17GM/SCOOPFUL	N77736	001	May 26, 2006	Jan	CAHN

FOR SOLUTION; ORAL
POLYETHYLENE GLYCOL 3350

			@ TEVA PHARMS	17GM/SCOOPFUL	N77445	001	May 04, 2006	Jan	DISC

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
MICRO-K

>D>			KV PHARM	8MEQ	N18238	001		Feb	DISC
>A>			@	8MEQ	N18238	001		Feb	DISC

MICRO-K 10

>D>	AB	+	KV PHARM	10MEQ	N18238	002	May 14, 1984	Feb	DISC
>A>			@	10MEQ	N18238	002	May 14, 1984	Feb	DISC

POTASSIUM CHLORIDE

>D>	AB		KV PHARM	10MEQ	N70980	001	Feb 17, 1987	Feb	DISC
>A>			@	10MEQ	N70980	001	Feb 17, 1987	Feb	DISC
>D>	AB		WATSON LABS FLORIDA	8MEQ	N77419	001	Jun 02, 2008	Feb	CTEC
>A>				8MEQ	N77419	001	Jun 02, 2008	Feb	CTEC
>D>	AB			10MEQ	N77419	002	Jun 02, 2008	Feb	CRLD
>A>		+		10MEQ	N77419	002	Jun 02, 2008	Feb	CRLD

TABLET, EXTENDED RELEASE; ORAL
POTASSIUM CHLORIDE

	AB	+	WATSON LABS FLORIDA	10MEQ	N75604	001	Apr 10, 2002	Jan	CRLD

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL
PREDNISOLONE SODIUM PHOSPHATE

>A>	AA		AMNEAL PHARMS	EQ 15MG BASE/5ML	N78345	001	Mar 10, 2009	Feb	NEWA

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
PROPRANOLOL HYDROCHLORIDE

>A>	AB		UPSHER SMITH	60MG	N78311	001	Mar 06, 2009	Feb	NEWA
>A>	AB			80MG	N78311	002	Mar 06, 2009	Feb	NEWA
>A>	AB			120MG	N78311	003	Mar 06, 2009	Feb	NEWA
>A>	AB			160MG	N78311	004	Mar 06, 2009	Feb	NEWA

RAMIPRIL

CAPSULE; ORAL
RAMIPRIL

>A>	AB		RANBAXY	5MG	N78849	001	Mar 06, 2009	Feb	NEWA
>A>	AB			10MG	N78849	002	Mar 06, 2009	Feb	NEWA

RANITIDINE HYDROCHLORIDE

SYRUP; ORAL
RANITIDINE

>D>									
>D>	AA		AMNEAL PHARMS	EQ 15MG BASE/ML	N78312	001	Sep 02, 2008	Feb	CTNA

RANITIDINE HYDROCHLORIDE

>A>									
>A>	AA		AMNEAL PHARMS	EQ 15MG BASE/ML	N78312	001	Sep 02, 2008	Feb	CTNA
>A>	AA		WOCKHARDT	EQ 15MG BASE/ML	N79212	001	Feb 23, 2009	Feb	NEWA

RISPERIDONE

SOLUTION; ORAL
RISPERDAL

	AA	+	ORTHO MCNEIL JANSSEN	1MG/ML	N20588	001	Jun 10, 1996	Jan	CFTG

RISPERIDONE

	AA		TEVA	1MG/ML	N76440	001	Jan 30, 2009	Jan	NEWA

TABLET, ORALLY DISINTEGRATING; ORAL

RISPERDAL

>D>		ORTHO MCNEIL JANSSEN	0.5MG	N21444	001	Apr 02, 2003	Feb	CFTG
>A>	AB		0.5MG	N21444	001	Apr 02, 2003	Feb	CFTG
>D>			2MG	N21444	003	Apr 02, 2003	Feb	CFTG
>A>	AB		2MG	N21444	003	Apr 02, 2003	Feb	CFTG

>A> RISPERIDONE

>A>	AB	DR REDDYS LABS LTD	0.5MG	N77328	001	Feb 24, 2009	Feb	NEWA
>A>	AB		2MG	N77328	003	Feb 24, 2009	Feb	NEWA

SERTRALINE HYDROCHLORIDE

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

>A>	AB	AUSTARPHARMA LLC	EQ 25MG BASE	N78677	001	Mar 04, 2009	Feb	NEWA
>A>	AB		EQ 50MG BASE	N78677	002	Mar 04, 2009	Feb	NEWA
>A>	AB		EQ 100MG BASE	N78677	003	Mar 04, 2009	Feb	NEWA

SUMATRIPTAN SUCCINATE

INJECTABLE; SUBCUTANEOUS

IMITREX

AP	+	GLAXOSMITHKLINE	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N20080	001	Dec 28, 1992	Jan	CFTG

SUMATRIPTAN SUCCINATE

>A>	AP	APP PHARMS	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N79242	001	Mar 02, 2009	Feb	NEWA
	AP	BEDFORD	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N79123	001	Feb 06, 2009	Jan	NEWA
	AP	SANDOZ	EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML)	N78067	002	Feb 06, 2009	Jan	NEWA
	AP		EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N78067	001	Feb 06, 2009	Jan	NEWA
	AP	TEVA PARENTERAL	EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML)	N78318	001	Feb 06, 2009	Jan	NEWA
	AP		EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N78318	002	Feb 06, 2009	Jan	NEWA
	AP		EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N77907	001	Feb 06, 2009	Jan	NEWA
	AP	WOCKHARDT	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N78593	001	Feb 06, 2009	Jan	NEWA

TABLET; ORAL

IMITREX

	AB	GLAXOSMITHKLINE	EQ 25MG BASE	N20132	002	Jun 01, 1995	Jan	CFTG
	AB		EQ 50MG BASE	N20132	003	Jun 01, 1995	Jan	CFTG
	AB	+	EQ 100MG BASE	N20132	001	Jun 01, 1995	Jan	CFTG

SUMATRIPTAN SUCCINATE

	AB	RANBAXY	EQ 100MG BASE	N76572	001	Feb 09, 2009	Jan	NEWA
	AB	TEVA	EQ 25MG BASE	N76840	001	Feb 09, 2009	Jan	NEWA
	AB		EQ 50MG BASE	N76840	002	Feb 09, 2009	Jan	NEWA
	AB		EQ 100MG BASE	N76840	003	Feb 09, 2009	Jan	NEWA

TEMOZOLOMIDE

POWDER; INTRAVENOUS

TEMODAR

>A>	+	SCHERING	100MG/VIAL	N22277	001	Feb 27, 2009	Feb	NEWA

TERIPARATIDE RECOMBINANT HUMAN

INJECTABLE; SUBCUTANEOUS

FORTEO

>A>		LILLY	0.6MG/2.4ML (0.25MG/ML)	N21318	002	Jun 25, 2008	Feb	NEWA

INJECTABLE; SUBCUTANEOUS
FORTEO

>D>		+	LILLY	EQ 0.75MG/3ML (0.25MG/ML)	N21318	001	Nov 26, 2002	Feb	CPOT
>A>		+		0.75MG/3ML (0.25MG/ML)	N21318	001	Nov 26, 2002	Feb	CPOT

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC
TIMOPTIC

>A>	AT	+	ATON	EQ 0.25% BASE	N18086	001		Feb	CAHN
>A>	AT	+		EQ 0.5% BASE	N18086	002		Feb	CAHN
>D>	AT	+	MERCK	EQ 0.25% BASE	N18086	001		Feb	CAHN
>D>	AT	+		EQ 0.5% BASE	N18086	002		Feb	CAHN

TIMOPTIC IN OCUDOSE

>A>		+	ATON	EQ 0.25% BASE	N19463	001	Nov 05, 1986	Feb	CAHN
>A>		+		EQ 0.5% BASE	N19463	002	Nov 05, 1986	Feb	CAHN
>D>		+	MERCK	EQ 0.25% BASE	N19463	001	Nov 05, 1986	Feb	CAHN
>D>		+		EQ 0.5% BASE	N19463	002	Nov 05, 1986	Feb	CAHN

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC
TIMOPTIC-XE

>A>	AB	+	ATON	EQ 0.25% BASE	N20330	001	Nov 04, 1993	Feb	CAHN
>A>	AB	+		EQ 0.5% BASE	N20330	002	Nov 04, 1993	Feb	CAHN
>D>	AB	+	MERCK	EQ 0.25% BASE	N20330	001	Nov 04, 1993	Feb	CAHN
>D>	AB	+		EQ 0.5% BASE	N20330	002	Nov 04, 1993	Feb	CAHN

TORSEMIDE

TABLET; ORAL
TORSEMIDE

	AB		HETERO DRUGS	5MG	N79234	001	Jan 27, 2009	Jan	NEWA
	AB			10MG	N79234	002	Jan 27, 2009	Jan	NEWA
	AB			20MG	N79234	003	Jan 27, 2009	Jan	NEWA
	AB			100MG	N79234	004	Jan 27, 2009	Jan	NEWA

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HYDROCHLORIDE

>D>	AB		ACTAVIS ELIZABETH	50MG	N71636	001	Apr 18, 1988	Feb	CAHN
>D>	AB			100MG	N71514	001	Apr 18, 1988	Feb	CAHN
>A>	AB		ALVOGEN	50MG	N71636	001	Apr 18, 1988	Feb	CAHN
>A>	AB			100MG	N71514	001	Apr 18, 1988	Feb	CAHN

TRYPAN BLUE

SOLUTION; OPHTHALMIC
MEMBRANEBLUE

>A>									
>A>		+	DORC	0.15%	N22278	001	Feb 20, 2009	Feb	NEWA

CETIRIZINE HYDROCHLORIDE

TABLET; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

>A>		ORCHID HLTHCARE	5MG	N78862	001	Feb 19, 2009	Feb	NEWA
>A>			10MG	N78862	002	Feb 19, 2009	Feb	NEWA

CETIRIZINE HYDROCHLORIDE HIVES

>A>		ORCHID HLTHCARE	5MG	N78862	003	Feb 19, 2009	Feb	NEWA
>A>			10MG	N78862	004	Feb 19, 2009	Feb	NEWA

DEXTROMETHORPHAN POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

DELSYM

>D>	+	ADAMS RESP THERAP	EQ 30MG HBR/5ML	N18658	001	Oct 08, 1982	Feb	CAHN
>A>	+	RECKITT BENCKISER	EQ 30MG HBR/5ML	N18658	001	Oct 08, 1982	Feb	CAHN

IBUPROFEN

CAPSULE; ORAL

>D> IBUPROFEN

>D>	+	BANNER PHARMACAPS	200MG	N21472	001	Oct 18, 2002	Feb	CTNA

>A> MIDOL LIQUID GELS

>A>	+	BANNER PHARMACAPS	200MG	N21472	001	Oct 18, 2002	Feb	CTNA

INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN

INJECTABLE; INJECTION

HUMULIN 50/50

		@ LILLY	50 UNITS/ML;50 UNITS/ML	N20100	001	Apr 29, 1992	Jan	DISC

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL

NICOTINE POLACRILEX

>A>		IVAX PHARMS	EQ 2MG BASE	N76880	001	Feb 18, 2009	Feb	NEWA
>A>			EQ 4MG BASE	N77850	001	Feb 18, 2009	Feb	NEWA

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 2009

NO FEBRUARY 2009 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 2009 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2009

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AMIODARONE HYDROCHLORIDE - NEXTERONE						
022325 001	5134127	Jan 23, 2010	DP			
	5376645	Jan 23, 2010	DP			
	6869939	May 04, 2022	DP			
AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE - PREVPAC						
050757 001	4628098	May 10, 2009	DS			
	4628098*PED	Nov 10, 2009				
	5013743	Feb 12, 2010	U-452			
	5013743*PED	Aug 12, 2010				
	5045321	Sep 03, 2008	DP			
	5045321*PED	Mar 03, 2009				
	5093132	Sep 03, 2008	DP			
	5093132*PED	Mar 03, 2009				
	5433959	Sep 03, 2008	DP			
	5433959*PED	Mar 03, 2009				
ANASTROZOLE - ARIMIDEX						
020541 001	RE36617	Dec 27, 2009	DS DP U-946			
AZITHROMYCIN - AZASITE						
050810 001	5192535	Mar 09, 2010	DP U-709			
	6239113	Mar 31, 2019	U-709			
	6569443	Mar 31, 2019	DP U-709			
	6861411	Nov 25, 2018	U-709			
	7056893	Mar 31, 2019	DP U-709			
BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE - ACANYA						
050819 001	5733886	Mar 31, 2015	DP U-124			
	6117843	Feb 18, 2012	DP			
BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE - DUAC						
050741 001	**>A>** 5466446	Feb 16, 2014	DS DP			
BETAMETHASONE VALERATE - LUXIQ						
020934 001	7078058	May 24, 2017	DP			
BIMATOPROST - LATISSE						
022369 001					**>A>** NP	Dec 24, 2011
BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT						
021929 001					**>A>** I-582	Feb 27, 2012
BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT						
021929 002					**>A>** I-582	Feb 27, 2012
CALCITRIOL - VECTICAL						
022087 001					NDF	Jan 23, 2012
CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - PEPCID COMPLETE						
020958 001	5075114	May 23, 2010	DP			
	5075114*PED	Nov 23, 2010				
	6814978	Aug 26, 2021	DP			
	6814978*PED	Feb 26, 2022				

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CICLESONIDE - ALVESCO						
021658 002					NDF	Jan 10, 2011
					NCE	Oct 20, 2011
CICLESONIDE - ALVESCO						
021658 003					NDF	Jan 10, 2011
					NCE	Oct 20, 2011
CLOBETASOL PROPIONATE - OLUX						
021142 001	6126920	Mar 01, 2016	U-484			
CLOPIDOGREL BISULFATE - PLAVIX						
020839 002	**>A>** 4847265	Nov 17, 2011	DS DP			
	>A> 6429210	Jun 10, 2019	DS DP			
	>A> 6504030	Jun 10, 2019	DS			
COLESEVELAM HYDROCHLORIDE - WELCHOL						
021141 001	**>A>** 5607669	Jun 10, 2014	U-323			
	>A> 5607669*PED	Dec 10, 2014				
	>A> 5679717	Apr 29, 2014	U-323			
	>A> 5679717*PED	Oct 29, 2014				
	>A> 5693675	Dec 02, 2014				
	>A> 5693675*PED	Jun 02, 2015				
	>A> 5917007	Apr 29, 2014	U-323			
	>A> 5917007*PED	Oct 29, 2014				
	>A> 5919832	Jun 10, 2014				
	>A> 5919832*PED	Dec 10, 2014				
	>A> 6066678	Jun 10, 2014	U-323			
	>A> 6066678*PED	Dec 10, 2014				
	>A> 6433026	Jun 10, 2014				
	>A> 6433026*PED	Dec 10, 2014				
COLESEVELAM HYDROCHLORIDE - WELCHOL						
021176 001	**>A>** 5607669	Jun 10, 2014	U-323		**>A>** I-553	Jan 18, 2011
	>A> 5607669*PED	Dec 10, 2014			**>A>** PED	Jul 18, 2011
	>A> 5679717	Apr 29, 2014	U-323			
	>A> 5679717*PED	Oct 29, 2014				
	>A> 5693675	Dec 02, 2014	DS			
	>A> 5693675*PED	Jun 02, 2015				
	>A> 5917007	Apr 29, 2014	DS U-323			
	>A> 5917007*PED	Oct 29, 2014				
	>A> 5919832	Apr 29, 2014	DS			
	>A> 5919832*PED	Oct 29, 2014				
	>A> 6066678	Apr 29, 2014	DS U-323			
	>A> 6066678*PED	Oct 29, 2014				
	>A> 6433026	Apr 29, 2014	DS			
	>A> 6433026*PED	Oct 29, 2014				
	>A> 6784254	Apr 29, 2014	DS DP			
	>A> 6784254*PED	Oct 29, 2014				
	>A> 7101960	Apr 29, 2014	DS DP U-757			
	>A> 7101960*PED	Oct 29, 2014				
	>A> 7229613	Apr 17, 2022	U-851			
	>A> 7229613*PED	Oct 17, 2022				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2009

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DEGARELIX ACETATE - DEGARELIX ACETATE						
022201 001	5925730	Apr 11, 2017	DS DP U-943			
DEGARELIX ACETATE - DEGARELIX ACETATE						
022201 002	5925730	Apr 11, 2017	DS DP U-943			
DEXAMETHASONE; TOBRAMYCIN - TOBRADEX ST						
050818 001	**>A>** 5149694	Sep 22, 2009	U-953			
DEXLANSOPRAZOLE - KAPIDEX						
022287 001	**>A>** 5045321	Sep 03, 2008	DP		**>A>** NP	Jan 30, 2012
	>A> 5045321*PED	Mar 03, 2009			**>A>** PED	Jul 30, 2012
	>A> 5093132	Sep 03, 2008	DP U-949			
	>A> 5093132	Sep 03, 2008	DP U-950			
	>A> 5093132	Sep 03, 2008	DP U-951			
	>A> 5093132*PED	Mar 03, 2009				
	>A> 5433959	Sep 03, 2008	DP U-949			
	>A> 5433959	Sep 03, 2008	DP U-950			
	>A> 5433959	Sep 03, 2008	DP U-951			
	>A> 5433959*PED	Mar 03, 2009				
	>A> 6462058	Jun 15, 2020	DS DP U-951			
	>A> 6462058	Jun 15, 2020	DS DP U-950			
	>A> 6462058	Jun 15, 2020	DS DP U-949			
	>A> 6462058*PED	Dec 15, 2020				
	>A> 6664276	Jun 15, 2020	DS DP U-949			
	>A> 6664276	Jun 15, 2020	DS DP U-950			
	>A> 6664276	Jun 15, 2020	DS DP U-951			
	>A> 6664276*PED	Dec 15, 2020				
	>A> 6939971	Jun 15, 2020	U-949			
	>A> 6939971	Jun 15, 2020	U-950			
	>A> 6939971	Jun 15, 2020	U-951			
	>A> 6939971*PED	Dec 15, 2020				
	>A> 7285668	Jun 15, 2020	DS			
	>A> 7285668*PED	Dec 15, 2020				

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DEXLANSOPRAZOLE - KAPIDEX						
022287 002	**>A>** 5045321	Sep 03, 2008	DP		**>A>** NP	Jan 30, 2012
	>A> 5045321*PED	Mar 03, 2009			**>A>** PED	Jul 30, 2012
	>A> 5093132	Sep 03, 2008	DP U-949			
	>A> 5093132	Sep 03, 2008	DP U-950			
	>A> 5093132	Sep 03, 2008	DP U-951			
	>A> 5093132*PED	Mar 03, 2009				
	>A> 5433959	Sep 03, 2008	DP U-949			
	>A> 5433959	Sep 03, 2008	DP U-950			
	>A> 5433959	Sep 03, 2008	DP U-951			
	>A> 5433959*PED	Mar 03, 2009				
	>A> 6462058	Jun 15, 2020	DS DP U-951			
	>A> 6462058	Jun 15, 2020	DS DP U-950			
	>A> 6462058	Jun 15, 2020	DS DP U-949			
	>A> 6462058*PED	Dec 15, 2020				
	>A> 6664276	Jun 15, 2020	DS DP U-949			
	>A> 6664276	Jun 15, 2020	DS DP U-950			
	>A> 6664276	Jun 15, 2020	DS DP U-951			
	>A> 6664276*PED	Dec 15, 2020				
	>A> 6939971	Jun 15, 2020	U-949			
	>A> 6939971	Jun 15, 2020	U-950			
	>A> 6939971	Jun 15, 2020	U-951			
	>A> 6939971*PED	Dec 15, 2020				
	>A> 7285668	Jun 15, 2020	DS			
	>A> 7285668*PED	Dec 15, 2020				
DIVALPROEX SODIUM - DIVALPROEX SODIUM						
077567 002					PC	Aug 01, 2009
ELTROMBOPAG OLAMINE - PROMACTA						
022291 001	7473686	Jul 24, 2021	DS DP U-930			
ELTROMBOPAG OLAMINE - PROMACTA						
022291 002	7473686	Jul 24, 2021	DS DP U-930			
ESTRADIOL - ELESTRIN						
021813 001	**>A>** 7470433	Aug 03, 2021	DP			
FEBUXOSTAT - ULORIC						
021856 001	**>A>** 5614520	Mar 25, 2014	DS DP U-954		**>A>** NCE	Feb 13, 2014
	>A> 6225474	Jun 18, 2019	DS			
	>A> 7361676	Mar 08, 2024	DP			
FEBUXOSTAT - ULORIC						
021856 002	**>A>** 5614520	Mar 25, 2014	DS DP U-954		**>A>** NCE	Feb 13, 2014
	>A> 6225474	Jun 18, 2019	DS			
	>A> 7361676	Mar 08, 2024	DP			
FLUDARABINE PHOSPHATE - FLUDARABINE PHOSPHATE						
022273 001	**>A>** 7148207	Dec 20, 2022	DP U-944		**>A>** NDF	Dec 18, 2011

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FLUTICASONE PROPIONATE - FLOVENT DISKUS 100						
020833 002	**>A>** 5590645	Mar 01, 2011	DP			
	>A> 5590645*PED	Sep 01, 2011				
	>A> 5860419	Mar 01, 2011	DP			
	>A> 5860419*PED	Sep 01, 2011				
	>A> 5873360	Feb 23, 2016	DP			
	>A> 5873360*PED	Aug 23, 2016				
	>A> 6032666	Mar 01, 2011	DP			
	>A> 6032666*PED	Sep 01, 2011				
	>A> 6378519	Mar 01, 2011	DP			
	>A> 6378519*PED	Sep 01, 2011				
	>A> 6536427	Mar 01, 2011	DP			
	>A> 6536427*PED	Sep 01, 2011				
	>A> 6792945	Mar 01, 2011	DP			
	>A> 6792945*PED	Sep 01, 2011				
	>A> 7225808	Mar 01, 2011	DP			
	>A> 7225808*PED	Sep 01, 2011				
	>A> 7389775	Mar 01, 2011	DP			
	>A> 7389775*PED	Sep 01, 2011				
FLUTICASONE PROPIONATE - FLOVENT DISKUS 250						
020833 003	**>A>** 5590645	Mar 01, 2011	DP			
	>A> 5590645*PED	Sep 01, 2011				
	>A> 5860419	Mar 01, 2011	DP			
	>A> 5860419*PED	Sep 01, 2011				
	>A> 5873360	Feb 23, 2016	DP			
	>A> 5873360*PED	Aug 23, 2016				
	>A> 6032666	Mar 01, 2011	DP			
	>A> 6032666*PED	Sep 01, 2011				
	>A> 6378519	Mar 01, 2011	DP			
	>A> 6378519*PED	Sep 01, 2011				
	>A> 6536427	Mar 01, 2011	DP			
	>A> 6536427*PED	Sep 01, 2011				
	>A> 6792945	Mar 01, 2011	DP			
	>A> 6792945*PED	Sep 01, 2011				
	>A> 7225808	Mar 01, 2011	DP			
	>A> 7225808*PED	Sep 01, 2011				
	>A> 7389775	Mar 01, 2011	DP			
	>A> 7389775*PED	Sep 01, 2011				

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FLUTICASONE PROPIONATE - FLOVENT DISKUS 50						
020833 001	**>A>** 5590645	Mar 01, 2011	DP			
	>A> 5590645*PED	Sep 01, 2011				
	>A> 5860419	Mar 01, 2011	DP			
	>A> 5860419*PED	Sep 01, 2011				
	>A> 5873360	Feb 23, 2016	DP			
	>A> 5873360*PED	Aug 23, 2016				
	>A> 6032666	Mar 01, 2011	DP			
	>A> 6032666*PED	Sep 01, 2011				
	>A> 6378519	Mar 01, 2011	DP			
	>A> 6378519*PED	Sep 01, 2011				
	>A> 6536427*PED	Sep 01, 2011				
	>A> 6792945	Mar 01, 2011	DP			
	>A> 6792945*PED	Sep 01, 2011				
	>A> 7225808	Mar 01, 2011	DP			
	>A> 7225808*PED	Sep 01, 2011				
	>A> 7389775	Mar 01, 2011	DP			
	>A> 7389775*PED	Sep 01, 2011				
FLUTICASONE PROPIONATE - FLOVENT HFA						
021433 001	**>A>** 5658549	Aug 19, 2014	DP U-710			
	>A> 5658549*PED	Feb 19, 2015				
	>A> 5674472	Oct 07, 2014	DP			
	>A> 5674472*PED	Apr 07, 2015				
	>A> 6170717	Dec 23, 2017	DP			
	>A> 6170717*PED	Jun 23, 2018				
	>A> 6251368	Dec 04, 2012	DP			
	>A> 6251368*PED	Jun 04, 2013				
	>A> 6253762	Apr 14, 2015	DP U-582			
	>A> 6253762*PED	Oct 14, 2015				
	>A> 6315173	Jun 23, 2017	DP			
	>A> 6315173*PED	Jun 23, 2018				
	>A> 6510969	Dec 23, 2017	DP			
	>A> 6510969*PED	Jun 23, 2018				
	>A> 6546928	Apr 14, 2015	DP U-583			
	>A> 6546928*PED	Oct 14, 2015				
	>A> 6743413	Jun 01, 2021	U-581			
	>A> 6743413*PED	Dec 01, 2021				

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
FLUTICASONE PROPIONATE - FLOVENT HFA						
021433 002	**>A>** 5658549	Aug 19, 2014	DP U-710			
	>A> 5658549*PED	Feb 19, 2015				
	>A> 5674472	Oct 07, 2014	DP			
	>A> 5674472*PED	Apr 07, 2015				
	>A> 6170717	Dec 23, 2017	DP			
	>A> 6170717*PED	Jun 23, 2018				
	>A> 6251368	Dec 04, 2012	DP			
	>A> 6251368*PED	Jun 04, 2013				
	>A> 6253762	Apr 14, 2015	DP U-582			
	>A> 6253762*PED	Oct 14, 2015				
	>A> 6315173	Dec 23, 2017	DP			
	>A> 6315173*PED	Jun 23, 2018				
	>A> 6510969	Dec 23, 2017	DP			
	>A> 6510969*PED	Jun 23, 2018				
	>A> 6546928	Apr 14, 2015	DP U-583			
	>A> 6546928*PED	Oct 14, 2015				
	>A> 6743413	Jun 01, 2021	U-581			
	>A> 6743413*PED	Dec 01, 2021				
FLUTICASONE PROPIONATE - FLOVENT HFA						
021433 003	**>A>** 5658549	Aug 19, 2014	DP U-710			
	>A> 5658549*PED	Feb 19, 2015	U-710			
	>A> 5674472	Oct 07, 2014	DP			
	>A> 5674472*PED	Apr 07, 2015				
	>A> 6170717	Dec 23, 2017	DP			
	>A> 6170717*PED	Jun 23, 2018				
	>A> 6251368	Dec 04, 2012	DP			
	>A> 6251368*PED	Jun 04, 2013				
	>A> 6253762	Apr 14, 2015	DP U-582			
	>A> 6253762*PED	Oct 14, 2015	U-582			
	>A> 6315173	Dec 23, 2017	DP			
	>A> 6315173*PED	Jun 23, 2018	DP			
	>A> 6510969	Dec 23, 2017	DP			
	>A> 6510969*PED	Jun 23, 2018	DP			
	>A> 6546928	Apr 14, 2015	DP U-583			
	>A> 6546928*PED	Oct 14, 2015	U-583			
	>A> 6743413	Jun 01, 2021	U-581			
	>A> 6743413*PED	Dec 01, 2021	U-581			

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FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50						
021077 001	**>A>** 5590645	Mar 01, 2011	DP			
	>A> 5590645*PED	Sep 01, 2011				
	>A> 5860419	Mar 01, 2011	DP			
	>A> 5860419*PED	Sep 01, 2011				
	>A> 5873360	Feb 23, 2016	DP			
	>A> 5873360*PED	Aug 23, 2016				
	>A> 6032666	Mar 01, 2011	DP			
	>A> 6032666*PED	Sep 01, 2011				
	>A> 6378519	Mar 01, 2011	DP			
	>A> 6378519*PED	Sep 01, 2011				
	>A> 6792945	Mar 01, 2011	DP			
	>A> 6792945*PED	Sep 01, 2011				
	>A> 7225808	Mar 01, 2011	DP			
	>A> 7225808*PED	Sep 01, 2011				
	>A> 7389775	Mar 01, 2011	DP			
	>A> 7389775*PED	Sep 01, 2011				
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50						
021077 002	**>A>** 5590645	Mar 01, 2011	DP			
	>A> 5590645*PED	Sep 01, 2011				
	>A> 5860419	Mar 01, 2011	DP			
	>A> 5860419*PED	Sep 01, 2011				
	>A> 5873360	Feb 23, 2016	DP			
	>A> 5873360*PED	Aug 23, 2016				
	>A> 6032666	Mar 01, 2011	DP			
	>A> 6032666*PED	Sep 01, 2011				
	>A> 6378519	Mar 01, 2011	DP			
	>A> 6378519*PED	Sep 01, 2011				
	>A> 6792945	Mar 01, 2011	DP			
	>A> 6792945*PED	Sep 01, 2011				
	>A> 7225808	Mar 01, 2011	DP			
	>A> 7225808*PED	Sep 01, 2011				
	>A> 7389775	Mar 01, 2011	DP			
	>A> 7389775*PED	Sep 01, 2011				

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FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50						
021077 003	**>A>** 5590645	Mar 01, 2011	DP			
	>A> 5590645*PED	Sep 01, 2011				
	>A> 5860419	Mar 01, 2011	DP			
	>A> 5860419*PED	Sep 01, 2011				
	>A> 5873360	Feb 23, 2016	DP			
	>A> 5873360*PED	Aug 23, 2016				
	>A> 6032666	Mar 01, 2011	DP			
	>A> 6032666*PED	Sep 01, 2011				
	>A> 6378519	Mar 01, 2011	DP			
	>A> 6378519*PED	Sep 01, 2011				
	>A> 6792945	Mar 01, 2011	DP			
	>A> 6792945*PED	Sep 01, 2011				
	>A> 7225808	Mar 01, 2011	DP			
	>A> 7225808*PED	Sep 01, 2011				
	>A> 7389775	Mar 01, 2011	DP			
	>A> 7389775*PED	Sep 01, 2011				
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA						
021254 001	**>A>** 5658549	Aug 19, 2014	DP		U-738	
	>A> 5658549*PED	Feb 19, 2015			U-738	
	>A> 5674472	Oct 07, 2014	DP			
	>A> 5674472*PED	Apr 07, 2015				
	>A> 6251368	Dec 04, 2012	DP			
	>A> 6251368*PED	Jun 04, 2013				
	>A> 6253762	Apr 14, 2015	DP		U-738	
	>A> 6253762*PED	Oct 14, 2015			U-738	
	>A> 6315173	Dec 23, 2017	DP			
	>A> 6315173*PED	Jun 23, 2018				
	>A> 6510969	Dec 23, 2017				
	>A> 6510969*PED	Jun 23, 2018				
	>A> 6546928	Apr 14, 2015	DP			
	>A> 6546928*PED	Oct 14, 2015				
	>A> 6743413	Jun 01, 2021			U-841	
	>A> 6743413*PED	Dec 01, 2021			U-841	

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FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA						
021254 002	**>A>** 5658549	Aug 19, 2014	DP U-738			
	>A> 5658549*PED	Feb 19, 2015	DP U-738			
	>A> 5674472	Oct 07, 2014	DP			
	>A> 5674472*PED	Apr 07, 2015	DP			
	>A> 6251368	Dec 04, 2012	DP			
	>A> 6251368*PED	Jun 04, 2013	DP			
	>A> 6253762	Apr 14, 2015	DP U-738			
	>A> 6253762*PED	Oct 14, 2015	DP U-738			
	>A> 6315173	Dec 23, 2017	DP			
	>A> 6315173*PED	Jun 23, 2018	DP			
	>A> 6510969	Dec 23, 2017	DP			
	>A> 6510969*PED	Jun 23, 2018	DP			
	>A> 6546928	Apr 14, 2015	DP			
	>A> 6546928*PED	Oct 14, 2015	DP			
	>A> 6743413	Jun 01, 2021	U-841			
	>A> 6743413*PED	Dec 01, 2021	U-841			
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA						
021254 003	**>A>** 5658549	Aug 19, 2014	DP U-738			
	>A> 5658549*PED	Feb 19, 2015	DP U-738			
	>A> 5674472	Oct 07, 2014	DP			
	>A> 5674472*PED	Apr 07, 2015	DP			
	>A> 6251368	Dec 04, 2012	DP			
	>A> 6251368*PED	Jun 04, 2013	DP			
	>A> 6253762	Apr 14, 2015	DP U-738			
	>A> 6253762*PED	Oct 14, 2015	DP U-738			
	>A> 6315173	Dec 23, 2017	DP			
	>A> 6315173*PED	Jun 23, 2018	DP			
	>A> 6510969	Dec 23, 2017	DP			
	>A> 6510969*PED	Jun 23, 2018	DP			
	>A> 6546928	Apr 14, 2015	DP			
	>A> 6546928*PED	Oct 14, 2015	DP			
	>A> 6743413	Jun 01, 2021	U-841			
	>A> 6743413*PED	Dec 01, 2021	U-841			
FLUVOXAMINE MALEATE - LUVOX						
021519 001					**>A>** M-83	Apr 14, 2011
FLUVOXAMINE MALEATE - LUVOX						
021519 002					**>A>** M-83	Apr 14, 2011
FLUVOXAMINE MALEATE - LUVOX						
021519 003					**>A>** M-83	Apr 14, 2011
FOSPROPOFOL DISODIUM - LUSEDRA						
022244 001	6204257	Jun 07, 2018	DS DP U-945		**>A>** NCE	Dec 12, 2013
GADODIAMIDE - OMNISCAN						
022066 002	**>A>** 5362475	Nov 08, 2011	DS			
HYDROCHLOROTHIAZIDE; TELMISARTAN - MICARDIS HCT						
021162 003	5591762	Jan 07, 2014	DS DP U-3			
IMATINIB MESYLATE - GLEEVEC						
021588 001					**>A>** I-583	Dec 19, 2011

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IMATINIB MESYLATE - GLEEVEC							
021588 002						**>A>** I-583	Dec 19, 2011
INSULIN DETEMIR RECOMBINANT - LEVEMIR							
021536 001		5750497	May 16, 2019	DS DP U-668			
INSULIN GLARGINE RECOMBINANT - LANTUS							
021081 001		5656722	Aug 12, 2014	DS DP U-948			
		5656722*PED	Feb 12, 2015				
		7476652	Jun 13, 2023	DP			
		7476652*PED	Dec 13, 2023				
IODIXANOL - VISIPAQUE 270							
020351 001	**>A>**	5366722	Nov 22, 2011	DP			
	>A>	RE36418	Jul 12, 2011	DP			
IODIXANOL - VISIPAQUE 270							
020808 001	**>A>**	5366722	Nov 22, 2011	DP			
	>A>	RE36418	Jul 12, 2011	DP			
IODIXANOL - VISIPAQUE 320							
020351 002	**>A>**	RE36418	Jul 12, 2011	DP			
IODIXANOL - VISIPAQUE 320							
020808 002	**>A>**	RE36418	Jul 12, 2011	DP			
LANSOPRAZOLE - PREVACID							
021428 001		7431942	May 17, 2019	DP			
		7431942*PED	Nov 17, 2019				
LANSOPRAZOLE - PREVACID							
021428 002		7431942	May 17, 2019	DP			
		7431942*PED	Nov 17, 2019				
LANSOPRAZOLE - PREVACID IV							
021566 001		4628098	May 10, 2009	DS			
		4628098*PED	Nov 10, 2009				
		7396841	Aug 17, 2021	DP U-947			
		7396841*PED	Feb 17, 2022				
LANSOPRAZOLE; NAPROXEN - PREVACID NAPRAPAC 500 (COPACKAGED)							
021507 004		4628098	May 10, 2009	DS			
		4628098*PED	Nov 10, 2009				
		5045321	Sep 03, 2008	DP			
		5045321*PED	Mar 03, 2009				
		5093132	Sep 03, 2008	DP			
		5093132*PED	Mar 03, 2009				
		5433959	Sep 03, 2008	DP			
		5433959*PED	Mar 03, 2009				
LANTHANUM CARBONATE - FOSRENOL							
021468 001		5968976	Oct 26, 2018	DP U-613			
LANTHANUM CARBONATE - FOSRENOL							
021468 002		5968976	Oct 26, 2018	DP U-613			
LANTHANUM CARBONATE - FOSRENOL							
021468 003		5968976	Oct 26, 2018	DP U-613			

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LANTHANUM CARBONATE - FOSRENOL						
021468 004	5968976	Oct 26, 2018	DP U-613			
LEVETIRACETAM - KEPPRA XR						
022285 002					**>A>** NDF	Sep 12, 2011
LIDOCAINE HYDROCHLORIDE - ZINGO						
022114 001					NPP	Jan 08, 2012
MILNACIPRAN HYDROCHLORIDE - SAVELLA						
022256 001					NCE	Jan 14, 2014
MILNACIPRAN HYDROCHLORIDE - SAVELLA						
022256 002					NCE	Jan 14, 2014
MILNACIPRAN HYDROCHLORIDE - SAVELLA						
022256 003					NCE	Jan 14, 2014
MILNACIPRAN HYDROCHLORIDE - SAVELLA						
022256 004					NCE	Jan 14, 2014
MORPHINE SULFATE - AVINZA						
021260 005	**>A>** 6066339	Nov 25, 2017	DP			
MORPHINE SULFATE - AVINZA						
021260 006	**>A>** 6066339	Nov 25, 2017	DP			
NITROGLYCERIN - NITROMIST						
021780 001	5869082	Apr 16, 2016	DP			
OXYBUTYNIN CHLORIDE - OXYBUTYNIN CHLORIDE						
022204 001					NDF	Jan 27, 2012
PANTOPRAZOLE SODIUM - PROTONIX						
020987 001	**>A>** 4758579	Jul 19, 2010				
	>A> 4758579*PED	Jan 19, 2011				
	>A> 5997903	Dec 07, 2016				
	>A> 5997903*PED	Jun 07, 2017				
PANTOPRAZOLE SODIUM - PROTONIX						
020987 002	**>A>** 4758579	Jul 19, 2010				
	>A> 4758579*PED	Jan 19, 2011				
	>A> 5997903	Dec 07, 2016				
	>A> 5997903*PED	Jun 07, 2017				
PANTOPRAZOLE SODIUM - PROTONIX						
022020 001	**>A>** 4758579	Jul 19, 2010	DS DP U-859			
	>A> 4758579*PED	Jan 19, 2011				
PANTOPRAZOLE SODIUM - PROTONIX IV						
020988 001	**>A>** 4758579	Jul 19, 2010				
	>A> 4758579*PED	Jan 19, 2011				
	>A> 6780881	Nov 17, 2021	DP			
	>A> 6780881*PED	May 17, 2022				
	>A> 7351723	Nov 17, 2021	DP			
	>A> 7351723*PED	May 17, 2022				

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PRAMLINTIDE ACETATE - SYMLIN						
021332 002	5814600	Sep 29, 2015	U-639			
	5814600	Sep 29, 2015	U-638			
	5814600	Sep 29, 2015	U-637			
	5998367	Mar 08, 2011	DS DP			
	6114304	Sep 05, 2017	U-640			
	6114304	Sep 05, 2017	U-637			
	6608029	Sep 07, 2013	U-641			
	6608029	Sep 07, 2013	U-640			
	6608029	Sep 07, 2013	U-637			
	6610824	Mar 03, 2011	DS			
	7407934	Mar 08, 2011	U-640			
	7407934	Mar 08, 2011	U-637			
PRAMLINTIDE ACETATE - SYMLIN						
021332 003	5814600	Sep 29, 2015	U-639			
	5814600	Sep 29, 2015	U-638			
	5814600	Sep 29, 2015	U-637			
	5998367	Mar 08, 2011	DS DP			
	6114304	Sep 05, 2017	U-640			
	6114304	Sep 05, 2017	U-637			
	6608029	Sep 07, 2013	U-641			
	6608029	Sep 07, 2013	U-640			
	6608029	Sep 07, 2013	U-637			
	6610824	Mar 03, 2011	DS			
	7407934	Mar 08, 2011	U-640			
	7407934	Mar 08, 2011	U-637			
QUETIAPINE FUMARATE - SEROQUEL						
020639 001	4879288	Sep 26, 2011	DS DP U-550		I-560	May 13, 2011
	4879288*PED	Mar 26, 2012			I-503	Oct 20, 2009
					PED	Nov 13, 2011
					PED	Apr 20, 2010
QUETIAPINE FUMARATE - SEROQUEL						
020639 002	4879288	Sep 26, 2011	DS DP U-550		I-560	May 13, 2011
	4879288*PED	Mar 26, 2012			I-503	Oct 20, 2009
					PED	Nov 13, 2011
					PED	Apr 20, 2010
QUETIAPINE FUMARATE - SEROQUEL						
020639 003	4879288	Sep 26, 2011	DS DP U-550		I-560	May 13, 2011
	4879288*PED	Mar 26, 2012			I-503	Oct 20, 2009
					PED	Nov 13, 2011
					PED	Apr 20, 2010
QUETIAPINE FUMARATE - SEROQUEL						
020639 004	4879288	Sep 26, 2011	DS DP U-550		I-560	May 13, 2011
	4879288*PED	Mar 26, 2012			I-503	Oct 20, 2009
					PED	Nov 13, 2011
					PED	Apr 20, 2010
QUETIAPINE FUMARATE - SEROQUEL						
020639 005	4879288	Sep 26, 2011	DS DP U-550		I-560	May 13, 2011
	4879288*PED	Mar 26, 2012			I-503	Oct 20, 2009
					PED	Nov 13, 2011
					PED	Apr 20, 2010

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QUETIAPINE FUMARATE - SEROQUEL							
020639 006		4879288	Sep 26, 2011	DS DP U-550		I-560	May 13, 2011
		4879288*PED	Mar 26, 2012			I-503	Oct 20, 2009
						PED	Nov 13, 2011
						PED	Apr 20, 2010
QUETIAPINE FUMARATE - SEROQUEL							
020639 007		4879288	Sep 26, 2011	DS DP U-550		I-560	May 13, 2011
		4879288*PED	Mar 26, 2012			I-503	Oct 20, 2009
						PED	Nov 13, 2011
						PED	Apr 20, 2010
QUETIAPINE FUMARATE - SEROQUEL XR							
022047 001	**>A>**	4879288	Sep 26, 2011	DS DP U-814		D-117	Oct 08, 2011
	>A>	4879288	Sep 26, 2011	DS DP U-601		I-576	Oct 08, 2011
	>A>	4879288*PED	Mar 26, 2012			I-575	Oct 08, 2011
	>A>	5948437	May 28, 2017	DP U-814		I-574	Oct 08, 2011
	>A>	5948437	May 28, 2017	DP U-601		NDF	May 17, 2010
	>A>	5948437*PED	Nov 28, 2017			PED	Apr 08, 2012
						PED	Nov 17, 2010
QUETIAPINE FUMARATE - SEROQUEL XR							
022047 002	**>A>**	4879288	Sep 26, 2011	DS DP U-814		D-117	Oct 08, 2011
	>A>	4879288	Sep 26, 2011	DS DP U-601		I-576	Oct 08, 2011
	>A>	4879288*PED	Mar 26, 2012			I-575	Oct 08, 2011
	>A>	5948437	May 28, 2017	DP U-814		I-574	Oct 08, 2011
	>A>	5948437	May 28, 2017	DP U-601		NDF	May 17, 2010
	>A>	5948437*PED	Nov 28, 2017			PED	Apr 08, 2012
						PED	Nov 17, 2010
QUETIAPINE FUMARATE - SEROQUEL XR							
022047 003	**>A>**	4879288	Sep 26, 2011	DS DP U-814		D-117	Oct 08, 2011
	>A>	4879288	Sep 26, 2011	DS DP U-601		I-576	Oct 08, 2011
	>A>	4879288*PED	Mar 26, 2012			I-575	Oct 08, 2011
	>A>	5948437	May 28, 2017	DP U-814		I-574	Oct 08, 2011
	>A>	5948437	May 28, 2017	DP U-601		NDF	May 17, 2010
	>A>	5948437*PED	Nov 28, 2017			PED	Apr 08, 2012
						PED	Nov 17, 2010
QUETIAPINE FUMARATE - SEROQUEL XR							
022047 004	**>A>**	4879288	Sep 26, 2011	DS DP U-814		D-117	Oct 08, 2011
	>A>	4879288	Sep 26, 2011	DS DP U-601		I-576	Oct 08, 2011
	>A>	4879288*PED	Mar 26, 2012			I-575	Oct 08, 2011
	>A>	5948437	May 28, 2017	DP U-814		I-574	Oct 08, 2011
	>A>	5948437	May 28, 2017	DP U-601		NDF	May 17, 2010
	>A>	5948437*PED	Nov 28, 2017			PED	Apr 08, 2012
						PED	Nov 17, 2010
QUETIAPINE FUMARATE - SEROQUEL XR							
022047 005	**>A>**	4879288	Sep 26, 2011	DS DP U-814		D-117	Oct 08, 2011
	>A>	4879288	Sep 26, 2011	DS DP U-601		I-576	Oct 08, 2011
	>A>	4879288*PED	Mar 26, 2012			I-575	Oct 08, 2011
	>A>	5948437	May 28, 2017	DP U-814		I-574	Oct 08, 2011
	>A>	5948437	May 28, 2017	DP U-601		NDF	May 17, 2010
	>A>	5948437*PED	Nov 28, 2017			PED	Apr 08, 2012
						PED	Nov 17, 2010
REMIFENTANIL HYDROCHLORIDE - ULTIVA							
020630 001	**>A>**	5019583	Jul 12, 2010	DS DP U-952			
	>A>	5019583*PED	Jan 12, 2011				

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REMIFENTANIL HYDROCHLORIDE - ULTIVA						
020630 002	**>A>** 5019583	Jul 12, 2010	DS DP U-952			
	>A> 5019583*PED	Jan 12, 2011				
REMIFENTANIL HYDROCHLORIDE - ULTIVA						
020630 003	**>A>** 5019583	Jul 12, 2010	DS DP U-952			
	>A> 5019583*PED	Jan 12, 2011				
RISPERIDONE - RISPERIDONE						
076440 001					PC	Jul 29, 2009
SALMETEROL XINAFOATE - SEREVENT						
020692 001	**>A>** 5590645	Mar 01, 2011	DP			
	>A> 5590645*PED	Sep 01, 2011				
	>A> 5860419	Mar 01, 2011	DP			
	>A> 5860419*PED	Sep 01, 2011				
	>A> 5873360	Feb 23, 2016	DP			
	>A> 5873360*PED	Aug 23, 2016				
	>A> 6032666	Mar 01, 2011	DP			
	>A> 6032666*PED	Sep 01, 2011				
	>A> 6378519	Mar 01, 2011	DP			
	>A> 6378519*PED	Sep 01, 2011				
	>A> 6536427	Mar 01, 2011	DP			
	>A> 6536427*PED	Sep 01, 2011				
	>A> 6792945	Mar 01, 2011	DP			
	>A> 6792945*PED	Sep 01, 2011				
	>A> 7225808	Mar 01, 2011	DP			
	>A> 7225808*PED	Sep 01, 2011				
	>A> 7389775	Mar 01, 2011	DP			
	>A> 7389775*PED	Sep 01, 2011				
SUMATRIPTAN SUCCINATE - SUMATRIPTAN SUCCINATE						
076572 001					**>A>** PC	Aug 09, 2009
SUMATRIPTAN SUCCINATE - SUMATRIPTAN SUCCINATE						
076840 003					**>A>** PC	Aug 09, 2009
TRAMADOL HYDROCHLORIDE - RYZOLT						
021745 001					NP	Dec 30, 2011
TRAMADOL HYDROCHLORIDE - RYZOLT						
021745 002					NP	Dec 30, 2011
TRAMADOL HYDROCHLORIDE - RYZOLT						
021745 003					NP	Dec 30, 2011
TRYPAN BLUE - MEMBRANEBLUE						
022278 001					**>A>** NCE	Dec 16, 2009
ZOLEDRONIC ACID - RECLAST						
021817 001					I-581	Dec 19, 2011

Footnote:

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

PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 28th 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