APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

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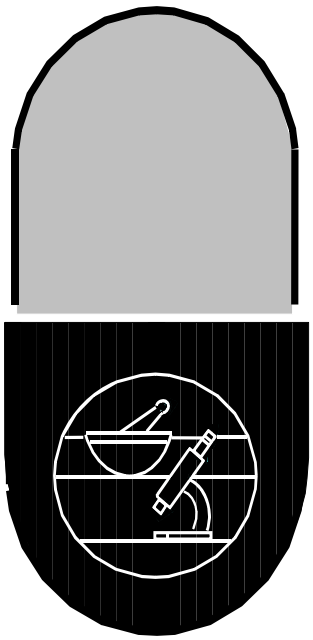
CUMULATIVE SUPPLEMENT 01
January 2009



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

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THERAPEUTIC EQUIVALENCE EVALUATIONS

29th EDITION

Cumulative Supplement 1

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CUMULATIVE SUPPLEMENT 1
January 2009

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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

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.

ALBUTEROL

AEROSOL, METERED; INHALATION

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

ALBUTEROL SULFATE

SOLUTION; INHALATION

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

AMILORIDE HYDROCHLORIDE

TABLET; ORAL

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

AMINOCAPROIC ACID

TABLET; ORAL

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

AMLODIPINE BESYLATE

TABLET; ORAL

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

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

		ORPHENGESIC						
>D>		@ PAR PHARM	385MG;30MG;25MG	N75141	001	May 29, 1998	Jan	CAHN
>A>		@ SOLCO HLTHCARE	385MG;30MG;25MG	N75141	001	May 29, 1998	Jan	CAHN
		ORPHENGESIC FORTE						
>D>		@ PAR PHARM	770MG;60MG;50MG	N75141	002	May 29, 1998	Jan	CAHN
>A>		@ SOLCO HLTHCARE	770MG;60MG;50MG	N75141	002	May 29, 1998	Jan	CAHN

ATRACURIUM BESYLATE

INJECTABLE; INJECTION

		ATRACURIUM BESYLATE						
>D>	AP	HOSPIRA	10MG/ML	N74740	001	Mar 28, 1997	Jan	DISC
>A>		@	10MG/ML	N74740	001	Mar 28, 1997	Jan	DISC
		ATRACURIUM BESYLATE PRESERVATIVE FREE						
>D>	AP	HOSPIRA	10MG/ML	N74741	001	Mar 28, 1997	Jan	DISC
>A>		@	10MG/ML	N74741	001	Mar 28, 1997	Jan	DISC

CALCITRIOL

OINTMENT; TOPICAL

VECTICAL

>A>		+	GALDERMA LABS LP	3UGM/GM	N22087	001	Jan 23, 2009	Jan	NEWA

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL

CARBAMAZEPINE

>D>	AB		CARACO	100MG	N75712	001	Jul 05, 2001	Jan	CAHN
>A>	AB		TORRENT PHARMS	100MG	N75712	001	Jul 05, 2001	Jan	CAHN

CHOLINE FENOFIBRATE

CAPSULE, DELAYED RELEASE; ORAL

TRILIPEX

>D>			ABBOTT LABS	EQ 45MG FENOFIBRIC ACID	N22224	001	Dec 15, 2008	Jan	CTNA
>D>		+		EQ 135MG FENOFIBRIC ACID	N22224	002	Dec 15, 2008	Jan	CTNA

TRILIPIX

>A>			ABBOTT LABS	EQ 45MG FENOFIBRIC ACID	N22224	001	Dec 15, 2008	Jan	CTNA
>A>		+		EQ 135MG FENOFIBRIC ACID	N22224	002	Dec 15, 2008	Jan	CTNA

CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL

CIPROFLOXACIN HYDROCHLORIDE

>D>	AB		TEVA	EQ 250MG BASE	N76136	001	Jun 09, 2004	Jan	DISC
>A>		@		EQ 250MG BASE	N76136	001	Jun 09, 2004	Jan	DISC
>D>	AB			EQ 500MG BASE	N76136	002	Jun 09, 2004	Jan	DISC
>A>		@		EQ 500MG BASE	N76136	002	Jun 09, 2004	Jan	DISC
>D>	AB			EQ 750MG BASE	N76136	003	Jun 09, 2004	Jan	DISC
>A>		@		EQ 750MG BASE	N76136	003	Jun 09, 2004	Jan	DISC

>A> DEXLANSOPRAZOLE

CAPSULE, DELAYED RELEASE; ORAL

KAPIDEX

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

DIVALPROEX SODIUM

CAPSULE, DELAYED REL PELLETS; ORAL

DEPAKOTE

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

DIVALPROEX SODIUM

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

TABLET, EXTENDED RELEASE; ORAL

DEPAKOTE ER

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

DIVALPROEX SODIUM

>A>	AB		MYLAN	EQ 250MG VALPROIC ACID	N77567	001	Jan 29, 2009	Jan	NEWA
>A>	AB			EQ 500MG VALPROIC ACID	N77567	002	Jan 29, 2009	Jan	NEWA
>A>	AB		WOCKHARDT	EQ 250MG VALPROIC ACID	N78705	002	Feb 10, 2009	Jan	NEWA

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

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

ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYL

>D>			GRANULE; ORAL						
>D>			ERYZOLE						
>D>	AB		ALRA	EQ 200MG BASE/5ML;EQ 600MG BASE/5ML	N62758	001	Jun 15, 1988	Jan	DISC
>A>			@	EQ 200MG BASE/5ML;EQ 600MG BASE/5ML	N62758	001	Jun 15, 1988	Jan	DISC
>D>			PEDIAZOLE						
>D>	AB	+	ROSS LABS	EQ 200MG BASE/5ML;EQ 600MG BASE/5ML	N50529	001		Jan	DISC
>A>			@	EQ 200MG BASE/5ML;EQ 600MG BASE/5ML	N50529	001		Jan	DISC

GALANTAMINE HYDROBROMIDE

SOLUTION; ORAL

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

TABLET; ORAL

GALANTAMINE HYDROBROMIDE

>A>	AB		PAR PHARM	EQ 4MG BASE	N77604	001	Feb 06, 2009	Jan	NEWA
>A>	AB			EQ 8MG BASE	N77604	002	Feb 06, 2009	Jan	NEWA
>A>	AB			EQ 12MG BASE	N77604	003	Feb 06, 2009	Jan	NEWA
>A>	AB		ROXANE	EQ 4MG BASE	N77608	001	Feb 11, 2009	Jan	NEWA
>A>	AB			EQ 8MG BASE	N77608	002	Feb 11, 2009	Jan	NEWA
>A>	AB			EQ 12MG BASE	N77608	003	Feb 11, 2009	Jan	NEWA

IBUPROFEN

TABLET; ORAL

IBUPROFEN

>A>	AB		SHASUN USA	400MG	N78329	001	Feb 05, 2009	Jan	NEWA
>A>	AB			600MG	N78329	002	Feb 05, 2009	Jan	NEWA
>A>	AB			800MG	N78329	003	Feb 05, 2009	Jan	NEWA

IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION

IRINOTECAN HYDROCHLORIDE

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

KETOCONAZOLE

GEL; TOPICAL

XOLEGEL

>D>		+	BARRIER THERAP	2%	N21946	001	Jul 28, 2006	Jan	CAHN
>A>		+	STIEFEL LABS INC	2%	N21946	001	Jul 28, 2006	Jan	CAHN

LAMOTRIGINE

TABLET; ORAL

LAMOTRIGINE

>A>	AB	APOTEX INC	25MG	N78625	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N78625	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N78625	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N78625	004	Jan 27, 2009	Jan	NEWA
>A>	AB	AUROBINDO PHARMA	25MG	N78956	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N78956	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N78956	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N78956	004	Jan 27, 2009	Jan	NEWA
>A>	AB	CADISTA PHARMS	25MG	N79132	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N79132	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N79132	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N79132	004	Jan 27, 2009	Jan	NEWA
>A>	AB	DR REDDYS LABS LTD	25MG	N76708	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N76708	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N76708	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N76708	004	Jan 27, 2009	Jan	NEWA
>A>	AB	GENPHARM ULC	25MG	N77428	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N77428	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N77428	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N77428	004	Jan 27, 2009	Jan	NEWA
>A>	AB	MATRIX LABS LTD	25MG	N78443	001	Feb 11, 2009	Jan	NEWA
>A>	AB		100MG	N78443	002	Feb 11, 2009	Jan	NEWA
>A>	AB		150MG	N78443	003	Feb 11, 2009	Jan	NEWA
>A>	AB		200MG	N78443	004	Feb 11, 2009	Jan	NEWA
>A>	AB	MYLAN	25MG	N77420	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N77420	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N77420	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N77420	004	Jan 27, 2009	Jan	NEWA
>A>	AB	ROXANE	25MG	N77392	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N77392	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N77392	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N77392	004	Jan 27, 2009	Jan	NEWA
>A>	AB	SANDOZ	25MG	N78645	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N78645	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N78645	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N78645	004	Jan 27, 2009	Jan	NEWA
>A>	AB	TARO PHARM INDS	25MG	N78525	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N78525	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N78525	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N78525	004	Jan 27, 2009	Jan	NEWA
>A>	AB	TORRENT PHARMS	25MG	N78947	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N78947	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N78947	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N78947	004	Jan 27, 2009	Jan	NEWA
>A>	AB	UPSHER SMITH	25MG	N78310	001	Feb 04, 2009	Jan	NEWA
>A>	AB		100MG	N78310	002	Feb 04, 2009	Jan	NEWA
>A>	AB		150MG	N78310	003	Feb 04, 2009	Jan	NEWA
>A>	AB		200MG	N78310	004	Feb 04, 2009	Jan	NEWA
>A>	AB	WOCKHARDT	25MG	N78982	001	Jan 27, 2009	Jan	NEWA
>A>	AB		100MG	N78982	002	Jan 27, 2009	Jan	NEWA
>A>	AB		150MG	N78982	003	Jan 27, 2009	Jan	NEWA
>A>	AB		200MG	N78982	004	Jan 27, 2009	Jan	NEWA

TABLET; ORAL
LAMOTRIGINE

>A>	AB		ZYDUS PHARMS USA	25MG	N77633	001	Jan 27, 2009	Jan	NEWA
>A>				50MG	N77633	002	Jan 27, 2009	Jan	NEWA
>A>	AB			100MG	N77633	003	Jan 27, 2009	Jan	NEWA
>A>	AB			150MG	N77633	004	Jan 27, 2009	Jan	NEWA
>A>	AB			200MG	N77633	005	Jan 27, 2009	Jan	NEWA
>A>				250MG	N77633	006	Jan 27, 2009	Jan	NEWA

TABLET, CHEWABLE; ORAL
LAMOTRIGINE

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

LEVETIRACETAM

SOLUTION; ORAL
LEVETIRACETAM

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

TABLET; ORAL
LEVETIRACETAM

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

LINDANE

SHAMPOO; TOPICAL
LINDANE

>D>	AT	+	AL AND S	1%	N87266	001		Jan	CAHN
>A>	AT	+	OLTA PHARMS	1%	N87266	001		Jan	CAHN

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE

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

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
ANTIVERT

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

MEQUINOL; TRETINOIN

SOLUTION; TOPICAL
SOLAGE

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

METFORMIN HYDROCHLORIDE

TABLET; ORAL
METFORMIN HYDROCHLORIDE

>D>	AB	ACTAVIS ELIZABETH	500MG	N76033	001	Jan 24, 2002	Jan	CAHN
>D>	AB		850MG	N76033	002	Jan 24, 2002	Jan	CAHN
>D>	AB		1GM	N76033	003	Jan 24, 2002	Jan	CAHN
>A>	AB	ALVOGEN	500MG	N76033	001	Jan 24, 2002	Jan	CAHN
>A>	AB		850MG	N76033	002	Jan 24, 2002	Jan	CAHN
>A>	AB		1GM	N76033	003	Jan 24, 2002	Jan	CAHN

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

>D>		@ PAR PHARM	500MG	N86989	001		Jan	CAHN
>D>		@	750MG	N86988	001		Jan	CAHN
>A>		@ SOLCO HLTHCARE	500MG	N86989	001		Jan	CAHN
>A>		@	750MG	N86988	001		Jan	CAHN

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE ACETATE

>A>	AP	SANDOZ	40MG/ML	N40719	001	Jan 29, 2009	Jan	NEWA
>A>	AP		80MG/ML	N40719	002	Jan 29, 2009	Jan	NEWA

METOPROLOL TARTRATE

TABLET; ORAL
METOPROLOL TARTRATE

>D>		@ PAR PHARM	50MG	N74453	001	Apr 27, 1995	Jan	CAHN
>D>		@	100MG	N74453	002	Apr 27, 1995	Jan	CAHN
>A>		@ SOLCO HLTHCARE	50MG	N74453	001	Apr 27, 1995	Jan	CAHN
>A>		@	100MG	N74453	002	Apr 27, 1995	Jan	CAHN

MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE

OINTMENT; TOPICAL
VUSION

>D>	+	BARRIER	0.25%;81.35%;15%	N21026	001	Feb 16, 2006	Jan	CAHN
>A>	+	STIEFEL LABS INC	0.25%;81.35%;15%	N21026	001	Feb 16, 2006	Jan	CAHN

>A> MILNACIPRAN HYDROCHLORIDE

>A> TABLET; ORAL
>A> SAVELLA

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

MINOCYCLINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
>A> MINOCYCLINE HYDROCHLORIDE

>A>	AB	IMPAX LABS INC	EQ 45MG BASE	N90024	001	Feb 03, 2009	Jan	NEWA
>A>	AB		EQ 90MG BASE	N90024	002	Feb 03, 2009	Jan	NEWA
>A>	AB		EQ 135MG BASE	N90024	003	Feb 03, 2009	Jan	NEWA

SOLODYN

>D>		MEDICIS	EQ 45MG BASE	N50808	001	May 08, 2006	Jan	CFTG
>A>	AB		EQ 45MG BASE	N50808	001	May 08, 2006	Jan	CFTG

TABLET, EXTENDED RELEASE; ORAL
SOLODYN

>D>			MEDICIS	EQ 90MG BASE	N50808	002	May 08, 2006	Jan	CFTG
>A>	AB			EQ 90MG BASE	N50808	002	May 08, 2006	Jan	CFTG
>D>		+		EQ 135MG BASE	N50808	003	May 08, 2006	Jan	CFTG
>A>	AB	+		EQ 135MG BASE	N50808	003	May 08, 2006	Jan	CFTG

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL
OMEPRAZOLE

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

OXYBUTYNIN CHLORIDE

>A>				GEL; TRANSDERMAL					
>A>				OXYBUTYNIN CHLORIDE					
>A>		+	WATSON LABS	10%(100MG/PACKET)	N22204	001	Jan 27, 2009	Jan	NEWA

TABLET, EXTENDED RELEASE; ORAL
OXYBUTYIN CHLORIDE

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

PHENYTOIN SODIUM

CAPSULE; ORAL
PROMPT PHENYTOIN SODIUM

>D>	BX	+	IVAX PHARMS	100MG PROMPT	N80259	001		Jan	DISC
>A>			@	100MG PROMPT	N80259	001		Jan	DISC

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL
POLYETHYLENE GLYCOL 3350

>A>	AA		GAVIS PHARMS	17GM/SCOOPFUL	N77736	001	May 26, 2006	Jan	CAHN
>D>	AA		KALI LABS	17GM/SCOOPFUL	N77736	001	May 26, 2006	Jan	CAHN
>D>	AA		TEVA PHARMS	17GM/SCOOPFUL	N77445	001	May 04, 2006	Jan	DISC
>A>			@	17GM/SCOOPFUL	N77445	001	May 04, 2006	Jan	DISC

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL
POTASSIUM CHLORIDE

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

RISPERIDONE

SOLUTION; ORAL
RISPERDAL

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

RISPERIDONE

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

SUMATRIPTAN SUCCINATE

INJECTABLE; SUBCUTANEOUS
IMITREX

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

			INJECTABLE; SUBCUTANEOUS							
			IMITREX							
>A>	AP	+	GLAXOSMITHKLINE	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N20080	001	Dec 28, 1992	Jan	CFTG	
			SUMATRIPTAN SUCCINATE							
>A>	AP		BEDFORD	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N79123	001	Feb 06, 2009	Jan	NEWA	
>A>	AP		SANDOZ	EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML)	N78067	002	Feb 06, 2009	Jan	NEWA	
>A>	AP			EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N78067	001	Feb 06, 2009	Jan	NEWA	
>A>	AP		TEVA PARENTERAL	EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML)	N78318	001	Feb 06, 2009	Jan	NEWA	
>A>	AP			EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N78318	002	Feb 06, 2009	Jan	NEWA	
>A>	AP			EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N77907	001	Feb 06, 2009	Jan	NEWA	
>A>	AP		WOCKHARDT	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N78593	001	Feb 06, 2009	Jan	NEWA	
			TABLET; ORAL							
			IMITREX							
>D>			GLAXOSMITHKLINE	EQ 25MG BASE	N20132	002	Jun 01, 1995	Jan	CFTG	
>A>	AB			EQ 25MG BASE	N20132	002	Jun 01, 1995	Jan	CFTG	
>D>				EQ 50MG BASE	N20132	003	Jun 01, 1995	Jan	CFTG	
>A>	AB			EQ 50MG BASE	N20132	003	Jun 01, 1995	Jan	CFTG	
>D>		+		EQ 100MG BASE	N20132	001	Jun 01, 1995	Jan	CFTG	
>A>	AB	+		EQ 100MG BASE	N20132	001	Jun 01, 1995	Jan	CFTG	
>A>			SUMATRIPTAN SUCCINATE							
>A>	AB		RANBAXY	EQ 100MG BASE	N76572	001	Feb 09, 2009	Jan	NEWA	
>A>	AB		TEVA	EQ 25MG BASE	N76840	001	Feb 09, 2009	Jan	NEWA	
>A>	AB			EQ 50MG BASE	N76840	002	Feb 09, 2009	Jan	NEWA	
>A>	AB			EQ 100MG BASE	N76840	003	Feb 09, 2009	Jan	NEWA	
		TORSEMIDE								
			TABLET; ORAL							
			TORSEMIDE							
>A>	AB		HETERO DRUGS	5MG	N79234	001	Jan 27, 2009	Jan	NEWA	
>A>	AB			10MG	N79234	002	Jan 27, 2009	Jan	NEWA	
>A>	AB			20MG	N79234	003	Jan 27, 2009	Jan	NEWA	
>A>	AB			100MG	N79234	004	Jan 27, 2009	Jan	NEWA	

INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN

INJECTABLE; INJECTION

>D>		HUMULIN 50/50						
>D>	+	LILLY	50 UNITS/ML;50 UNITS/ML	N20100	001	Apr 29, 1992	Jan	DISC
>A>		@	50 UNITS/ML;50 UNITS/ML	N20100	001	Apr 29, 1992	Jan	DISC

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST

CUMULATIVE SUPPLEMENT NUMBER 01 JANUARY 2009

NO JANUARY 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 JANUARY 2009 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2009

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
AMIODARONE HYDROCHLORIDE - NEXTERONE						
022325 001	**>A>** 5134127	Jan 23, 2010	DP			
	>A> 5376645	Jan 23, 2010	DP			
	>A> 6869939	May 04, 2022	DP			
AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE - PREVPAC						
050757 001	**>A>** 4628098	May 10, 2009	DS			
	>A> 4628098*PED	Nov 10, 2009				
	>A> 5013743	Feb 12, 2010	U-452			
	>A> 5013743*PED	Aug 12, 2010				
	>A> 5045321	Sep 03, 2008	DP			
	>A> 5045321*PED	Mar 03, 2009				
	>A> 5093132	Sep 03, 2008	DP			
	>A> 5093132*PED	Mar 03, 2009				
	>A> 5433959	Sep 03, 2008	DP			
	>A> 5433959*PED	Mar 03, 2009				
ANASTROZOLE - ARIMIDEX						
020541 001	**>A>** RE36617	Dec 27, 2009	DS DP U-946			
AZITHROMYCIN - AZASITE						
050810 001	**>A>** 5192535	Mar 09, 2010	DP U-709			
	>A> 6239113	Mar 31, 2019	U-709			
	>A> 6569443	Mar 31, 2019	DP U-709			
	>A> 6861411	Nov 25, 2018	U-709			
	>A> 7056893	Mar 31, 2019	DP U-709			
BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE - ACANYA						
050819 001	**>A>** 5733886	Mar 31, 2015	DP U-124			
	>A> 6117843	Feb 18, 2012	DP			
BETAMETHASONE VALERATE - LUXIQ						
020934 001	**>A>** 7078058	May 24, 2017	DS DP			
CALCITRIOL - VECTICAL						
022087 001					**>A>** NDF	Jan 23, 2012
CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - PEPCID COMPLETE						
020958 001	**>A>** 5075114	May 23, 2010	DP			
	>A> 5075114*PED	Nov 23, 2010				
	>A> 6814978	Aug 26, 2021	DP			
	>A> 6814978*PED	Feb 26, 2022				
CICLESONIDE - ALVESCO						
021658 002					**>A>** NDF	Jan 10, 2011
					>A> NCE	Oct 20, 2011
CICLESONIDE - ALVESCO						
021658 003					**>A>** NDF	Jan 10, 2011
					>A> NCE	Oct 20, 2011
CLOBETASOL PROPIONATE - OLUX						
021142 001	**>A>** 6126920	Mar 01, 2016	U-484			
DEGARELIX ACETATE - DEGARELIX ACETATE						
022201 001	**>A>** 5925730	Apr 11, 2017	DS DP U-943			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2009

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DEGARELIX ACETATE - DEGARELIX ACETATE						
022201 002	**>A>** 5925730	Apr 11, 2017	DS DP U-943			
DIVALPROEX SODIUM - DIVALPROEX SODIUM						
077567 002					**>A>** PC	Aug 01, 2009
ELTROMBOPAG OLAMINE - PROMACTA						
022291 001	**>A>** 7473686	Jul 24, 2021	DS DP U-930			
ELTROMBOPAG OLAMINE - PROMACTA						
022291 002	**>A>** 7473686	Jul 24, 2021	DS DP U-930			
FLUDARABINE PHOSPHATE - FLUDARABINE PHOSPHATE						
022273 001	**>A>** 7148207	Dec 20, 2021	DP U-944			
FOSPROPOFOL DISODIUM - LUSEDRA						
022244 001	**>A>** 6204257	Jun 07, 2018	DS DP U-945			
HYDROCHLOROTHIAZIDE; TELMISARTAN - MICARDIS HCT						
021162 003	**>A>** 5591762	Jan 07, 2014	DS DP U-3			
INSULIN DETEMIR RECOMBINANT - LEVEMIR						
021536 001	**>A>** 5750497	May 16, 2019	DS DP U-668			
INSULIN GLARGINE RECOMBINANT - LANTUS						
021081 001	**>A>** 5656722	Aug 12, 2014	DS DP U-948			
	>A> 5656722*PED	Feb 12, 2015				
	>A> 7476652	Jun 13, 2023	DP			
	>A> 7476652*PED	Dec 13, 2023				
LANSOPRAZOLE - PREVACID						
021428 001	**>A>** 7431942	May 17, 2019	DP			
	>A> 7431942*PED	Nov 17, 2019				
LANSOPRAZOLE - PREVACID						
021428 002	**>A>** 7431942	May 17, 2019	DP			
	>A> 7431942*PED	Nov 17, 2019				
LANSOPRAZOLE - PREVACID IV						
021566 001	**>A>** 4628098	May 10, 2009	DS			
	>A> 4628098*PED	Nov 10, 2009				
	>A> 7396841	Aug 17, 2021	DP U-947			
	>A> 7396841*PED	Feb 17, 2022				
LANSOPRAZOLE; NAPROXEN - PREVACID NAPRAPAC 500 (COPACKAGED)						
021507 004	**>A>** 4628098	May 10, 2009	DS			
	>A> 4628098*PED	Nov 10, 2009				
	>A> 5045321	Sep 03, 2008	DP			
	>A> 5045321*PED	Mar 03, 2009				
	>A> 5093132	Sep 03, 2008	DP			
	>A> 5093132*PED	Mar 03, 2009				
	>A> 5433959	Sep 03, 2008	DP			
	>A> 5433959*PED	Mar 03, 2009				
LANTHANUM CARBONATE - FOSRENOL						
021468 001	**>A>** 5968976	Oct 26, 2018	DP U-613			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2009

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LANTHANUM CARBONATE - FOSRENOL						
021468 002	**>A>** 5968976	Oct 26, 2018	DP U-613			
LANTHANUM CARBONATE - FOSRENOL						
021468 003	**>A>** 5968976	Oct 26, 2018	DP U-613			
LANTHANUM CARBONATE - FOSRENOL						
021468 004	**>A>** 5968976	Oct 26, 2018	DP U-613			
LIDOCAINE HYDROCHLORIDE - ZINGO						
022114 001					**>A>** NPP	Jan 08, 2012
MILNACIPRAN HYDROCHLORIDE - SAVELLA						
022256 001					**>A>** NCE	Jan 14, 2014
MILNACIPRAN HYDROCHLORIDE - SAVELLA						
022256 002					**>A>** NCE	Jan 14, 2014
MILNACIPRAN HYDROCHLORIDE - SAVELLA						
022256 003					**>A>** NCE	Jan 14, 2014
MILNACIPRAN HYDROCHLORIDE - SAVELLA						
022256 004					**>A>** NCE	Jan 14, 2014
NITROGLYCERIN - NITROMIST						
021780 001	**>A>** 5869082	Apr 16, 2016	DP			
OXYBUTYNIN CHLORIDE - OXYBUTYNIN CHLORIDE						
022204 001					**>A>** NDF	Jan 27, 2012
PRAMLINTIDE ACETATE - SYMLIN						
021332 002	**>A>** 5814600	Sep 29, 2015	U-639			
	>A> 5814600	Sep 29, 2015	U-638			
	>A> 5814600	Sep 29, 2015	U-637			
	>A> 5998367	Mar 08, 2011	DS DP			
	>A> 6114304	Sep 05, 2017	U-640			
	>A> 6114304	Sep 05, 2017	U-637			
	>A> 6608029	Sep 07, 2013	U-641			
	>A> 6608029	Sep 07, 2013	U-640			
	>A> 6608029	Sep 07, 2013	U-637			
	>A> 6610824	Mar 03, 2011	DS			
	>A> 7407934	Mar 08, 2011	U-640			
	>A> 7407934	Mar 08, 2011	U-637			
PRAMLINTIDE ACETATE - SYMLIN						
021332 003	**>A>** 5814600	Sep 29, 2015	U-639			
	>A> 5814600	Sep 29, 2015	U-638			
	>A> 5814600	Sep 29, 2015	U-637			
	>A> 5998367	Mar 08, 2011	DS DP			
	>A> 6114304	Sep 05, 2017	U-640			
	>A> 6114304	Sep 05, 2017	U-637			
	>A> 6608029	Sep 07, 2013	U-641			
	>A> 6608029	Sep 07, 2013	U-640			
	>A> 6608029	Sep 07, 2013	U-637			
	>A> 6610824	Mar 03, 2011	DS			
	>A> 7407934	Mar 08, 2011	U-640			
	>A> 7407934	Mar 08, 2011	U-637			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2009

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

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2009

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
QUETIAPINE FUMARATE - SEROQUEL XR						
022047 003	**>A>** 4879288	Sep 26, 2011	DS DP U-814		**>A>** D-117	Oct 08, 2011
	>A> 4879288*PED	Mar 26, 2012			**>A>** I-576	Oct 08, 2011
	>A> 5948437	May 28, 2017	DP U-814		**>A>** I-575	Oct 08, 2011
	>A> 5948437*PED	Nov 28, 2017			**>A>** I-574	Oct 08, 2011
					>A> NDF	May 17, 2010
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QUETIAPINE FUMARATE - SEROQUEL XR						
022047 004	**>A>** 4879288	Sep 26, 2011	DS DP U-814		**>A>** D-117	Oct 08, 2011
	>A> 4879288*PED	Mar 26, 2012			**>A>** I-576	Oct 08, 2011
	>A> 5948437	May 28, 2017	DP U-814		**>A>** I-575	Oct 08, 2011
	>A> 5948437*PED	Nov 28, 2017			**>A>** I-574	Oct 08, 2011
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QUETIAPINE FUMARATE - SEROQUEL XR						
022047 005	**>A>** 4879288	Sep 26, 2011	DS DP U-814		**>A>** D-117	Oct 08, 2011
	>A> 4879288*PED	Mar 26, 2012			**>A>** I-576	Oct 08, 2011
	>A> 5948437	May 28, 2017	DP U-814		**>A>** I-575	Oct 08, 2011
	>A> 5948437*PED	Nov 28, 2017			**>A>** I-574	Oct 08, 2011
					>A> NDF	May 17, 2010
					>A> PED	Apr 08, 2012
					>A> PED	Nov 17, 2010
RISPERIDONE - RISPERIDONE						
076440 001					**>A>** PC	Jul 29, 2009
TRAMADOL HYDROCHLORIDE - RYZOLT						
021745 001					**>A>** NP	Dec 30, 2011
TRAMADOL HYDROCHLORIDE - RYZOLT						
021745 002					**>A>** NP	Dec 30, 2011
TRAMADOL HYDROCHLORIDE - RYZOLT						
021745 003					**>A>** NP	Dec 30, 2011
ZOLEDRONIC ACID - RECLAST						
021817 001					**>A>** 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