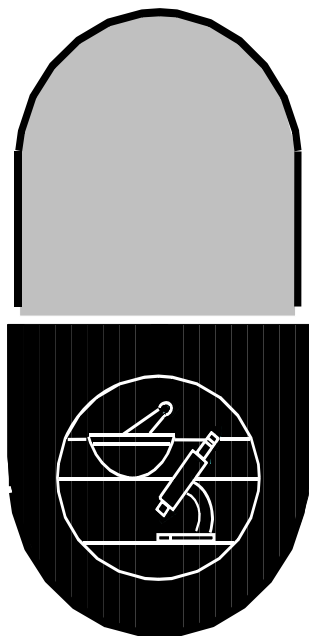


**CUMULATIVE
SUPPLEMENT 02
February 2009**



**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**

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 2

February 2009

CONTENTS

	<i>PAGE</i>
1.0 INTRODUCTION	iii
1.1 How to use the Cumulative Supplement	iii
1.2 Cumulative Supplement Content.....	iv
1.3 Applicant Name Changes.....	v
1.4 Availability of the Edition	v
1.5 Report of Counts for the Prescription Drug Product List	vi
1.6 Cumulative Supplement Legend	vii
DRUG PRODUCT LISTS	
Prescription Drug Product List	1-1
OTC Drug Product List	2-1
Drug Products with Approval under Section 505 of the Act	
Administered by the Center for Biologics Evaluation and Research List.....	3-1
Orphan Product Designations and Approvals List	4-1
Drug Products Which Must Demonstrate in vivo Bioavailability	
Only if Product Fails to Achieve Adequate Dissolution	5-1
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Patent and Exclusivity Lists	A-1
B. Patent and Exclusivity Terms	B-1

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

29th EDITION

**CUMULATIVE SUPPLEMENT 2
February 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

<u>FORMER APPLICANT NAME</u> (FORMER ABBREVIATED NAME)	<u>NEW APPLICANT NAME</u> (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

<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 - 28TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2009

1-1

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-SMOOTHIE/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

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

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

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

>A>		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>	WATSON LABS FLORIDA	250MG	N77408 001	Mar 02, 2009	Feb	NEWA
>A>		500MG	N77408 002	Mar 02, 2009	Feb	NEWA
>A>		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

MALATHION

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

ALUPENT

>D>						
>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>		NIMOTOP					
>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

>D> MICRO-K

>D> AB KV PHARM 8MEQ N18238 001 Feb DISC

>A> @ 8MEQ N18238 001 Feb DISC

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

>A> RANITIDINE HYDROCHLORIDE

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

OTC DRUG PRODUCT LIST - 29TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2009

2-1

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

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	5134127	Jan 23, 2010	DP			
	5376645	Jan 23, 2010	DP			
	6869939	May 04, 2022	DP			
<u>AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE - PREVPAC</u>						
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				
<u>ANASTROZOLE - ARIMIDEX</u>						
020541 001	RE36617	Dec 27, 2009	DS DP	U-946		
<u>AZITHROMYCIN - AZASITE</u>						
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		
<u>BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE - ACANYA</u>						
050819 001	5733886	Mar 31, 2015	DP	U-124		
	6117843	Feb 18, 2012	DP			
<u>BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE - DUAC</u>						
050741 001	>A> 5466446	Feb 16, 2014	DS DP			
<u>BETAMETHASONE VALERATE - LUXIQ</u>						
020934 001	7078058	May 24, 2017	DP			
<u>BIMATOPROST - LATISSE</u>						
022369 001				>A> NP		Dec 24, 2011
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
021929 001				>A> I-582		Feb 27, 2012
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
021929 002				>A> I-582		Feb 27, 2012
<u>CALCITRIOL - VECTICAL</u>						
022087 001				NDF		Jan 23, 2012
<u>CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - PEPCID COMPLETE</u>						
020958 001	5075114	May 23, 2010	DP			
	5075114*PED	Nov 23, 2010				
	6814978	Aug 26, 2021	DP			
	6814978*PED	Feb 26, 2022				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>CICLESONIDE - ALVESCO</u>						
021658 002					NDF NCE	Jan 10, 2011 Oct 20, 2011
<u>CICLESONIDE - ALVESCO</u>						
021658 003					NDF NCE	Jan 10, 2011 Oct 20, 2011
<u>CLOBETASOL PROPIONATE - OLUX</u>						
021142 001	6126920	Mar 01, 2016		U-484		
<u>CLOPIDOGREL BISULFATE - PLAVIX</u>						
020839 002	>A> 4847265	Nov 17, 2011	DS DP			
	>A> 6429210	Jun 10, 2019	DS DP			
	>A> 6504030	Jun 10, 2019	DS			
<u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u>						
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				
<u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u>						
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

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 001	5925730	Apr 11, 2017	DS DP U-943			
<u>DEGARELIX ACETATE - DEGARELIX ACETATE</u>						
022201 002	5925730	Apr 11, 2017	DS DP U-943			
<u>DEXAMETHASONE; TOBRAMYCIN - TOBRADEX ST</u>						
050818 001	>A> 5149694	Sep 22, 2009				
<u>DEXLANSOPRAZOLE - KAPIDEX</u>						
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				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>DEXLANSOPRAZOLE - KAPIDEX</u>						
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				
<u>DIVALPROEX SODIUM - DIVALPROEX SODIUM</u>						
077567 002					PC	Aug 01, 2009
<u>ELTROMBOPAG OLAMINE - PROMACTA</u>						
022291 001	7473686	Jul 24, 2021	DS DP U-930			
<u>ELTROMBOPAG OLAMINE - PROMACTA</u>						
022291 002	7473686	Jul 24, 2021	DS DP U-930			
<u>ESTRADIOL - ELESTRIN</u>						
021813 001	>A> 7470433	Aug 03, 2021	DP			
<u>FEBUXOSTAT - ULORIC</u>						
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			
<u>FEBUXOSTAT - ULORIC</u>						
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			
<u>FLUDARABINE PHOSPHATE - FLUDARABINE PHOSPHATE</u>						
022273 001	>A> 7148207	Dec 20, 2022	DP U-944		>A> NDF	Dec 18, 2011

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>FLUTICASONE PROPIONATE - FLOVENT DISKUS 100</u>						
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				
<u>FLUTICASONE PROPIONATE - FLOVENT DISKUS 250</u>						
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				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>FLUTICASONE PROPIONATE - FLOVENT DISKUS 50</u>						
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				
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>						
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				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>FLUTICASONE PROPIONATE - FLOVENT HFA</u>						
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				
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>						
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			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u>						
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				
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u>						
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				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u>						
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				
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
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	

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
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			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
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			
<u>FLUVOXAMINE MALEATE - LUVOX</u>						
021519 001					>A> M-83	Apr 14, 2011
<u>FLUVOXAMINE MALEATE - LUVOX</u>						
021519 002					>A> M-83	Apr 14, 2011
<u>FLUVOXAMINE MALEATE - LUVOX</u>						
021519 003					>A> M-83	Apr 14, 2011
<u>FOSPROPOFOL DISODIUM - LUSEDRA</u>						
022244 001	6204257	Jun 07, 2018	DS DP U-945		>A> NCE	Dec 12, 2013
<u>GADODIAMIDE - OMNISCAN</u>						
022066 002	>A> 5362475	Nov 08, 2011	DS			
<u>HYDROCHLOROTHIAZIDE; TELMISARTAN - MICARDIS HCT</u>						
021162 003	5591762	Jan 07, 2014	DS DP U-3			
<u>IMATINIB MESYLATE - GLEEVEC</u>						
021588 001					>A> I-583	Dec 19, 2011

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>IMATINIB MESYLATE - GLEEVEC</u>						
021588 002					>A> I-583	Dec 19, 2011
<u>INSULIN DETEMIR RECOMBINANT - LEVEMIR</u>						
021536 001	5750497	May 16, 2019	DS DP U-668			
<u>INSULIN GLARGINE RECOMBINANT - LANTUS</u>						
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				
<u>IODIXANOL - VISIPAQUE 270</u>						
020351 001	>A> 5366722	Nov 22, 2011	DP			
	>A> RE36418	Jul 12, 2011	DP			
<u>IODIXANOL - VISIPAQUE 270</u>						
020808 001	>A> 5366722	Nov 22, 2011	DP			
	>A> RE36418	Jul 12, 2011	DP			
<u>IODIXANOL - VISIPAQUE 320</u>						
020351 002	>A> RE36418	Jul 12, 2011	DP			
<u>IODIXANOL - VISIPAQUE 320</u>						
020808 002	>A> RE36418	Jul 12, 2011	DP			
<u>LANSOPRAZOLE - PREVACID</u>						
021428 001	7431942	May 17, 2019	DP			
	7431942*PED	Nov 17, 2019				
<u>LANSOPRAZOLE - PREVACID</u>						
021428 002	7431942	May 17, 2019	DP			
	7431942*PED	Nov 17, 2019				
<u>LANSOPRAZOLE - PREVACID IV</u>						
021566 001	4628098	May 10, 2009	DS			
	4628098*PED	Nov 10, 2009				
	7396841	Aug 17, 2021	DP U-947			
	7396841*PED	Feb 17, 2022				
<u>LANSOPRAZOLE; NAPROXEN - PREVACID NAPRAPAC 500 (COPACKAGED)</u>						
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				
<u>LANTHANUM CARBONATE - FOSRENOL</u>						
021468 001	5968976	Oct 26, 2018	DP U-613			
<u>LANTHANUM CARBONATE - FOSRENOL</u>						
021468 002	5968976	Oct 26, 2018	DP U-613			
<u>LANTHANUM CARBONATE - FOSRENOL</u>						
021468 003	5968976	Oct 26, 2018	DP U-613			

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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 004	5968976	Oct 26, 2018	DP U-613			
<u>LEVETIRACETAM - KEPBRA XR</u>						
022285 002					>A> NDF	Sep 12, 2011
<u>LIDOCAINE HYDROCHLORIDE - ZINGO</u>						
022114 001					NPP	Jan 08, 2012
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
022256 001					NCE	Jan 14, 2014
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
022256 002					NCE	Jan 14, 2014
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
022256 003					NCE	Jan 14, 2014
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
022256 004					NCE	Jan 14, 2014
<u>MORPHINE SULFATE - AVINZA</u>						
021260 005	>A> 6066339	Nov 25, 2017	DP			
<u>MORPHINE SULFATE - AVINZA</u>						
021260 006	>A> 6066339	Nov 25, 2017	DP			
<u>NITROGLYCERIN - NITROMIST</u>						
021780 001	5869082	Apr 16, 2016	DP			
<u>OXYBUTYNIN CHLORIDE - OXYBUTYNIN CHLORIDE</u>						
022204 001					NDF	Jan 27, 2012
<u>PANTOPRAZOLE SODIUM - PROTONIX</u>						
020987 001	>A> 4758579	Jul 19, 2010				
	>A> 4758579*PED	Jan 19, 2011				
	>A> 5997903	Dec 07, 2016				
	>A> 5997903*PED	Jun 07, 2017				
<u>PANTOPRAZOLE SODIUM - PROTONIX</u>						
020987 002	>A> 4758579	Jul 19, 2010				
	>A> 4758579*PED	Jan 19, 2011				
	>A> 5997903	Dec 07, 2016				
	>A> 5997903*PED	Jun 07, 2017				
<u>PANTOPRAZOLE SODIUM - PROTONIX</u>						
022020 001	>A> 4758579	Jul 19, 2010	DS DP U-859			
	>A> 4758579*PED	Jan 19, 2011				
<u>PANTOPRAZOLE SODIUM - PROTONIX IV</u>						
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				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>PRAMLINTIDE ACETATE - SYMLIN</u>						
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			
<u>PRAMLINTIDE ACETATE - SYMLIN</u>						
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			
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
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

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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 006	4879288	Sep 26, 2011	DS DP U-550		I-560	May 13, 2011
	4879288*PED	Mar 26, 2012			I-503 PED PED	Oct 20, 2009 Nov 13, 2011 Apr 20, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
020639 007	4879288	Sep 26, 2011	DS DP U-550		I-560	May 13, 2011
	4879288*PED	Mar 26, 2012			I-503 PED PED	Oct 20, 2009 Nov 13, 2011 Apr 20, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>						
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 I-574	Oct 08, 2011 Oct 08, 2011
	>A> 5948437	May 28, 2017	DP U-814		NDF	May 17, 2010
	>A> 5948437	May 28, 2017	DP U-601		PED	Apr 08, 2012
	>A> 5948437*PED	Nov 28, 2017			PED	Nov 17, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>						
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 I-574	Oct 08, 2011 Oct 08, 2011
	>A> 5948437	May 28, 2017	DP U-814		NDF	May 17, 2010
	>A> 5948437	May 28, 2017	DP U-601		PED	Apr 08, 2012
	>A> 5948437*PED	Nov 28, 2017			PED	Nov 17, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>						
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 I-574	Oct 08, 2011 Oct 08, 2011
	>A> 5948437	May 28, 2017	DP U-814		NDF	May 17, 2010
	>A> 5948437	May 28, 2017	DP U-601		PED	Apr 08, 2012
	>A> 5948437*PED	Nov 28, 2017			PED	Nov 17, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>						
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 I-574	Oct 08, 2011 Oct 08, 2011
	>A> 5948437	May 28, 2017	DP U-814		NDF	May 17, 2010
	>A> 5948437	May 28, 2017	DP U-601		PED	Apr 08, 2012
	>A> 5948437*PED	Nov 28, 2017			PED	Nov 17, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>						
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 I-574	Oct 08, 2011 Oct 08, 2011
	>A> 5948437	May 28, 2017	DP U-814		NDF	May 17, 2010
	>A> 5948437	May 28, 2017	DP U-601		PED	Apr 08, 2012
	>A> 5948437*PED	Nov 28, 2017			PED	Nov 17, 2010
<u>REMIFENTANIL HYDROCHLORIDE - ULTIVA</u>						
020630 001	>A> 5019583	Jul 12, 2010	DS DP U-952			
	>A> 5019583*PED	Jan 12, 2011				

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 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>REMIFENTANIL HYDROCHLORIDE - ULTIVA</u>						
020630 002	>A> 5019583	Jul 12, 2010	DS DP U-952			
	>A> 5019583*PED	Jan 12, 2011				
<u>REMIFENTANIL HYDROCHLORIDE - ULTIVA</u>						
020630 003	>A> 5019583	Jul 12, 2010	DS DP U-952			
	>A> 5019583*PED	Jan 12, 2011				
<u>RISPERIDONE - RISPERIDONE</u>						
076440 001					PC	Jul 29, 2009
<u>SALMETEROL XINAFOATE - SEREVENT</u>						
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				
<u>SUMATRIPTAN SUCCINATE - SUMATRIPTAN SUCCINATE</u>						
076572 001					>A> PC	Aug 09, 2009
<u>SUMATRIPTAN SUCCINATE - SUMATRIPTAN SUCCINATE</u>						
076840 003					>A> PC	Aug 09, 2009
<u>TRAMADOL HYDROCHLORIDE - RYZOLT</u>						
021745 001					NP	Dec 30, 2011
<u>TRAMADOL HYDROCHLORIDE - RYZOLT</u>						
021745 002					NP	Dec 30, 2011
<u>TRAMADOL HYDROCHLORIDE - RYZOLT</u>						
021745 003					NP	Dec 30, 2011
<u>TRYPAN BLUE - MEMBRANEBLUE</u>						
022278 001					>A> NCE	Dec 16, 2009
<u>ZOLEDRONIC ACID - RECLAST</u>						
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>