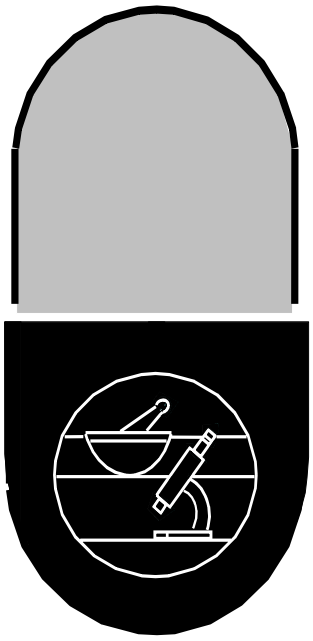
CUMULATIVE SUPPLEMENT 1
JANUARY 2005



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

25th EDITION

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

2005

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

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CONTENTS

PAGE

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1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 25th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 25th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 26th 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 Data are indicated by the symbol **>ADD>** to the left of the line on which new information exists. The **>ADD>** 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 Lists are arranged in alphabetical order by active ingredient name. In addition, the trade name will be displayed to the right of the active ingredient name for each product. 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 APPLICANT NAME CHANGES

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

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

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
SHIRE LABORATORIES INC (SHIRE LABS)	SHIRE DEVELOPMENT INC (SHIRE)
SHIRE PHARMACEUTICAL DEVELOPMENT INC (SHIRE PHARM)	SHIRE DEVELOPMENT INC (SHIRE)

1.3 AVAILABILITY OF THE EDITION

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements will not be available in a published paper version. Since 1997, the Electronic Orange Book (EOB http://www.fda.gov/cder/ob/default.htm, has been available on the internet and has become the updated-every-month Orange Book.

By early April, the 25th edition and current monthly supplement will be available in an electronic downloadable Portable Document Format (PDF) at the EOB home page by clicking on the EOB Preface. The PDF annual and cumulative supplements will duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The Electronic Orange Book Query (EOB) is at http://www.fda.gov/cder/ob/default.htm. 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. Currently, In addition to monthly updates, in the public interest, the EOB is updated on a daily basis with new generic product approval information and new patent information. Current month updates are accomplished by the third week of the following month.

The Internet version of the Orange Book annual edition is at http://www.fda.gov/cder/ob/docs/preface/ectablec.htm The Internet version of the monthly supplement is at http://www.fda.gov/cder/orange/supplement/cspreface.htm .

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 zipped into eobzip.exe. The files are updated concurrently with the monthly cumulative supplements. Appendix A and Appendix B text files of the annual Orange Book Edition are updated quarterly.

The 25th annual edition of the 2005 Orange Book Patent and Exclusivity List is at http://www.fda.gov/cder/orange/24bookpub.pdf.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at http://www.fda.gov/cder/orange/supplement/patents.pdf.

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.

1.4 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 2004) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST
COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 2004	MAR 2005	JUN 2005	SEP 2005
DRUG PRODUCTS LISTED	11082			
SINGLE SOURCE	2427 (21.9%)			
MULTISOURCE	8547 (77.1%)			
THERAPEUTICALLY EQUIVALENT	8327 (75.1%)			
NOT THERAPEUTICALLY EQUIVALENT	220 (2.0%)			
EXCEPTIONS[1]	108 (1.0%)			
NEW MOLECULAR ENTITIES APPROVED	9			

NUMBER OF APPLICANTS 625

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

1.5 CUMULATIVE SUPPLEMENT LEGEND

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

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

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

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

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.
WDAG	Withdrawn. The applicant holder has notified the FDA in writing that the product in no longer being marketed resulting in the product approval being withdrawn by mutual agreement. The product will be listed in the Discontinued Section.
WDRP	Withdrawn. The application approval has been withdrawn for failure to provide Annual Reports. The product will be moved to the Discontinued Section in the next edition.

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

ACETIC ACID

>D>	AT		MORTON GROVE	2%	N40166	001	Jul 26, 1996	Jan	CRLD
>A>	AT	+		2%	N40166	001	Jul 26, 1996	Jan	CRLD
>D>			VOSOL						
>D>	AT	+	MEDPOINTE PHARM HLC	2%	N12179	001		Jan	DISC
>A>			@	2%	N12179	001		Jan	DISC

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

>D>	AN		DEY	EQ 0.083% BASE	N72652	001	Feb 21, 1992	Jan	CRLD
>A>	AN	+		EQ 0.083% BASE	N72652	001	Feb 21, 1992	Jan	CRLD

ALPRAZOLAM

>A>			TABLET, ORALLY DISINTEGRATING; ORAL						
>A>			NIRAVAM						
>A>			SCHWARZ PHARMA	0.25MG	N21726	001	Jan 19, 2005	Jan	NEWA
>A>				0.5MG	N21726	002	Jan 19, 2005	Jan	NEWA
>A>				1MG	N21726	003	Jan 19, 2005	Jan	NEWA
>A>		+		2MG	N21726	004	Jan 19, 2005	Jan	NEWA

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

>A>	AB		HIKMA PHARMS	200MG/5ML;EQ 28.5MG BASE/5ML	N65191	002	Jan 25, 2005	Jan	NEWA
>A>	AB			400MG/5ML;EQ 57MG BASE/5ML	N65191	001	Jan 25, 2005	Jan	NEWA

TABLET, CHEWABLE; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

>A>	AB		TEVA	200MG;EQ 28.5MG BASE	N65205	001	Feb 09, 2005	Jan	NEWA
>A>	AB			400MG;EQ 57MG BASE	N65205	002	Feb 09, 2005	Jan	NEWA

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

>D>			@ IBI	EQ 125MG BASE/VIAL	N62797	001	Jul 12, 1993	Jan	CMFD
>D>	AP			EQ 2GM BASE/VIAL	N62797	002	Jul 12, 1993	Jan	CAHN
>A>	AP		INSTITUTO BIOCHEMICO	EQ 125MG BASE/VIAL	N62797	001	Jul 12, 1993	Jan	CMFD
>A>	AP			EQ 2GM BASE/VIAL	N62797	002	Jul 12, 1993	Jan	CAHN

ATENOLOL

TABLET; ORAL

ATENOLOL

>A>	AB		ZYDUS PHARMS USA	25MG	N76900	001	Jan 28, 2005	Jan	NEWA
>A>	AB			50MG	N76900	002	Jan 28, 2005	Jan	NEWA
>A>	AB			100MG	N76900	003	Jan 28, 2005	Jan	NEWA

BETAMETHASONE DIPROPIONATE

OINTMENT; TOPICAL

>D>			ALPHATREX						
>D>	AB		SAVAGE LABS	EQ 0.05% BASE	N19143	001	Sep 04, 1984	Jan	DISC
>A>			@	EQ 0.05% BASE	N19143	001	Sep 04, 1984	Jan	DISC

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN

>A>	AB	BELCHER	EQ 250MG BASE	N62713	001	Jul 15, 1988	Jan	CAHN
>A>	AB		EQ 500MG BASE	N62713	002	Jul 15, 1988	Jan	CAHN
>D>	AB	LABS ATRAL	EQ 250MG BASE	N62713	001	Jul 15, 1988	Jan	CAHN
>D>	AB		EQ 500MG BASE	N62713	002	Jul 15, 1988	Jan	CAHN
>D>	AB	MJ PHARMS	EQ 250MG BASE	N62791	001	Jun 11, 1987	Jan	CAHN
>D>	AB		EQ 500MG BASE	N62791	002	Jun 11, 1987	Jan	CAHN
>A>	AB	SUN PHARM INDS (IN)	EQ 250MG BASE	N62791	001	Jun 11, 1987	Jan	CAHN
>A>	AB		EQ 500MG BASE	N62791	002	Jun 11, 1987	Jan	CAHN

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CIPROFLOXACIN

>A>	AT	HITECH PHARMA	EQ 0.3% BASE	N76673	001	Jan 21, 2005	Jan	NEWA

TABLET; ORAL
CIPROFLOXACIN

>A>	AB	COBALT	EQ 100MG BASE	N76794	001	Feb 10, 2005	Jan	NEWA
>A>	AB	TARO	EQ 100MG BASE	N76912	001	Feb 18, 2005	Jan	NEWA

CITALOPRAM HYDROBROMIDE

TABLET; ORAL
CITALOPRAM HYDROBROMIDE

>A>	AB	MYLAN	EQ 10MG BASE	N77039	001	Feb 03, 2005	Jan	NEWA
>A>	AB		EQ 20MG BASE	N77039	002	Feb 03, 2005	Jan	NEWA
>A>	AB		EQ 40MG BASE	N77039	003	Feb 03, 2005	Jan	NEWA

CLARITHROMYCIN

TABLET, EXTENDED RELEASE; ORAL
>A> CLARITHROMYCIN

>A>		RANBAXY	1GM	N65210	001	Jan 26, 2005	Jan	NEWA

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL
CLINDAMYCIN HYDROCHLORIDE

>A>	AB	ZYDUS PHARMS USA	EQ 75MG BASE	N65217	001	Jan 31, 2005	Jan	NEWA
>A>	AB		EQ 150MG BASE	N65217	002	Jan 31, 2005	Jan	NEWA
>A>	AB		EQ 300MG BASE	N65217	003	Jan 31, 2005	Jan	NEWA

CYANOCOBALAMIN

>A> SPRAY, METERED; NASAL
>A> NASCOBAL

>A>	+	NASTECH PHARM	0.5MG/SPRAY	N21642	001	Jan 31, 2005	Jan	NEWA

DALTEPARIN SODIUM

INJECTABLE; INJECTION
FRAGMIN

>A>	+	PHARMACIA AND UPJOHN	7,500 IU/0.3ML	N20287	005	Apr 04, 2002	Jan	NEWA

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL
DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)

>A>	AB	APOTEX	0.01MG/SPRAY	N76703	001	Jan 27, 2005	Jan	NEWA

ERYTHROMYCIN

SOLUTION; TOPICAL

ERYMAX

>D>	AT		ALLERGAN HERBERT	2%	N62508	002	Jul 11, 1985	Jan	CAHN
>A>	AT		MERZ PHARMS	2%	N62508	002	Jul 11, 1985	Jan	CAHN

ESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED REL PELLETS; ORAL

NEXIUM

>D>		+	ASTRAZENECA	EQ 20MG BASE	N21153	001	Feb 20, 2001	Jan	CRLD
>A>				EQ 20MG BASE	N21153	001	Feb 20, 2001	Jan	CRLD

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

>D>	BX	+	BERLEX	0.025MG/24HR	N20375	004	Mar 05, 1999	Jan	CFTG
>A>	AB2	+		0.025MG/24HR	N20375	004	Mar 05, 1999	Jan	CFTG
>D>	BX	+		0.075MG/24HR	N20375	003	Mar 23, 1998	Jan	CFTG
>A>	AB2	+		0.075MG/24HR	N20375	003	Mar 23, 1998	Jan	CFTG

>D>

ESCLIM

>D>	BX		WOMEN FIRST HLTHCARE	0.025MG/24HR	N20847	001	Aug 04, 1998	Jan	DISC
>A>		@		0.025MG/24HR	N20847	001	Aug 04, 1998	Jan	DISC
>D>	BX			0.0375MG/24HR	N20847	002	Aug 04, 1998	Jan	DISC
>A>		@		0.0375MG/24HR	N20847	002	Aug 04, 1998	Jan	DISC
>D>	BX			0.05MG/24HR	N20847	003	Aug 04, 1998	Jan	DISC
>A>		@		0.05MG/24HR	N20847	003	Aug 04, 1998	Jan	DISC
>D>	BX			0.075MG/24HR	N20847	004	Aug 04, 1998	Jan	DISC
>A>		@		0.075MG/24HR	N20847	004	Aug 04, 1998	Jan	DISC
>D>	BX			0.1MG/24HR	N20847	005	Aug 04, 1998	Jan	DISC
>A>		@		0.1MG/24HR	N20847	005	Aug 04, 1998	Jan	DISC

ESTRADIOL

>A>	AB2		MYLAN TECHNOLOGIES	0.025MG/24HR	N75182	003	Jan 26, 2005	Jan	NEWA
>A>	AB2			0.075MG/24HR	N75182	002	Jan 26, 2005	Jan	NEWA

VIVELLE

>D>	AB1	+	NOVARTIS	0.025MG/24HR	N20323	005	Aug 16, 2000	Jan	DISC
>A>		@		0.025MG/24HR	N20323	005	Aug 16, 2000	Jan	DISC
>D>	AB1	+		0.05MG/24HR	N20323	002	Oct 28, 1994	Jan	CRLD
>A>	AB1			0.05MG/24HR	N20323	002	Oct 28, 1994	Jan	CRLD
>D>	AB1	+		0.1MG/24HR	N20323	004	Oct 28, 1994	Jan	CRLD
>A>	AB1			0.1MG/24HR	N20323	004	Oct 28, 1994	Jan	CRLD

VIVELLE-DOT

>D>	AB1		NOVARTIS	0.025MG/24HR	N20538	009	May 03, 2002	Jan	CRLD
>A>	BX	+		0.025MG/24HR	N20538	009	May 03, 2002	Jan	CRLD
>D>	BX			0.0375MG/24HR	N20538	005	Jan 08, 1999	Jan	CRLD
>A>	BX	+		0.0375MG/24HR	N20538	005	Jan 08, 1999	Jan	CRLD
>D>	AB1			0.05MG/24HR	N20538	006	Jan 08, 1999	Jan	CRLD
>A>	AB1	+		0.05MG/24HR	N20538	006	Jan 08, 1999	Jan	CRLD
>D>	BX			0.075MG/24HR	N20538	007	Jan 08, 1999	Jan	CRLD
>A>	BX	+		0.075MG/24HR	N20538	007	Jan 08, 1999	Jan	CRLD
>D>	AB1			0.1MG/24HR	N20538	008	Jan 08, 1999	Jan	CRLD
>A>	AB1	+		0.1MG/24HR	N20538	008	Jan 08, 1999	Jan	CRLD

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION

FENOLDOPAM MESYLATE

>A>	AP	SABEX 2002	EQ 10MG BASE/ML	N77155	001	Feb 15, 2005	Jan	NEWA

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL

DURAGESIC

>D>	+	ALZA	0.6MG/24HR	N19813	004	Aug 07, 1990	Jan	CFTG
>D>			1.2MG/24HR	N19813	003	Aug 07, 1990	Jan	CFTG
>D>			1.8MG/24HR	N19813	002	Aug 07, 1990	Jan	CFTG
>D>			2.4MG/24HR	N19813	001	Aug 07, 1990	Jan	CFTG

DURAGESIC-100

>A>	AB	ALZA	100UGM/HR	N19813	001	Aug 07, 1990	Jan	CFTG

DURAGESIC-25

>A>	AB	+ ALZA	25UGM/HR	N19813	004	Aug 07, 1990	Jan	CFTG

DURAGESIC-50

>A>	AB	ALZA	50UGM/HR	N19813	003	Aug 07, 1990	Jan	CFTG

DURAGESIC-75

>A>	AB	ALZA	75UGM/HR	N19813	002	Aug 07, 1990	Jan	CFTG
>A>		FENTANYL						
>A>	AB	MYLAN TECHNOLOGIES	25UGM/HR	N76258	001	Jan 28, 2005	Jan	NEWA
>A>	AB		50UGM/HR	N76258	002	Jan 28, 2005	Jan	NEWA
>A>	AB		75UGM/HR	N76258	003	Jan 28, 2005	Jan	NEWA
>A>	AB		100UGM/HR	N76258	004	Jan 28, 2005	Jan	NEWA

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION

FLOVENT

>D>		GLAXOSMITHKLINE	0.044MG/INH	N20548	001	Mar 27, 1996	Jan	CRLD
>A>	+		0.044MG/INH	N20548	001	Mar 27, 1996	Jan	CRLD
>D>			0.11MG/INH	N20548	002	Mar 27, 1996	Jan	CRLD
>A>	+		0.11MG/INH	N20548	002	Mar 27, 1996	Jan	CRLD

FLOVENT HFA

>D>		GLAXOSMITHKLINE	0.044MG/INH	N21433	003	May 14, 2004	Jan	CRLD
>A>	+		0.044MG/INH	N21433	003	May 14, 2004	Jan	CRLD
>D>			0.11MG/INH	N21433	002	May 14, 2004	Jan	CRLD
>A>	+		0.11MG/INH	N21433	002	May 14, 2004	Jan	CRLD

FOLLITROPIN ALFA/BETA

INJECTABLE; SUBCUTANEOUS

FOLLISTIM AQ

>D>		ORGANON USA INC	300 IU/0.525ML	N21211	001	Mar 23, 2004	Jan	CPOT
>A>	+		300 IU/0.36ML	N21211	001	Mar 23, 2004	Jan	CPOT
>D>	+		600 IU/0.885ML	N21211	002	Mar 23, 2004	Jan	CPOT
>A>	+		600 IU/0.72ML	N21211	002	Mar 23, 2004	Jan	CPOT

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE; ORAL

REMINYL

>D>		JOHNSON AND JOHNSON	EQ 8MG BASE	N21615	001	Dec 22, 2004	Jan	CRLD
>A>	+		EQ 8MG BASE	N21615	001	Dec 22, 2004	Jan	CRLD
>D>	+		EQ 24MG BASE	N21615	003	Dec 22, 2004	Jan	CRLD
>A>			EQ 24MG BASE	N21615	003	Dec 22, 2004	Jan	CRLD

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HCL

>A>	AB	TEVA	1.25MG;250MG	N76821	001	Jan 27, 2005	Jan	NEWA
>A>	AB		2.5MG;500MG	N76821	002	Jan 27, 2005	Jan	NEWA
>A>	AB		5MG;500MG	N76821	003	Jan 27, 2005	Jan	NEWA

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

>D>	AA	AXIOM PHARM	1.5MG/5ML;5MG/5ML	N40285	001	Jul 19, 1999	Jan	CAHN
>A>	AA	IVAX PHARMS	1.5MG/5ML;5MG/5ML	N40285	001	Jul 19, 1999	Jan	CAHN

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS

ELIGARD

>D>		+ ATRIX	22.5MG/VIAL	N21379	001	Jul 24, 2002	Jan	CAHN
>A>		+ QLT USA	22.5MG/VIAL	N21379	001	Jul 24, 2002	Jan	CAHN

LEVOFLOXACIN

TABLET; ORAL

LEVAQUIN

>D>		+ ORTHO MCNEIL PHARM	750MG	N20634	003	Sep 08, 2000	Jan	CFTG
>A>	AB	+	750MG	N20634	003	Sep 08, 2000	Jan	CFTG

>A> LEVOFLOXACIN

>A>	AB	TEVA	750MG	N76361	003	Jan 26, 2005	Jan	NEWA

LORAZEPAM

SOLUTION; ORAL

LORAZEPAM

>D>		@ ROXANE	0.5MG/5ML	N74648	001	Mar 18, 1997	Jan	CMFD
>A>			0.5MG/5ML	N74648	001	Mar 18, 1997	Jan	CMFD

>D> MANGAFODIPIR TRISODIUM

>D> INJECTABLE; INJECTION

>D> TESLASCAN

>D>		+ GE HEALTHCARE	37.9MG/ML	N20652	001	Nov 26, 1997	Jan	DISC
>A>		@	37.9MG/ML	N20652	001	Nov 26, 1997	Jan	DISC

METHYLDOPA

TABLET; ORAL

>D> ALDOMET

>D>	AB	+ MERCK	500MG	N13400	002		Jan	DISC
>A>		@	500MG	N13400	002		Jan	DISC

METHYLDOPA

>D>	AB	MYLAN	500MG	N70076	001	Apr 18, 1985	Jan	CRLD
>A>	AB	+	500MG	N70076	001	Apr 18, 1985	Jan	CRLD

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION

>D> ALDOMET

>D>	AP	+ MERCK	50MG/ML	N13401	001		Jan	DISC
>A>		@	50MG/ML	N13401	001		Jan	DISC

METHYLDOPATE HCL

>D>	AP	LUITPOLD	50MG/ML	N71279	001	Oct 02, 1987	Jan	CRLD

			INJECTABLE; INJECTION						
			METHYLDOPATE HCL						
>A>	AP	+	LUITPOLD	50MG/ML	N71279	001	Oct 02, 1987	Jan	CRLD
			METHYLERGONOVINE MALEATE						
			TABLET; ORAL						
			METHERGINE						
>D>			NOVARTIS	0.2MG	N06035	003		Jan	CRLD
>A>		+		0.2MG	N06035	003		Jan	CRLD
			MIDAZOLAM HYDROCHLORIDE						
			INJECTABLE; INJECTION						
			MIDAZOLAM HCL						
>A>	AP		INTL MEDICATED	EQ 1MG BASE/ML	N76144	001	Jan 26, 2005	Jan	NEWA
>A>	AP			EQ 5MG BASE/ML	N76144	002	Jan 26, 2005	Jan	NEWA
			MOMETASONE FUROATE						
			CREAM; TOPICAL						
			ELOCON						
>D>		+	SCHERING	0.1%	N19625	001	May 06, 1987	Jan	CFTG
>A>	AB	+		0.1%	N19625	001	May 06, 1987	Jan	CFTG
>A>			MOMETASONE FUROATE						
>A>	AB		TARO	0.1%	N76679	001	Dec 21, 2004	Jan	NEWA
			OXALIPLATIN						
			INJECTABLE; IV (INFUSION)						
			ELOXATIN						
>A>		+	SANOFI SYNTHELABO	50MG/10ML (5MG/ML)	N21759	001	Jan 31, 2005	Jan	NEWA
>A>		+		100MG/20ML (5MG/ML)	N21759	002	Jan 31, 2005	Jan	NEWA
			PACLITAXEL						
>A>			FOR SUSPENSION; IV (INFUSION)						
>A>			ABRAXANE						
>A>		+	AM BIOSCIENCE	100MG/VIAL	N21660	001	Jan 07, 2005	Jan	NEWA
			PENTOBARBITAL SODIUM						
>D>			CAPSULE; ORAL						
>D>			SODIUM PENTOBARBITAL						
>D>		+	VALEANT PHARM INTL	100MG	N83264	001		Jan	DISC
>A>		@		100MG	N83264	001		Jan	DISC
			POTASSIUM CITRATE						
			TABLET, EXTENDED RELEASE; ORAL						
>D>			POTASSIUM CITRATE						
>D>			MISSION PHARMA	5MEQ	N19071	001	Aug 30, 1985	Jan	CTNA
>D>		+		10MEQ	N19071	002	Aug 31, 1992	Jan	CTNA
>A>			UROCIT-K						
>A>			MISSION PHARMA	5MEQ	N19071	001	Aug 30, 1985	Jan	CTNA
>A>		+		10MEQ	N19071	002	Aug 31, 1992	Jan	CTNA
			PREDNISOLONE						
			SYRUP; ORAL						
			PREDNISOLONE						
>D>	AA		AXIOM PHARM	15MG/5ML	N40287	001	May 28, 1999	Jan	CAHN
>A>	AA		IVAX PHARMS	15MG/5ML	N40287	001	May 28, 1999	Jan	CAHN

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
PROMETHAZINE HCL

>D>	AB	ABLE	12.5MG	N40558	001	Jul 01, 2004	Jan	CTEC
>A>			12.5MG	N40558	001	Jul 01, 2004	Jan	CTEC

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL
QUINAPRIL HCL

>A>	AB	PAR PHARM	EQ 5MG BASE	N76036	001	Jan 28, 2005	Jan	NEWA
>A>	AB		EQ 10MG BASE	N76036	002	Jan 28, 2005	Jan	NEWA
>A>	AB		EQ 20MG BASE	N76036	003	Jan 28, 2005	Jan	NEWA
>A>	AB		EQ 40MG BASE	N76036	004	Jan 28, 2005	Jan	NEWA

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

>A>	AB	INTERPHARM	400MG;80MG	N76899	001	Jan 27, 2005	Jan	NEWA
>A>	AB		800MG;160MG	N76899	002	Jan 27, 2005	Jan	NEWA

TACROLIMUS

CAPSULE; ORAL
PROGRAF

>D>		FUJISAWA HLTHCARE	EQ 1MG BASE	N50708	001	Apr 08, 1994	Jan	CRLD
>A>	+		EQ 1MG BASE	N50708	001	Apr 08, 1994	Jan	CRLD

TERCONAZOLE

CREAM; VAGINAL
TERCONAZOLE

>A>	AB	ALTANA	0.4%	N76712	001	Feb 18, 2005	Jan	NEWA

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION
TESTOSTERONE CYPIONATE

>A>	AO	PADDOCK	200MG/ML	N40530	001	Jan 31, 2005	Jan	NEWA

TOREMIFENE CITRATE

TABLET; ORAL
FARESTON

>A>	+	GTX INC	EQ 60MG BASE	N20497	001	May 29, 1997	Jan	CAHN
>D>	+	ORION	EQ 60MG BASE	N20497	001	May 29, 1997	Jan	CAHN

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL
PRIMSOL

>D>		@ ASCENT PEDS	EQ 25MG BASE/5ML	N74374	001	Jun 23, 1995	Jan	CAHN
>D>	+		EQ 50MG BASE/5ML	N74973	001	Jan 24, 2000	Jan	CAHN
>A>		@ TARO PHARMS NORTH	EQ 25MG BASE/5ML	N74374	001	Jun 23, 1995	Jan	CAHN
>A>	+		EQ 50MG BASE/5ML	N74973	001	Jan 24, 2000	Jan	CAHN

LORATADINE

SYRUP; ORAL

>D>		CLARITIN HIVES RELIEF						
>D>	+	SCHERING	1MG/ML	N20641	003	Nov 19, 2003	Jan	DISC
>A>		@	1MG/ML	N20641	003	Nov 19, 2003	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 2005

NO JANUARY 2005 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 2005 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnote for information regarding report content

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021710 001	CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627		
>ADD>			5912013	JUN 15, 2016	DP		
>ADD>	021710 002	CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627		
>ADD>			5912013	JUN 15, 2016	DP		
>ADD>	021710 003	CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627		
>ADD>			5912013	JUN 15, 2016	DP		
>ADD>	021673 001	CLOFARABINE;CLOLAR	5661136	AUG 26, 2014	U626		
>ADD>			5384310	MAY 23, 2009	DS DP		
>ADD>			4918179	JUN 14, 2005	DS		
>ADD>	021168 001	DIVALPROEX SODIUM;DEPAKOTE ER	6720004	DEC 18, 2018	DP		
>ADD>	021168 002	DIVALPROEX SODIUM;DEPAKOTE ER	6720004	DEC 18, 2018	DP		
>ADD>	021337 001	ERTAPENEM SODIUM;INVANZ	5478820	FEB 02, 2013		NCE	NOV 21, 2006
>ADD>			5652233	FEB 02, 2013		PED	MAY 21, 2007
>ADD>			5952323	MAY 15, 2017			
>ADD>			5478820*PED	AUG 02, 2013			
>ADD>			5652233*PED	AUG 02, 2013			
>ADD>			5952323*PED	NOV 15, 2017			
>ADD>	076323 001	ESMOLOL HYDROCHLORIDE;ESMOLOL HCL				PC	MAY 01, 2005
>ADD>	021476 001	ESZOPICLONE;LUNESTA	6444673	JAN 16, 2012	DS DP		
>ADD>			6319926	JAN 16, 2012	U620		
>ADD>	021476 002	ESZOPICLONE;LUNESTA	6444673	JAN 16, 2012	DS DP		
>ADD>			6319926	JAN 16, 2012	U620		
>ADD>	021476 003	ESZOPICLONE;LUNESTA	6444673	JAN 16, 2012	DS DP		
>ADD>			6319926	JAN 16, 2012	U620		
>ADD>	020747 001	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
>ADD>	020747 002	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
>ADD>	020747 003	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
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>ADD>	020747 005	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
>ADD>	020747 006	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
>ADD>	021077 002	FLUTICASONE PROPIONATE;ADVAIR DISKUS 250/50	6536427	MAR 01, 2011	DP		
>ADD>	021169 001	GALANTAMINE HYDROBROMIDE;REMINYL	6358527	JUN 06, 2017	DP U322		
>ADD>	021169 002	GALANTAMINE HYDROBROMIDE;REMINYL	6358527	JUN 06, 2017	DP U322		
>ADD>	021169 003	GALANTAMINE HYDROBROMIDE;REMINYL	6358527	JUN 06, 2017	DP U322		
>ADD>	020509 001	GEMCITABINE HYDROCHLORIDE;GEMZAR	4808614	MAY 15, 2010	DS	I-428	MAY 19, 2007
>ADD>			5464826	NOV 07, 2012	U146	PED	NOV 19, 2007
>ADD>			4808614*PED	NOV 15, 2010			
>ADD>			5464826*PED	MAY 07, 2013			
>ADD>	020509 002	GEMCITABINE HYDROCHLORIDE;GEMZAR	5464826	NOV 07, 2012	U146	I-428	MAY 19, 2007
>ADD>			4808614	MAY 15, 2010	DS	PED	NOV 19, 2007
>ADD>			4808614*PED	NOV 15, 2010			
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>ADD>	020239 003	GRANISETRON HYDROCHLORIDE;KYTRIL				I-369	AUG 16, 2005
>ADD>	020239 004	GRANISETRON HYDROCHLORIDE;KYTRIL				I-369	AUG 16, 2005
>ADD>	021335 001	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015			
>ADD>	021335 002	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015			
>ADD>	021588 001	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015			
>ADD>	021588 002	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015			
>ADD>	020726 001	LETROZOLE;FEMARA				I-446	OCT 29, 2007
>ADD>	021731 001	LEUPROLIDE ACETATE;ELIGARD	RE37950	OCT 03, 2008	DP U621		
>ADD>			4938763	OCT 03, 2008	DP U621		
>ADD>			5278201	JAN 11, 2011	DP		
>ADD>			5324519	JUN 28, 2011	DP		
>ADD>			5599552	FEB 04, 2014	DP U621		
>ADD>			5739176	OCT 03, 2008	DP U621		
>ADD>			6395293	SEP 28, 2013	DP		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
>ADD>			6565874	OCT 28, 2018	DP U621		
>ADD>			6626870	MAR 27, 2020	DP		
>ADD>			6773714	OCT 28, 2018	U621		
>ADD>	021130 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	DS U319	NCE	APR 18, 2005
>ADD>			6559305	JAN 29, 2021	DS	NPP	DEC 19, 2005
>ADD>			6514529	MAR 15, 2021	DP	I-402	JUL 22, 2006
>ADD>			5688792*PED	MAY 18, 2015		I-431	JUN 23, 2007
>ADD>			6514529*PED	SEP 15, 2021		PED	JAN 22, 2007
>ADD>			6559305*PED	JUL 29, 2021		PED	OCT 18, 2005
>ADD>						PED	DEC 23, 2007
>ADD>						PED	JUN 19, 2006
>ADD>	021130 002	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	DS U319	NCE	APR 18, 2005
>ADD>			6559305	JAN 29, 2021	DS	NPP	DEC 19, 2005
>ADD>			6514529	MAR 15, 2021	DP	I-402	JUL 22, 2006
>ADD>			5688792*PED	MAY 18, 2015		I-431	JUN 23, 2007
>ADD>			6514529*PED	SEP 15, 2021		PED	JAN 22, 2007
>ADD>			6559305*PED	JUL 29, 2021		PED	OCT 18, 2005
>ADD>						PED	DEC 23, 2007
>ADD>						PED	JUN 19, 2006
>ADD>	021131 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U319	NCE	APR 18, 2005
>ADD>			6559305	JAN 29, 2021	DS	NPP	DEC 19, 2005
>ADD>			5688792*PED	MAY 18, 2015		I-402	JUL 22, 2006
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>ADD>						PED	JAN 22, 2007
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>ADD>						PED	DEC 23, 2007
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>ADD>			5688792*PED	MAY 18, 2015		I-402	JUL 22, 2006
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>ADD>						PED	JAN 22, 2007
>ADD>						PED	DEC 23, 2007
>ADD>						PED	JUN 19, 2006
>ADD>	021583 001	MEDROXYPROGESTERONE ACETATE;DEPO-SUBQ PROVERA 10	6495534	MAY 15, 2020	DP		
>ADD>	076863 001	METFORMIN HYDROCHLORIDE;METFORMIN HCL				PC	APR 12, 2005
>ADD>	019962 001	METOPROLOL SUCCINATE;TOPROL-XL	5001161	SEP 18, 2007			
>ADD>			5081154	SEP 18, 2007			
>ADD>	019962 002	METOPROLOL SUCCINATE;TOPROL-XL	5001161	SEP 18, 2007			
>ADD>			5081154	SEP 18, 2007			
>ADD>	019962 003	METOPROLOL SUCCINATE;TOPROL-XL	5001161	SEP 18, 2007			
>ADD>			5081154	SEP 18, 2007			
>ADD>	019962 004	METOPROLOL SUCCINATE;TOPROL-XL	5081154	SEP 18, 2007	U107		
>ADD>			5001161	SEP 18, 2007	U107		
>ADD>	020762 001	MOMETASONE FUROATE MONOHYDRATE;NASONEX	5837699	JAN 27, 2014	DP U625		
>ADD>			6127353	OCT 03, 2017	DS DP		
>ADD>			6723713	JAN 27, 2014	U625		
>ADD>	021204 001	NATEGLINIDE;STARLIX	RE34878	SEP 08, 2009			
>ADD>			6844008	NOV 14, 2017	DP U214		
>ADD>	021204 002	NATEGLINIDE;STARLIX	RE34878	SEP 08, 2009			
>ADD>			6844008	NOV 14, 2017	DP U214		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021706 001	OMEPRAZOLE;ZEGERID	5840737	JUL 16, 2016	DS U623		
>ADD>			6489346	JUL 16, 2016	DS DP U624		
>ADD>			6645988	JUL 16, 2016	DS DP U623		
>ADD>			6780882	JUL 16, 2016	DS DP U624		
>ADD>			6699885	JUL 16, 2016			
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					U624		
>ADD>	021660 001	PACLITAXEL;ABRAXANE				NP	JAN 07, 2008
>ADD>	021756 001	PEGAPTANIB SODIUM;MACUGEN	6051698	SEP 17, 2012	DS		
>ADD>			5919455	OCT 27, 2013	DS		
>ADD>			5932462	AUG 03, 2016	DS		
>ADD>			6113906	OCT 27, 2013	DS		
>ADD>			6011020	JAN 04, 2017	DS		
>ADD>			6426335	JUN 11, 2010	U622		
>ADD>			6147204	JUN 11, 2010	DS		
>ADD>	021446 001	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
>ADD>			6197819	MAR 06, 2018	DS DP		
>ADD>	021446 002	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
>ADD>			6197819	MAR 06, 2018	DS DP		
>ADD>	021446 003	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
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>ADD>	021446 004	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
>ADD>			6197819	MAR 06, 2018	DS DP		
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>ADD>			6197819	MAR 06, 2018	DS DP		
>ADD>	021446 006	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
>ADD>			6197819	MAR 06, 2018	DS DP		
>ADD>	021446 007	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
>ADD>			6197819	MAR 06, 2018	DS DP		
>ADD>	021446 008	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
>ADD>			6197819	MAR 06, 2018	DS DP		
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>ADD>			5362842	DEC 30, 2011	U48		
>ADD>			5859186	DEC 30, 2011	U55		
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					U55		
>ADD>	021060 002	ZICONOTIDE;PRIALT	5795864	JUN 27, 2015	DP		
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>ADD>			5859186	DEC 30, 2011	U55		
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PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES

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 submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:
   DS = Drug Substance claim
   DP = Drug Product claim
   U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at http://www.fda.gov/cder/orange/patex.htm

3. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.

4. *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.

PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 25th Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

The current complete list of Patent terms is available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/pattermsall.cfm

The current complete list of Exclusivity terms is available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/excltermsall.cfm