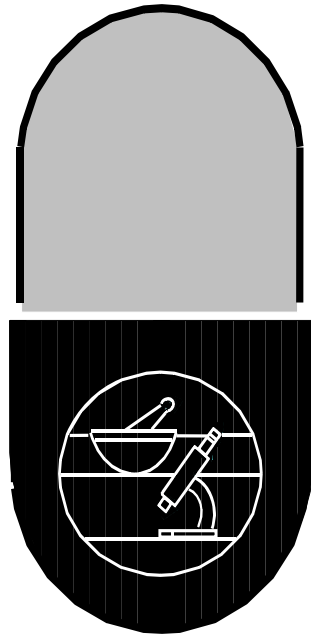


**CUMULATIVE
SUPPLEMENT 01
January 2009**



**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

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

29th EDITION

Cumulative Supplement 1

January 2009

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

29th EDITION

**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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.
 - Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
 - 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	NEW APPLICANT NAME
<u>(FORMER ABBREVIATED NAME)</u>	<u>(NEW ABBREVIATED NAME)</u>

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

<u>CATEGORIES COUNTED</u>	<u>DEC 2008</u>	<u>MAR 2009</u>	<u>JUN 2009</u>	<u>SEPT 2009</u>
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			

¹Amino acid-containing products of varying composition (see Introduction, page xx of the List).

1.6 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be preceded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.

CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.

PRESCRIPTION DRUG PRODUCT LIST - 29TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2009

1-1

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

>A>		OINTMENT; TOPICAL						
>A>		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
>A>		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>		<u>DEXLANSOPRAZOLE</u>						
>A>		CAPSULE, DELAYED RELEASE; ORAL						
>A>		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; ORALLAMOTRIGINE

>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; ORALLAMOTRIGINE

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

LEVETIRACETAMSOLUTION; ORALLEVETIRACETAM

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

>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

LINDANESHAMPOO; TOPICALLINDANE

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

LITHIUM CARBONATECAPSULE; ORALLITHIUM 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 HYDROCHLORIDETABLET; ORALANTIVERT

>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; TRETINOINSOLUTION; TOPICALSOLAGE

>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

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

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
>D>		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

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	
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

OTC DRUG PRODUCT LIST - 29TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2009

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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
<u>AMIODARONE HYDROCHLORIDE - NEXTERONE</u>						
022325 001	>A> 5134127	Jan 23, 2010	DP			
	>A> 5376645	Jan 23, 2010	DP			
	>A> 6869939	May 04, 2022	DP			
<u>AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE - PREVPAC</u>						
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				
<u>ANASTROZOLE - ARIMIDEX</u>						
020541 001	>A> RE36617	Dec 27, 2009	DS DP	U-946		
<u>AZITHROMYCIN - AZASITE</u>						
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		
<u>BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE - ACANYA</u>						
050819 001	>A> 5733886	Mar 31, 2015	DP	U-124		
	>A> 6117843	Feb 18, 2012	DP			
<u>BETAMETHASONE VALERATE - LUXIQ</u>						
020934 001	>A> 7078058	May 24, 2017	DS DP			
<u>CALCITRIOL - VECTICAL</u>						
022087 001					>A> NDF	Jan 23, 2012
<u>CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - PEPCID COMPLETE</u>						
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				
<u>CICLESONIDE - ALVESCO</u>						
021658 002					>A> NDF	Jan 10, 2011
					>A> NCE	Oct 20, 2011
<u>CICLESONIDE - ALVESCO</u>						
021658 003					>A> NDF	Jan 10, 2011
					>A> NCE	Oct 20, 2011
<u>CLOBETASOL PROPIONATE - OLUX</u>						
021142 001	>A> 6126920	Mar 01, 2016		U-484		
<u>DEGARELIX ACETATE - DEGARELIX ACETATE</u>						
022201 001	>A> 5925730	Apr 11, 2017	DS DP	U-943		

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
<u>DEGARELIX ACETATE - DEGARELIX ACETATE</u>						
022201 002	>A> 5925730	Apr 11, 2017	DS DP U-943			
<u>DIVALPROEX SODIUM - DIVALPROEX SODIUM</u>						
077567 002					>A> PC	Aug 01, 2009
<u>ELTROMBOPAG OLAMINE - PROMACTA</u>						
022291 001	>A> 7473686	Jul 24, 2021	DS DP U-930			
<u>ELTROMBOPAG OLAMINE - PROMACTA</u>						
022291 002	>A> 7473686	Jul 24, 2021	DS DP U-930			
<u>FLUDARABINE PHOSPHATE - FLUDARABINE PHOSPHATE</u>						
022273 001	>A> 7148207	Dec 20, 2021	DP U-944			
<u>FOSPROPOFOL DISODIUM - LUSEDRA</u>						
022244 001	>A> 6204257	Jun 07, 2018	DS DP U-945			
<u>HYDROCHLOROTHIAZIDE; TELMISARTAN - MICARDIS HCT</u>						
021162 003	>A> 5591762	Jan 07, 2014	DS DP U-3			
<u>INSULIN DETEMIR RECOMBINANT - LEVEMIR</u>						
021536 001	>A> 5750497	May 16, 2019	DS DP U-668			
<u>INSULIN GLARGINE RECOMBINANT - LANTUS</u>						
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				
<u>LANSOPRAZOLE - PREVACID</u>						
021428 001	>A> 7431942	May 17, 2019	DP			
	>A> 7431942*PED	Nov 17, 2019				
<u>LANSOPRAZOLE - PREVACID</u>						
021428 002	>A> 7431942	May 17, 2019	DP			
	>A> 7431942*PED	Nov 17, 2019				
<u>LANSOPRAZOLE - PREVACID IV</u>						
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				
<u>LANSOPRAZOLE; NAPROXEN - PREVACID NAPRAPAC 500 (COPACKAGED)</u>						
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				
<u>LANTHANUM CARBONATE - FOSRENOL</u>						
021468 001	>A> 5968976	Oct 26, 2018	DP U-613			

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
<u>LANTHANUM CARBONATE - FOSRENOL</u>						
021468 002	>A> 5968976	Oct 26, 2018	DP U-613			
<u>LANTHANUM CARBONATE - FOSRENOL</u>						
021468 003	>A> 5968976	Oct 26, 2018	DP U-613			
<u>LANTHANUM CARBONATE - FOSRENOL</u>						
021468 004	>A> 5968976	Oct 26, 2018	DP U-613			
<u>LIDOCAINE HYDROCHLORIDE - ZINGO</u>						
022114 001					>A> NPP	Jan 08, 2012
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
022256 001					>A> NCE	Jan 14, 2014
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
022256 002					>A> NCE	Jan 14, 2014
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
022256 003					>A> NCE	Jan 14, 2014
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
022256 004					>A> NCE	Jan 14, 2014
<u>NITROGLYCERIN - NITROMIST</u>						
021780 001	>A> 5869082	Apr 16, 2016	DP			
<u>OXYBUTYNIN CHLORIDE - OXYBUTYNIN CHLORIDE</u>						
022204 001					>A> NDF	Jan 27, 2012
<u>PRAMLINTIDE ACETATE - SYMLIN</u>						
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			
<u>PRAMLINTIDE ACETATE - SYMLIN</u>						
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

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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
					>A> PED	Nov 13, 2011
					>A> PED	Apr 20, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>						
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
					>A> PED	Apr 08, 2012
					>A> PED	Nov 17, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>						
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
					>A> PED	Apr 08, 2012
					>A> PED	Nov 17, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>						
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
					>A> NDF	May 17, 2010
					>A> PED	Apr 08, 2012
					>A> PED	Nov 17, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>						
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
<u>RISPERIDONE - RISPERIDONE</u>						
076440 001					>A> PC	Jul 29, 2009
<u>TRAMADOL HYDROCHLORIDE - RYZOLT</u>						
021745 001					>A> NP	Dec 30, 2011
<u>TRAMADOL HYDROCHLORIDE - RYZOLT</u>						
021745 002					>A> NP	Dec 30, 2011
<u>TRAMADOL HYDROCHLORIDE - RYZOLT</u>						
021745 003					>A> NP	Dec 30, 2011
<u>ZOLEDRONIC ACID - RECLAST</u>						
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>