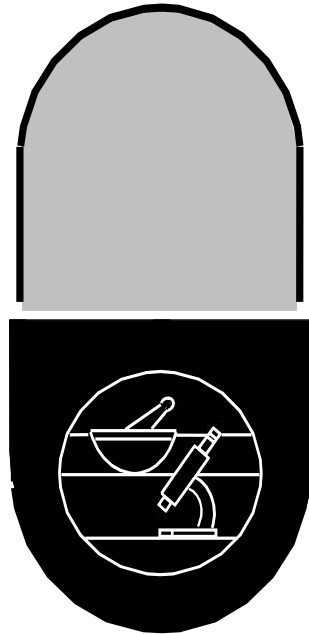


**CUMULATIVE  
SUPPLEMENT 2  
FEBRUARY 2005**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**25<sup>th</sup> 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

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**25<sup>th</sup> EDITION**

**Cumulative Supplement 1**

**February 2005**

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**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**25<sup>th</sup> EDITION**

**CUMULATIVE SUPPLEMENT 1  
February 2005**

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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

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

<u>CATEGORIES COUNTED</u>	<u>DEC 2004</u>	<u>MAR 2005</u>	<u>JUN 2005</u>	<u>SEP 2005</u>
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 <sup>1</sup>	108 (1.0%)
NEW MOLECULAR ENTITIES	
APPROVED	9
NUMBER OF APPLICANTS	625

<sup>1</sup>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 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.
WDAG	Withdrawn. The applicant holder has notified the FDA in writing that the product is 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.

PRESCRIPTION DRUG PRODUCT LIST - 25TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2005

1-1

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, APAP, AND CAFFEINE

>D>	AB	AXIOM PHARM	325MG;50MG;40MG	N89536 001	Feb 16, 1988	Feb	CAHN
>A>	AB	WATSON LABS	325MG;50MG;40MG	N89536 001	Feb 16, 1988	Feb	CAHN

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

ACETIC ACID

	AT	+ MORTON GROVE	2%	N40166 001	Jul 26, 1996	Jan	CRLD
>A>	AT	VINTAGE	2%	N40607 001	Feb 24, 2005	Feb	NEWA
		VOSOL					
		@ MEDPOINTE PHARM HLC	2%	N12179 001		Jan	DISC

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR

>D>	AP	ABBOTT	EQ 50MG BASE/ML	N75114 001	Jul 26, 1999	Feb	DISC
>A>		@	EQ 50MG BASE/ML	N75114 001	Jul 26, 1999	Feb	DISC

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

AN	+	DEY	EQ 0.083% BASE	N72652 001	Feb 21, 1992	Jan	CRLD
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ALPRAZOLAM

TABLET, ORALLY DISINTEGRATING; ORAL

NIRAVAM

		SCHWARZ PHARMA	0.25MG	N21726 001	Jan 19, 2005	Jan	NEWA
			0.5MG	N21726 002	Jan 19, 2005	Jan	NEWA
			1MG	N21726 003	Jan 19, 2005	Jan	NEWA
	+		2MG	N21726 004	Jan 19, 2005	Jan	NEWA

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

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

TABLET, CHEWABLE; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

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

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

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

ATENOLOL

TABLET; ORAL

ATENOLOL

AB		ZYDUS PHARMS USA	25MG	N76900 001	Jan 28, 2005	Jan	NEWA
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## TABLET; ORAL

## ATENOLOL

AB	ZYDUS PHARMS USA	50MG	N76900 002	Jan 28, 2005	Jan	NEWA
AB		100MG	N76900 003	Jan 28, 2005	Jan	NEWA

ATOMOXETINE HYDROCHLORIDE

## CAPSULE; ORAL

## STRATTERA

>A>	LILLY	80MG	N21411 007	Feb 14, 2005	Feb	NEWA
>A>		100MG	N21411 008	Feb 14, 2005	Feb	NEWA

BETAMETHASONE DIPROPIONATE

## OINTMENT; TOPICAL

## ALPHATREX

## @ SAVAGE LABS

EQ 0.05% BASE

N19143 001 Sep 04, 1984 Jan DISC

BUPRENORPHINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## BUPRENORPHINE HCL

>A>	AP	BEDFORD	EQ 0.3MG BASE/ML	N76931 001	Mar 02, 2005	Feb	NEWA
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CAFFEINE; ERGOTAMINE TARTRATE

## SUPPOSITORY; RECTAL

## MIGERGOT

## @ G AND W LABS

100MG;2MG

N86557 001 Oct 04, 1983 Feb CMFD

>A>	BR		100MG;2MG	N86557 001	Oct 04, 1983	Feb	CMFD
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CEPHALEXIN

## CAPSULE; ORAL

## CEPHALEXIN

AB	BELCHER	EQ 250MG BASE	N62713 001	Jul 15, 1988	Jan	CAHN	
AB		EQ 500MG BASE	N62713 002	Jul 15, 1988	Jan	CAHN	
AB	SUN PHARM INDS (IN)	EQ 250MG BASE	N62791 001	Jun 11, 1987	Jan	CAHN	
AB		EQ 500MG BASE	N62791 002	Jun 11, 1987	Jan	CAHN	
>A>	AB	YUNG SHIN PHARM	EQ 250MG BASE	N65152 001	Feb 24, 2005	Feb	NEWA
>A>	AB		EQ 500MG BASE	N65152 002	Feb 24, 2005	Feb	NEWA

CILOSTAZOL

## TABLET; ORAL

## CILOSTAZOL

>A>	AB	COREPHARMA	50MG	N77150 001	Mar 11, 2005	Feb	NEWA
>A>	AB	IVAX PHARMS	100MG	N77020 002	Mar 01, 2005	Feb	NEWA

CIPROFLOXACIN HYDROCHLORIDE

## SOLUTION/DROPS; OPHTHALMIC

## CIPROFLOXACIN

AT	HITECH PHARMA	EQ 0.3% BASE	N76673 001	Jan 21, 2005	Jan	NEWA
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## TABLET; ORAL

## CIPROFLOXACIN

AB	COBALT	EQ 100MG BASE	N76794 001	Feb 10, 2005	Jan	NEWA	
>A>	AB	SANDOZ	EQ 100MG BASE	N75939 001	Mar 03, 2005	Feb	NEWA
AB	TARO	EQ 100MG BASE	N76912 001	Feb 18, 2005	Jan	NEWA	

CITALOPRAM HYDROBROMIDE

TABLET; ORAL

CITALOPRAM HYDROBROMIDE

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

CLARITHROMYCIN

TABLET, EXTENDED RELEASE; ORAL

CLARITHROMYCIN

RANBAXY

1GM

N65210 001 Jan 26, 2005 Jan NEWA

TABLET; ORAL

CLARITHROMYCIN

>A>	AB	GENPHARM	250MG	N65195 001	Mar 11, 2005	Feb	NEWA
>A>	AB		500MG	N65195 002	Mar 11, 2005	Feb	NEWA

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HYDROCHLORIDE

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

CLOTRIMAZOLE

CREAM; TOPICAL

CLOTRIMAZOLE

>D>	AB	TARO	1%	N72640 001	Aug 31, 1993	Feb	CRLD
>A>	+		1%	N72640 001	Aug 31, 1993	Feb	CRLD
>D>		LOTTRIMIN					
>D>	AB	+ SCHERING PLOUGH	1%	N17619 001		Feb	DISC
>A>		@	1%	N17619 001		Feb	DISC
>D>		MYCELEX					
>D>	BT	BAYER PHARMS	1%	N18183 001		Feb	DISC
>A>		@	1%	N18183 001		Feb	DISC

CYANOCOBALAMIN

SPRAY, METERED; NASAL

NASCOBAL

>D>	+	NASTECH PHARM	0.5MG/SPRAY	N21642 001	Jan 31, 2005	Feb	CAHN
	+		0.5MG/SPRAY	N21642 001	Jan 31, 2005	Jan	NEWA
>A>	+	QUESTCOR PHARMS	0.5MG/SPRAY	N21642 001	Jan 31, 2005	Feb	CAHN

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL

CYPROHEPTADINE HCL

>D>	AA	ABC HOLDING	4MG	N88212 001	May 26, 1983	Feb	DISC
>A>		@	4MG	N88212 001	May 26, 1983	Feb	DISC

DALTEPARIN SODIUM

INJECTABLE; INJECTION

FRAGMIN

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

CAPSULE; ORAL

DANTRIUM

>D>		PROCTER AND GAMBLE	25MG	N17443 001		Feb	CFTG
>A>	AB		25MG	N17443 001		Feb	CFTG
>D>			50MG	N17443 003		Feb	CFTG
>A>	AB		50MG	N17443 003		Feb	CFTG
>D>		+	100MG	N17443 002		Feb	CFTG
>A>	AB	+	100MG	N17443 002		Feb	CFTG
>A>		DANTROLENE SODIUM					
>A>	AB	IMPAX LABS	25MG	N76856 001	Mar 01, 2005	Feb	NEWA
>A>	AB		50MG	N76856 002	Mar 01, 2005	Feb	NEWA
>A>	AB		100MG	N76856 003	Mar 01, 2005	Feb	NEWA

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)

AB		APOTEX	0.01MG/SPRAY	N76703 001	Jan 27, 2005	Jan	NEWA
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DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

>D>	AA	ABC HOLDING	25MG	N88267 001	Aug 25, 1983	Feb	DISC	
>A>		@	25MG	N88267 001	Aug 25, 1983	Feb	DISC	
>D>	AA		25MG	N88268 001	Aug 25, 1983	Feb	DISC	
>A>		@	25MG	N88268 001	Aug 25, 1983	Feb	DISC	
		TENUATE						
>D>	AA	+	AVENTIS PHARMS	25MG	N11722 002		Feb	CTEC
>A>		+		25MG	N11722 002		Feb	CTEC

DOXAZOSIN MESYLATE

>A>		TABLET, EXTENDED RELEASE; ORAL					
>A>		CARDURA XL					
>A>		PFIZER	EQ 4MG BASE	N21269 001	Feb 22, 2005	Feb	NEWA
>A>		+	EQ 8MG BASE	N21269 002	Feb 22, 2005	Feb	NEWA

ENALAPRIL MALEATE

TABLET; ORAL

ENALAPRIL MALEATE

>D>	AB	APOTHECON	2.5MG	N75583 001	Aug 22, 2000	Feb	DISC
>A>		@	2.5MG	N75583 001	Aug 22, 2000	Feb	DISC
>D>	AB		5MG	N75583 002	Aug 22, 2000	Feb	DISC
>A>		@	5MG	N75583 002	Aug 22, 2000	Feb	DISC
>D>	AB		10MG	N75583 003	Aug 22, 2000	Feb	DISC
>A>		@	10MG	N75583 003	Aug 22, 2000	Feb	DISC
>D>	AB		20MG	N75583 004	Aug 22, 2000	Feb	DISC
>A>		@	20MG	N75583 004	Aug 22, 2000	Feb	DISC

EPINEPHRINE

INJECTABLE; IM-SC

TWINJECT

>D>		+	HOLLISTER STIER LABS	EQ 0.3MG /DELIVERY	N20800 001	May 30, 2003	Feb	CTNA
>A>			TWINJECT 0.30					
>A>		+	HOLLISTER STIER LABS	EQ 0.3MG /DELIVERY	N20800 001	May 30, 2003	Feb	CTNA

ERYTHROMYCIN

SOLUTION; TOPICAL

ERYMAX

AT	MERZ PHARMS	2%	N62508 002	Jul 11, 1985	Jan	CAHN
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ERYTHROMYCIN ESTOLATE

&gt;D&gt; CAPSULE; ORAL

&gt;D&gt; ERYTHROMYCIN ESTOLATE

>D>	+	BARR	EQ 250MG BASE	N62162 002		Feb	DISC
-----	---	------	---------------	------------	--	-----	------

>A>		@	EQ 250MG BASE	N62162 002		Feb	DISC
-----	--	---	---------------	------------	--	-----	------

ESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED REL PELLETS; ORAL

NEXIUM

ASTRAZENECA EQ 20MG BASE

N21153 001	Feb 20, 2001	Jan	CRLD
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ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

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

ESCLIM

@ WOMEN FIRST HLTHCARE 0.025MG/24HR

N20847 001	Aug 04, 1998	Jan	DISC
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@ 0.0375MG/24HR

N20847 002	Aug 04, 1998	Jan	DISC
------------	--------------	-----	------

@ 0.05MG/24HR

N20847 003	Aug 04, 1998	Jan	DISC
------------	--------------	-----	------

@ 0.075MG/24HR

N20847 004	Aug 04, 1998	Jan	DISC
------------	--------------	-----	------

@ 0.1MG/24HR

N20847 005	Aug 04, 1998	Jan	DISC
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ESTRADIOL

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

@ NOVARTIS 0.025MG/24HR

N20323 005	Aug 16, 2000	Jan	DISC
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AB1			0.05MG/24HR	N20323 002	Oct 28, 1994	Jan	CRLD
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AB1			0.1MG/24HR	N20323 004	Oct 28, 1994	Jan	CRLD
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VIVELLE-DOT

BX	+	NOVARTIS	0.025MG/24HR	N20538 009	May 03, 2002	Jan	CRLD
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BX	+		0.0375MG/24HR	N20538 005	Jan 08, 1999	Jan	CRLD
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AB1	+		0.05MG/24HR	N20538 006	Jan 08, 1999	Jan	CRLD
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BX	+		0.075MG/24HR	N20538 007	Jan 08, 1999	Jan	CRLD
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AB1	+		0.1MG/24HR	N20538 008	Jan 08, 1999	Jan	CRLD
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ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

ORTHO-NOVUM 7/14-28

>D>								
>D>	AB	+	ORTHO MCNEIL PHARM	0.035MG,0.035MG;0.5MG,1MG	N19004 002	Apr 04, 1984	Feb	DISC

>A>			@	0.035MG,0.035MG;0.5MG,1MG	N19004 002	Apr 04, 1984	Feb	DISC
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FENOLDOPAM MESYLATE

INJECTABLE; INJECTION

FENOLDOPAM MESYLATE

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

FILM, EXTENDED RELEASE; TRANSDERMAL

DURAGESIC-100

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

DURAGESIC-12

&gt;A&gt; ALZA 12.5UGM/HR N19813 005 Feb 04, 2005 Feb NEWA

DURAGESIC-25

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

DURAGESIC-50

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

DURAGESIC-75

AB ALZA 75UGM/HR N19813 002 Aug 07, 1990 Jan CFTG

FENTANYL

AB MYLAN TECHNOLOGIES 25UGM/HR N76258 001 Jan 28, 2005 Jan NEWA

AB 50UGM/HR N76258 002 Jan 28, 2005 Jan NEWA

AB 75UGM/HR N76258 003 Jan 28, 2005 Jan NEWA

AB 100UGM/HR N76258 004 Jan 28, 2005 Jan NEWA

FLUOCINONIDE

CREAM; TOPICAL

VANOS

&gt;A&gt; + MEDICIS 0.1% N21758 001 Feb 11, 2005 Feb NEWA

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION

FLOVENT

+ GLAXOSMITHKLINE 0.044MG/INH N20548 001 Mar 27, 1996 Jan CRLD

+ 0.11MG/INH N20548 002 Mar 27, 1996 Jan CRLD

FLOVENT HFA

+ GLAXOSMITHKLINE 0.044MG/INH N21433 003 May 14, 2004 Jan CRLD

+ 0.11MG/INH N21433 002 May 14, 2004 Jan CRLD

FOLLITROPIN ALFA/BETA

INJECTABLE; SUBCUTANEOUS

FOLLISTIM AQ

&gt;A&gt; + ORGANON USA INC 150 IU/0.18ML N21211 003 Feb 11, 2004 Feb NEWA

+ 300 IU/0.36ML N21211 001 Mar 23, 2004 Jan CPOT

+ 600 IU/0.72ML N21211 002 Mar 23, 2004 Jan CPOT

&gt;A&gt; + 900 IU/1.08ML N21211 004 Feb 11, 2005 Feb NEWA

>D> FOMIVIRSEN SODIUM

INJECTABLE; INJECTION

VITRAVENE PRESERVATIVE FREE

&gt;D&gt; + NOVARTIS 6.6MG/ML N20961 001 Aug 26, 1998 Feb DISC

&gt;A&gt; @ 6.6MG/ML N20961 001 Aug 26, 1998 Feb DISC

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

&gt;D&gt; AP LUITPOLD 10MG/ML N18579 001 Nov 30, 1983 Feb CRLD

&gt;A&gt; AP + 10MG/ML N18579 001 Nov 30, 1983 Feb CRLD

&gt;D&gt; LASIX

&gt;D&gt; AP + AVENTIS PHARMS 10MG/ML N16363 001 Feb DISC

&gt;A&gt; @ 10MG/ML N16363 001 Feb DISC

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE; ORAL

REMINYL

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

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HCL

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

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

>D>	@	STERIS	2,000 UNITS/VIAL	N17016	009	Dec 27, 1984	Feb	CAHN
>D>	@		2,000 UNITS/VIAL	N17016	011	Feb 16, 1990	Feb	CAHN
>D>	@		5,000 UNITS/VIAL	N17016	006		Feb	CAHN
>D>	AP	+	10,000 UNITS/VIAL	N17016	007		Feb	CAHN
>D>	@		15,000 UNITS/VIAL	N17016	010	Feb 15, 1985	Feb	CAHN
>D>	@		20,000 UNITS/VIAL	N17016	004		Feb	CAHN
>A>	@	WATSON LABS (UTAH)	2,000 UNITS/VIAL	N17016	009	Dec 27, 1984	Feb	CAHN
>A>	@		2,000 UNITS/VIAL	N17016	011	Feb 16, 1990	Feb	CAHN
>A>	@		5,000 UNITS/VIAL	N17016	006		Feb	CAHN
>A>	AP	+	10,000 UNITS/VIAL	N17016	007		Feb	CAHN
>A>	@		15,000 UNITS/VIAL	N17016	010	Feb 15, 1985	Feb	CAHN
>A>	@		20,000 UNITS/VIAL	N17016	004		Feb	CAHN

GRISEOFULVIN, MICROCRYSTALLINE

SUSPENSION; ORAL

GRIFULVIN V

>D>	+	J AND J	125MG/5ML	N62483	001	Jan 26, 1984	Feb	CFTG
>A>	AB	+	125MG/5ML	N62483	001	Jan 26, 1984	Feb	CFTG
>A>			GRISEOFULVIN					
>A>	AB		STIEFEL	N65200	001	Mar 02, 2005	Feb	NEWA

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

AA	IVAX PHARMS	1.5MG/5ML;5MG/5ML	N40285	001	Jul 19, 1999	Jan	CAHN
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HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

>D>	AA	ABC HOLDING	10MG	N88846	001	Feb 26, 1985	Feb	DISC
>A>	@		10MG	N88846	001	Feb 26, 1985	Feb	DISC
>D>	AA		25MG	N88847	001	Feb 26, 1985	Feb	DISC
>A>	@		25MG	N88847	001	Feb 26, 1985	Feb	DISC
>D>	AA		50MG	N88848	001	Feb 26, 1985	Feb	DISC
>A>	@		50MG	N88848	001	Feb 26, 1985	Feb	DISC
>D>	AA		100MG	N88849	001	Feb 26, 1985	Feb	DISC
>A>	@		100MG	N88849	001	Feb 26, 1985	Feb	DISC



HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

>D>	AB	ABC HOLDING	25MG	N85683 001		Feb	DISC
>A>		@	25MG	N85683 001		Feb	DISC
>D>	AB		50MG	N83965 001		Feb	DISC
>A>		@	50MG	N83965 001		Feb	DISC
>D>	AB		50MG	N85672 001		Feb	DISC
>A>		@	50MG	N85672 001		Feb	DISC

HYDROMORPHONE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

PALLADONE

>D>	+	PURDUE PHARMA LP	16MG	N21044 002	Sep 24, 2004	Feb	CRLD
>A>			16MG	N21044 002	Sep 24, 2004	Feb	CRLD
>D>			32MG	N21044 004	Sep 24, 2004	Feb	CRLD
>A>	+		32MG	N21044 004	Sep 24, 2004	Feb	CRLD

IBANDRONATE SODIUM

TABLET; ORAL

BONIVA

>D>		@ ROCHE	EQ 2.5MG BASE	N21455 001	May 16, 2003	Feb	CMFD
>A>	+		EQ 2.5MG BASE	N21455 001	May 16, 2003	Feb	CMFD

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

>D>	AB	TEVA	10MG	N83729 001		Feb	DISC
>A>		@	10MG	N83729 001		Feb	DISC
>D>	AB		25MG	N83729 004		Feb	DISC
>A>		@	25MG	N83729 004		Feb	DISC
>D>	AB		50MG	N83729 003		Feb	DISC
>A>		@	50MG	N83729 003		Feb	DISC

IRON DEXTRAN

INJECTABLE; INJECTION

INFED

>D>	BP	+	SCHEIN	EQ 50MG IRON/ML	N17441 001	Feb	CAHN
>A>	BP	+	WATSON LABS (UTAH)	EQ 50MG IRON/ML	N17441 001	Feb	CAHN

KANAMYCIN SULFATE

>D>			CAPSULE; ORAL				
>D>			KANTREX				
>D>		+	APOTHECON	EQ 500MG BASE	N62726 001	Mar 06, 1987	Feb DISC
>A>			@	EQ 500MG BASE	N62726 001	Mar 06, 1987	Feb DISC

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS

ELIGARD

+ QLT USA 22.5MG/VIAL

N21379 001 Jul 24, 2002 Jan CAHN

LEVOFLOXACIN

TABLET; ORAL

LEVAQUIN

AB	+	ORTHO MCNEIL PHARM	750MG	N20634 003	Sep 08, 2000	Jan	CFTG
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		TABLET; ORAL							
		LEVOFLOXACIN							
AB		TEVA	750MG		N76361 003	Jan 26, 2005	Jan	NEWA	
		<u>LORAZEPAM</u>							
		SOLUTION; ORAL							
		LORAZEPAM							
		ROXANE	0.5MG/5ML		N74648 001	Mar 18, 1997	Jan	CMFD	
		<u>MANGAFODIPIR TRISODIUM</u>							
		INJECTABLE; INJECTION							
		TESLASCAN							
		@ GE HEALTHCARE	37.9MG/ML		N20652 001	Nov 26, 1997	Jan	DISC	
		<u>MECLIZINE HYDROCHLORIDE</u>							
		TABLET; ORAL							
		MECLIZINE HCL							
>D>	AA	ABC HOLDING	12.5MG		N85253 001		Feb	DISC	
>A>		@	12.5MG		N85253 001		Feb	DISC	
>D>	AA		25MG		N85252 001		Feb	DISC	
>A>		@	25MG		N85252 001		Feb	DISC	
		<u>MEQUINOL; TRETINOIN</u>							
		SOLUTION; TOPICAL							
		SOLAGE							
>A>	+	BARRIER	2%;0.01%		N20922 001	Dec 10, 1999	Feb	CAHN	
>D>	+	GALDERMA LABS	2%;0.01%		N20922 001	Dec 10, 1999	Feb	CAHN	
		<u>METHIMAZOLE</u>							
		TABLET; ORAL							
		METHIMAZOLE							
AB		CEDAR PHARMS	5MG		N40547 001	Feb 18, 2005	Jan	NEWA	
AB			10MG		N40547 002	Feb 18, 2005	Jan	NEWA	
AB			20MG		N40547 004	Feb 18, 2005	Jan	NEWA	
AB	+	GENPHARM	20MG		N40350 003	Jun 07, 2001	Jan	CFTG	
		<u>METHYLDOPA</u>							
		TABLET; ORAL							
		ALDOMET							
		@ MERCK	500MG		N13400 002		Jan	DISC	
		METHYLDOPA							
AB	+	MYLAN	500MG		N70076 001	Apr 18, 1985	Jan	CRLD	
		<u>METHYLDOPATE HYDROCHLORIDE</u>							
		INJECTABLE; INJECTION							
		ALDOMET							
		@ MERCK	50MG/ML		N13401 001		Jan	DISC	
		METHYLDOPATE HCL							
AP	+	LUITPOLD	50MG/ML		N71279 001	Oct 02, 1987	Jan	CRLD	
		<u>METHYLERGONOVINE MALEATE</u>							
		TABLET; ORAL							
		METHERGINE							
	+	NOVARTIS	0.2MG		N06035 003		Jan	CRLD	

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

DEPO-MEDROL

>D>	+	PHARMACIA AND UPJOHN	40MG/ML	N11757 001		Feb	CFTG
>A>	AB	+	40MG/ML	N11757 001		Feb	CFTG
>D>	+		80MG/ML	N11757 004		Feb	CFTG
>A>	AB	+	80MG/ML	N11757 004		Feb	CFTG
>A>		METHYLPREDNISOLONE ACETATE					
>A>	AB	SICOR PHARMS	40MG/ML	N40557 001	Feb 23, 2005	Feb	NEWA
>A>	AB		80MG/ML	N40557 002	Feb 23, 2005	Feb	NEWA

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HCL

AP		INTL MEDICATED	EQ 1MG BASE/ML	N76144 001	Jan 26, 2005	Jan	NEWA
AP			EQ 5MG BASE/ML	N76144 002	Jan 26, 2005	Jan	NEWA

MOMETASONE FUROATE

CREAM; TOPICAL

ELOCON

AB	+	SCHERING	0.1%	N19625 001	May 06, 1987	Jan	CFTG
AB		MOMETASONE FUROATE					
AB		TARO	0.1%	N76679 001	Dec 21, 2004	Jan	NEWA

OXALIPLATIN

INJECTABLE; IV (INFUSION)

ELOXATIN

+		SANOFI SYNTHELABO	50MG/10ML (5MG/ML)	N21759 001	Jan 31, 2005	Jan	NEWA
+			100MG/20ML (5MG/ML)	N21759 002	Jan 31, 2005	Jan	NEWA

PACLITAXEL

FOR SUSPENSION; IV (INFUSION)

ABRAXANE

+		AM BIOSCIENCE	100MG/VIAL	N21660 001	Jan 07, 2005	Jan	NEWA
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PENTOBARBITAL SODIUM

CAPSULE; ORAL

SODIUM PENTOBARBITAL

@		VALEANT PHARM INTL	100MG	N83264 001		Jan	DISC
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PHENDIMETRAZINE TARTRATE

TABLET; ORAL

BONTRIL PDM

>D>	AA		VALEANT	35MG	N85272 001		Feb	CRLD
>A>	AA	+		35MG	N85272 001		Feb	CRLD
>D>			CAM-METRAZINE					
>D>	AA	+	ABC HOLDING	35MG	N83922 001		Feb	DISC
>A>		@		35MG	N83922 001		Feb	DISC
>D>	AA			35MG	N85318 001		Feb	DISC
>A>		@		35MG	N85318 001		Feb	DISC
>D>	AA			35MG	N85320 001		Feb	DISC
>A>		@		35MG	N85320 001		Feb	DISC
>D>	AA			35MG	N85321 001		Feb	DISC
>A>		@		35MG	N85321 001		Feb	DISC
>D>	AA			35MG	N85511 001		Feb	DISC

## TABLET; ORAL

>D>		CAM-METRAZINE					
>A>		@ ABC HOLDING	35MG		N85511 001		Feb DISC
>D>	AA	CAMALL	35MG		N85756 001		Feb DISC
>A>		@	35MG		N85756 001		Feb DISC
		PHENDIMETRAZINE TARTRATE					
>D>	AA	ABC HOLDING	35MG		N85761 001		Feb DISC
>A>		@	35MG		N85761 001		Feb DISC
>D>	AA		35MG		N85941 001	Jun 27, 1983	Feb DISC
>A>		@	35MG		N85941 001	Jun 27, 1983	Feb DISC
>D>	AA	EON	35MG		N85830 001		Feb DISC
>A>		@	35MG		N85830 001		Feb DISC
>D>		X-TROZINE					
>D>	AA	SHIRE RICHWOOD	35MG		N86553 001		Feb DISC
>A>		@	35MG		N86553 001		Feb DISC
>D>	AA		35MG		N86554 001		Feb DISC
>A>		@	35MG		N86554 001		Feb DISC

PHENTERMINE HYDROCHLORIDE

## CAPSULE; ORAL

>D>		ONA-MAST					
>D>	AA	MAST MM	30MG		N86511 001		Feb DISC
>A>		@	30MG		N86511 001		Feb DISC
>D>	AA		30MG		N86516 001		Feb DISC
>A>		@	30MG		N86516 001		Feb DISC
		PHENTERMINE HCL					
>D>		ABC HOLDING	18.75MG		N88576 001	May 23, 1984	Feb DISC
>A>		@	18.75MG		N88576 001	May 23, 1984	Feb DISC
>D>	AA		30MG		N85417 001		Feb DISC
>A>		@	30MG		N85417 001		Feb DISC
>D>	AA		30MG		N86732 002		Feb DISC
>A>		@	30MG		N86732 002		Feb DISC
>D>	AA		30MG		N87215 001		Feb DISC
>A>		@	30MG		N87215 001		Feb DISC
>D>	AA		37.5MG		N87915 001	Dec 22, 1983	Feb DISC
>A>		@	37.5MG		N87915 001	Dec 22, 1983	Feb DISC
>D>	AA		37.5MG		N87918 001	Dec 22, 1983	Feb DISC
>A>		@	37.5MG		N87918 001	Dec 22, 1983	Feb DISC
>D>	AA		37.5MG		N87930 001	Oct 14, 1983	Feb DISC
>A>		@	37.5MG		N87930 001	Oct 14, 1983	Feb DISC
>D>	AA		37.5MG		N88610 001	Jun 04, 1984	Feb DISC
>A>		@	37.5MG		N88610 001	Jun 04, 1984	Feb DISC
>D>	AA		37.5MG		N88611 001	Jun 04, 1984	Feb DISC
>A>		@	37.5MG		N88611 001	Jun 04, 1984	Feb DISC
>D>	AA		37.5MG		N88625 001	Aug 23, 1984	Feb DISC
>A>		@	37.5MG		N88625 001	Aug 23, 1984	Feb DISC
>D>	AA	CAMALL	15MG		N86735 001		Feb DISC
>A>		@	15MG		N86735 001		Feb DISC
>D>	AA		30MG		N87226 001		Feb DISC
>A>		@	30MG		N87226 001		Feb DISC

## TABLET; ORAL

>D>		ONA MAST					
>D>	AA	MAST MM	8MG		N86260 001		Feb DISC
>A>		@	8MG		N86260 001		Feb DISC
		PHENTERMINE HCL					
>D>	AA	+ ABC HOLDING	8MG		N83923 001		Feb DISC
>A>		@	8MG		N83923 001		Feb DISC

TABLET; ORAL

## PHENTERMINE HCL

>D>	AA	ABC HOLDING	8MG	N85319 001		Feb	DISC
>A>		@	8MG	N85319 001		Feb	DISC
>D>	AA		37.5MG	N87805 001	Dec 06, 1982	Feb	DISC
>A>		@	37.5MG	N87805 001	Dec 06, 1982	Feb	DISC
>D>	AA		37.5MG	N88596 001	Apr 04, 1984	Feb	DISC
>A>		@	37.5MG	N88596 001	Apr 04, 1984	Feb	DISC

POTASSIUM CITRATE

## TABLET, EXTENDED RELEASE; ORAL

## UROCIT-K

		MISSION PHARMA	5MEQ	N19071 001	Aug 30, 1985	Jan	CTNA
		+	10MEQ	N19071 002	Aug 31, 1992	Jan	CTNA

PREDNISOLONE

## SYRUP; ORAL

## PREDNISOLONE

AA		IVAX PHARMS	15MG/5ML	N40287 001	May 28, 1999	Jan	CAHN
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PRIMIDONE

## TABLET; ORAL

## PRIMIDONE

>A>	AB	VINTAGE PHARMS	50MG	N40586 001	Feb 24, 2005	Feb	NEWA
>A>	AB		250MG	N40586 002	Feb 24, 2005	Feb	NEWA

PROGESTERONE

## INJECTABLE; INJECTION

## PROGESTERONE

>D>	AO	+ SCHEIN	50MG/ML	N17362 002		Feb	CAHN
>A>	AO	+ WATSON LABS (UTAH)	50MG/ML	N17362 002		Feb	CAHN

PROMETHAZINE HYDROCHLORIDE

## TABLET; ORAL

## PROMETHAZINE HCL

		ABLE	12.5MG	N40558 001	Jul 01, 2004	Jan	CTEC
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QUINAPRIL HYDROCHLORIDE

## TABLET; ORAL

## QUINAPRIL HCL

>A>	AB	EON	EQ 5MG BASE	N76803 001	Mar 02, 2005	Feb	NEWA
>A>	AB		EQ 10MG BASE	N76803 002	Mar 02, 2005	Feb	NEWA
>A>	AB		EQ 20MG BASE	N76803 003	Mar 02, 2005	Feb	NEWA
>A>	AB		EQ 40MG BASE	N76803 004	Mar 02, 2005	Feb	NEWA
	AB	PAR PHARM	EQ 5MG BASE	N76036 001	Jan 28, 2005	Jan	NEWA
	AB		EQ 10MG BASE	N76036 002	Jan 28, 2005	Jan	NEWA
	AB		EQ 20MG BASE	N76036 003	Jan 28, 2005	Jan	NEWA
	AB		EQ 40MG BASE	N76036 004	Jan 28, 2005	Jan	NEWA

RANITIDINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## RANITIDINE HCL

>A>	AP	BEN VENUE	EQ 25MG BASE/ML	N74777 001	Mar 02, 2005	Feb	NEWA
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>A>	<u>SODIUM BENZOATE; SODIUM PHENYLACETATE</u>				
>A>	SOLUTION; IV (INFUSION)				
>A>	AMMONUL				
>A>	+	UCYCLYD	10%;10% (5GM/50ML;5GM/50ML)	N20645 001	Feb 17, 2005 Feb NEWA
	<u>SOMATROPIN RECOMBINANT</u>				
>A>	INJECTABLE; SUBCUTANEOUS				
>A>	SEROSTIM LQ				
>A>		SERONO	6MG/0.05VIAL	N20604 005	Feb 11, 2005 Feb NEWA
	<u>SULFAMETHOXAZOLE; TRIMETHOPRIM</u>				
	TABLET; ORAL				
	SULFAMETHOXAZOLE AND TRIMETHOPRIM				
AB		INTERPHARM	400MG;80MG	N76899 001	Jan 27, 2005 Jan NEWA
AB			800MG;160MG	N76899 002	Jan 27, 2005 Jan NEWA
	<u>TACROLIMUS</u>				
	CAPSULE; ORAL				
	PROGRAF				
	+	FUJISAWA HLTHCARE	EQ 1MG BASE	N50708 001	Apr 08, 1994 Jan CRLD
	<u>TAMOXIFEN CITRATE</u>				
	TABLET; ORAL				
	TAMOXIFEN CITRATE				
>D>	AB	PHARMACHEMIE	EQ 10MG BASE	N74539 001	Mar 31, 2003 Feb DISC
>A>		@	EQ 10MG BASE	N74539 001	Mar 31, 2003 Feb DISC
	<u>TELITHROMYCIN</u>				
	TABLET; ORAL				
	KETEK				
>A>		AVENTIS PHARMS	300MG	N21144 002	Feb 09, 2005 Feb NEWA
	<u>TERCONAZOLE</u>				
	CREAM; VAGINAL				
	TERCONAZOLE				
AB		ALTANA	0.4%	N76712 001	Feb 18, 2005 Jan NEWA
	<u>TESTOSTERONE CYPIONATE</u>				
	INJECTABLE; INJECTION				
	TESTOSTERONE CYPIONATE				
AO		PADDOCK	200MG/ML	N40530 001	Jan 31, 2005 Jan NEWA
	<u>TETRACYCLINE HYDROCHLORIDE</u>				
	CAPSULE; ORAL				
	TETRACYCLINE HCL				
>D>	AB	MAST MM	250MG	N62085 001	Feb DISC
>A>		@	250MG	N62085 001	Feb DISC
	<u>TOREMIFENE CITRATE</u>				
	TABLET; ORAL				
	FARESTON				
	+	GTX INC	EQ 60MG BASE	N20497 001	May 29, 1997 Jan CAHN

TORSEMIDE

TABLET; ORAL

TORSEMIDE

>A>	AB	ROXANE	5MG	N76943 001	Mar 01, 2005	Feb	NEWA
>A>	AB		10MG	N76943 002	Mar 01, 2005	Feb	NEWA
>A>	AB		20MG	N76943 003	Mar 01, 2005	Feb	NEWA

>D> TRICHLORMETHIAZIDE

&gt;D&gt; TABLET; ORAL

&gt;D&gt; NAQUA

>D>	BP	+	SCHERING	4MG	N12265 002		Feb	DISC
>A>			@	4MG	N12265 002		Feb	DISC

TRICHLORMETHIAZIDE

>D>	BP		ABC HOLDING	4MG	N85568 001		Feb	DISC
>A>			@	4MG	N85568 001		Feb	DISC
>D>	BP		PAR PHARM	2MG	N87007 001		Feb	DISC
>A>			@	2MG	N87007 001		Feb	DISC
>D>	BP			4MG	N87005 001		Feb	DISC
>A>			@	4MG	N87005 001		Feb	DISC

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL

PRIMSOL

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

PRESCRIPTION DRUG PRODUCT LIST - 25TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2005

2-1

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

>A> WOCKHARDT 10MG N77146 001 Mar 07, 2005 Feb NEWA

LORATADINE

SYRUP; ORAL

CLARITIN HIVES RELIEF

@ SCHERING

1MG/ML

N20641 003 Nov 19, 2003 Jan DISC

MICONAZOLE NITRATE

CREAM; VAGINAL

MICONAZOLE 3

>A>

TARO

4%

N76773 001 Mar 02, 2005 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 01 FEBRUARY 2005**

NO FEBRUARY 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>

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**DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY  
ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION**

NO FEBRUARY 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>	021457 001	ALBUTEROL SULFATE;ALBUTEROL SULFATE HF	5605674	FEB 25, 2014	DP	
>ADD>			5695743	JUL 06, 2010	DP	
>ADD>			6352684	NOV 28, 2009	DP	
>ADD>	021726 001	ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP	
>ADD>			6024981	APR 09, 2018	DP	
>ADD>	021726 002	ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP	
>ADD>			6024981	APR 09, 2018	DP	
>ADD>	021726 003	ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP	
>ADD>			6024981	APR 09, 2018	DP	
>ADD>	021726 004	ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP	
>ADD>			6024981	APR 09, 2018	DP	
>ADD>	021713 001	ARIPIPIRAZOLE;ABILIFY				NCE NOV 15, 2007
>ADD>						I-437 SEP 29, 2007
>ADD>						I-401 AUG 28, 2006
>ADD>	021248 001	ARSENIC TRIOXIDE;TRISENOX	6855339	NOV 10, 2018	U617	
>ADD>			6861076	NOV 10, 2018	U617	
>ADD>	021411 007	ATOMOXETINE HYDROCHLORIDE;STRATTERA				NCE NOV 26, 2007
>ADD>						PED MAY 26, 2008
>ADD>	021411 008	ATOMOXETINE HYDROCHLORIDE;STRATTERA				NCE NOV 26, 2007
>ADD>						PED MAY 26, 2008
>ADD>	020838 001	CANDESARTAN CILEXETIL;ATACAND				I-448 FEB 22, 2008
>ADD>	020838 002	CANDESARTAN CILEXETIL;ATACAND				I-448 FEB 22, 2008
>ADD>	020838 003	CANDESARTAN CILEXETIL;ATACAND				I-448 FEB 22, 2008
>ADD>	020838 004	CANDESARTAN CILEXETIL;ATACAND				I-448 FEB 22, 2008
	021710 001	CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627	
			5912013	JUN 15, 2016	DP	
	021710 002	CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627	
			5912013	JUN 15, 2016	DP	
	021710 003	CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627	
			5912013	JUN 15, 2016	DP	
	021673 001	CLOFARABINE;CLOLAR	5661136	AUG 26, 2014	U626	
			5384310	MAY 23, 2009	DS DP	
			4918179	JUN 14, 2005	DS	
>ADD>	021572 001	DAPTOMYCIN;CUBICIN	6852689	SEP 24, 2019	U282	
>ADD>	021572 002	DAPTOMYCIN;CUBICIN	6852689	SEP 24, 2019	U282	
>ADD>	021605 001	DESLORATADINE;CLARINEX D 24 HOUR				NCE DEC 21, 2006
>ADD>						PED JUN 21, 2007
>ADD>	076068 001	DEXRAZOXANE HYDROCHLORIDE;DEXRAZOXANE				PC AUG 27, 2005
	021168 001	DIVALPROEX SODIUM;DEPAKOTE ER	6720004	DEC 18, 2018	DP	
	021168 002	DIVALPROEX SODIUM;DEPAKOTE ER	6720004	DEC 18, 2018	DP	
>ADD>	021269 001	DOXAZOSIN MESYLATE;CARDURA XL				NDF FEB 22, 2008
>ADD>	021269 002	DOXAZOSIN MESYLATE;CARDURA XL				NDF FEB 22, 2008
>ADD>	021437 001	EPLERENONE; INSPRA	4559332	APR 09, 2005	DS DP U537	
>ADD>	021437 002	EPLERENONE; INSPRA	4559332	APR 09, 2005	DS DP U537	
>ADD>	021437 003	EPLERENONE; INSPRA	4559332	APR 09, 2005	DS DP U537	
	021337 001	ERTAPENEM SODIUM; INVANZ	5478820	FEB 02, 2013		NCE NOV 21, 2006
			5652233	FEB 02, 2013		PED MAY 21, 2007
			5952323	MAY 15, 2017		
			5478820*PED	AUG 02, 2013		
			5652233*PED	AUG 02, 2013		
			5952323*PED	NOV 15, 2017		
	076323 001	ESMOLOL HYDROCHLORIDE;ESMOLOL HCL				PC MAY 01, 2005

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
021476 001	ESZOPICLONE; LUNESTA	6444673	JAN 16, 2012	DS DP		
		6319926	JAN 16, 2012		U620	
021476 002	ESZOPICLONE; LUNESTA	6444673	JAN 16, 2012	DS DP		
		6319926	JAN 16, 2012		U620	
021476 003	ESZOPICLONE; LUNESTA	6444673	JAN 16, 2012	DS DP		
		6319926	JAN 16, 2012		U620	
>ADD>	021712 001	FAMOTIDINE; FLUXID	6024981	APR 09, 2018	DP	
>ADD>			6221392	APR 09, 2018	DP	
>ADD>	021712 002	FAMOTIDINE; FLUXID	6024981	APR 09, 2018	DP	
>ADD>			6221392	APR 09, 2018	DP	
	020747 001	FENTANYL CITRATE; ACTIQ	5785989	MAY 01, 2005		
	020747 002	FENTANYL CITRATE; ACTIQ	5785989	MAY 01, 2005		
	020747 003	FENTANYL CITRATE; ACTIQ	5785989	MAY 01, 2005		
	020747 004	FENTANYL CITRATE; ACTIQ	5785989	MAY 01, 2005		
	020747 005	FENTANYL CITRATE; ACTIQ	5785989	MAY 01, 2005		
	020747 006	FENTANYL CITRATE; ACTIQ	5785989	MAY 01, 2005		
>ADD>	019813 005	FENTANYL; DURAGESIC-12				NPP MAY 20, 2006
>ADD>						PED NOV 20, 2006
>ADD>						NP FEB 11, 2008
	021758 001	FLUOCINONIDE; VANOS				
	021077 002	FLUTICASON PROPRIONATE; ADVAIR DISKUS 250/50	6536427	MAR 01, 2011	DP	
	021169 001	GALANTAMINE HYDROBROMIDE; REMINYL	6358527	JUN 06, 2017	DP U322	
	021169 002	GALANTAMINE HYDROBROMIDE; REMINYL	6358527	JUN 06, 2017	DP U322	
	021169 003	GALANTAMINE HYDROBROMIDE; REMINYL	6358527	JUN 06, 2017	DP U322	
	020509 001	GEMCITABINE HYDROCHLORIDE; GEMZAR	4808614	MAY 15, 2010	DS	I-428 MAY 19, 2007
			5464826	NOV 07, 2012		PED NOV 19, 2007
			4808614*PED	NOV 15, 2010		
			5464826*PED	MAY 07, 2013		
	020509 002	GEMCITABINE HYDROCHLORIDE; GEMZAR	5464826	NOV 07, 2012	U146	I-428 MAY 19, 2007
			4808614	MAY 15, 2010	DS	PED NOV 19, 2007
			4808614*PED	NOV 15, 2010		
			5464826*PED	MAY 07, 2013		
>ADD>	020239 003	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 29, 2007	DS DP U89	I-369 AUG 16, 2005
	020239 004	GRANISETRON HYDROCHLORIDE; KYTRIL				I-369 AUG 16, 2005
	021335 001	IMATINIB MESYLATE; GLEEVEC	5521184	JAN 04, 2015		
	021335 002	IMATINIB MESYLATE; GLEEVEC	5521184	JAN 04, 2015		
	021588 001	IMATINIB MESYLATE; GLEEVEC	5521184	JAN 04, 2015		
	021588 002	IMATINIB MESYLATE; GLEEVEC	5521184	JAN 04, 2015		
	020726 001	LETROZOLE; FEMARA				I-446 OCT 29, 2007
	021731 001	LEUPROLIDE ACETATE; ELIGARD	RE37950	OCT 03, 2008	DP U621	
			4938763	OCT 03, 2008	DP U621	
			5278201	JAN 11, 2011	DP	
			5324519	JUN 28, 2011	DP	
			5599552	FEB 04, 2014	DP U621	
			5739176	OCT 03, 2008	DP U621	
			6395293	SEP 28, 2013	DP	
			6565874	OCT 28, 2018	DP U621	
			6626870	MAR 27, 2020	DP	
			6773714	OCT 28, 2018	U621	
	021130 001	LINEZOLID; ZYVOX	5688792	NOV 18, 2014	DS U319	NCE APR 18, 2005
			6559305	JAN 29, 2021	DS	NPP DEC 19, 2005
			6514529	MAR 15, 2021	DP	I-402 JUL 22, 2006
			5688792*PED	MAY 18, 2015		I-431 JUN 23, 2007
			6514529*PED	SEP 15, 2021		PED JAN 22, 2007
			6559305*PED	JUL 29, 2021		PED OCT 18, 2005
						PED DEC 23, 2007
						PED JUN 19, 2006

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	
021130 002	LINEZOLID; ZYVOX	5688792	NOV 18, 2014	DS	U319	NCE	APR 18, 2005
		6559305	JAN 29, 2021	DS		NPP	DEC 19, 2005
		6514529	MAR 15, 2021		DP	I-402	JUL 22, 2006
		5688792*PED	MAY 18, 2015			I-431	JUN 23, 2007
		6514529*PED	SEP 15, 2021			PED	JAN 22, 2007
		6559305*PED	JUL 29, 2021			PED	OCT 18, 2005
						PED	DEC 23, 2007
						PED	JUN 19, 2006
021131 001	LINEZOLID; ZYVOX	5688792	NOV 18, 2014		U319	NCE	APR 18, 2005
		6559305	JAN 29, 2021	DS		NPP	DEC 19, 2005
		5688792*PED	MAY 18, 2015			I-402	JUL 22, 2006
		6559305*PED	JUL 29, 2021			I-431	JUN 23, 2007
						PED	JUN 19, 2006
						PED	JAN 22, 2007
						PED	OCT 18, 2005
						PED	DEC 23, 2007
021132 001	LINEZOLID; ZYVOX	5688792	NOV 18, 2014	DS	U319	NCE	APR 18, 2005
		6559305	JAN 29, 2021	DS		NPP	DEC 19, 2005
		5688792*PED	MAY 18, 2015			I-402	JUL 22, 2006
		6559305*PED	JUL 29, 2021			I-431	JUN 23, 2007
						PED	OCT 18, 2005
						PED	JAN 22, 2007
						PED	DEC 23, 2007
						PED	JUN 19, 2006
021583 001	MEDROXYPROGESTERONE ACETATE; DEPO-SUBQ PROVERA 10	6495534	MAY 15, 2020		DP		
076863 001	METFORMIN HYDROCHLORIDE; METFORMIN HCL					PC	APR 12, 2005
>ADD>	019962 001	METOPROLOL SUCCINATE; TOPROL-XL	5001161	SEP 18, 2007		D-95	FEB 15, 2008
			5081154	SEP 18, 2007			
>ADD>	019962 002	METOPROLOL SUCCINATE; TOPROL-XL	5001161	SEP 18, 2007		D-95	FEB 15, 2008
			5081154	SEP 18, 2007			
>ADD>	019962 003	METOPROLOL SUCCINATE; TOPROL-XL	5001161	SEP 18, 2007		D-95	FEB 15, 2008
			5081154	SEP 18, 2007			
>ADD>	019962 004	METOPROLOL SUCCINATE; TOPROL-XL	5001161	SEP 18, 2007		D-95	FEB 15, 2008
			5081154	SEP 18, 2007			
020762 001	MOMETASONE FUROATE MONOHYDRATE; NASONEX	5837699	JAN 27, 2014		DP	U625	
		6127353	OCT 03, 2017	DS	DP		
		6723713	JAN 27, 2014			U625	
		RE34878	SEP 08, 2009				
021204 001	NATEGLINIDE; STARLIX	6844008	NOV 14, 2017		DP	U214	
021204 002	NATEGLINIDE; STARLIX	RE34878	SEP 08, 2009				
		6844008	NOV 14, 2017		DP	U214	
021706 001	OMEPRAZOLE; ZEGERID	5840737	JUL 16, 2016	DS		U623	
		6489346	JUL 16, 2016	DS	DP	U624	
		6645988	JUL 16, 2016	DS	DP	U623	
		6780882	JUL 16, 2016	DS	DP	U624	
		6699885	JUL 16, 2016				
						U623	
						U624	
>ADD>	021759 001	OXALIPLATIN; ELOXATIN				NCE	AUG 09, 2007
>ADD>						I-441	NOV 04, 2007
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>ADD>						I-441	NOV 04, 2007

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
>ADD>	021014 001				NCE	JAN 14, 2005
>ADD>	021014 002				PED	JUL 14, 2005
>ADD>	021014 003				NCE	JAN 14, 2005
>ADD>	021285 001				PED	JUL 14, 2005
>ADD>	021660 001				NCE	JAN 14, 2005
>ADD>	021756 001				PED	JUL 14, 2005
					NP	JAN 07, 2008
		6051698	SEP 17, 2012	DS		
		5919455	OCT 27, 2013	DS		
		5932462	AUG 03, 2016	DS		
		6113906	OCT 27, 2013	DS		
		6011020	JAN 04, 2017	DS		
		6426335	JUN 11, 2010		U622	
		6147204	JUN 11, 2010	DS		
021446 001	PREGABALIN; LYRICA	6001876	JUL 16, 2017		U55	
		6197819	MAR 06, 2018	DS DP		
021446 002	PREGABALIN; LYRICA	6001876	JUL 16, 2017		U55	
		6197819	MAR 06, 2018	DS DP		
021446 003	PREGABALIN; LYRICA	6001876	JUL 16, 2017		U55	
		6197819	MAR 06, 2018	DS DP		
021446 004	PREGABALIN; LYRICA	6001876	JUL 16, 2017		U55	
		6197819	MAR 06, 2018	DS DP		
021446 005	PREGABALIN; LYRICA	6001876	JUL 16, 2017		U55	
		6197819	MAR 06, 2018	DS DP		
021446 006	PREGABALIN; LYRICA	6001876	JUL 16, 2017		U55	
		6197819	MAR 06, 2018	DS DP		
021446 007	PREGABALIN; LYRICA	6001876	JUL 16, 2017		U55	
		6197819	MAR 06, 2018	DS DP		
021446 008	PREGABALIN; LYRICA	6001876	JUL 16, 2017		U55	
		6197819	MAR 06, 2018	DS DP		
>ADD>	021511 001				I-447	FEB 25, 2008
>ADD>	020645 001				NDF	FEB 17, 2008
>ADD>					ODE	FEB 17, 2012
>ADD>	020505 001				I-41	AUG 11, 2007
>ADD>	020505 002				I-41	AUG 11, 2007
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>ADD>	020844 002				I-41	AUG 11, 2007
>ADD>	020844 003				I-41	AUG 11, 2007
>ADD>	021060 001					
		5364842	DEC 30, 2011		U48	
		5795864	JUN 27, 2015	DP	U55	
		5859186	DEC 30, 2011			
					U48	
					U55	
>ADD>	021060 002				U48	
		5364842	DEC 30, 2011		U48	
		5795864	JUN 27, 2015	DP	U55	
		5859186	DEC 30, 2011			
					U48	
					U55	



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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> 021060 003	ZICONOTIDE;PRIALT	5364842	DEC 30, 2011	U48		
.		5795864	JUN 27, 2015	DP U55		
.		5859186	DEC 30, 2011			
.				U48		
.				U55		
>ADD> 021060 004	ZICONOTIDE;PRIALT	5364842	DEC 30, 2011	U48		
.		5795864	JUN 27, 2015	DP U55		
.		5859186	DEC 30, 2011			
.				U48		
.				U55		

## 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, 25<sup>th</sup> 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>