

# **APPROVED DRUG PRODUCTS**

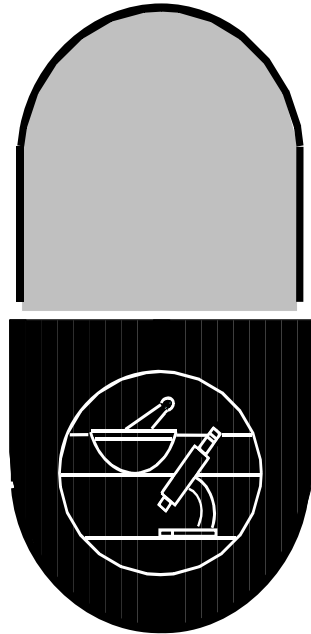
## **With Therapeutic Equivalence Evaluations**



**The "Orange Book"**

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**CUMULATIVE  
SUPPLEMENT 01  
January 2006**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**26<sup>th</sup> EDITION**

**Department of Health and Human Services**

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

**2006**

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

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**Cumulative Supplement 01**

**January 2006**

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Note:

Historically, the Electronic Orange Book (EOB) and Cumulative Supplement (CS) have been updated monthly, each month updated by the end of the third working week of the following month.

Since February 2005, we are also providing daily EOB product information for new generic drug approvals. Daily generic updates will provide the consumer with the most current listing of approved generic products. Previously, a first-time-generic approved early in the month would not be published in the CS for several weeks. Daily generic updates are especially important since the Orange Book listing may be relevant for substitution.

As a result, the monthly CS will include generic approvals and related product changes current to the day of publication (e.g., the June CS will include generic approvals up to the third week of July). Patent information is also current to the day of publication.

**APPROVED DRUG PRODUCTS  
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**26<sup>th</sup> EDITION**

**CUMULATIVE SUPPLEMENT 01  
January 2006**

**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, 26th 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 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 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)

CLAY PARK LABORATORIES INC  
(CLAY PARK)  
CLAY PARK LABS INC

PERRIGO NEW YORK INC  
(PERRIGO NEW YORK)  
PERRIGO NEW YORK INC

(CLAY PARK)  
UCB PHARMA INC  
(UCB PHARMA)

(PERRIGO NEW YORK)  
UCB INC  
(UCB INC)

### 1.3 AVAILABILITY OF THE EDITION

Commencing with the 26th 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.

The 26th edition and current monthly supplement are available in an electronic downloadable Portable Document Format (PDF) at the EOB home page by clicking on the Annual Edition. 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.

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>MAR 2005</u>	<u>JUN 2005</u>	<u>SEP 2005</u>	<u>DEC 2005</u>
DRUG PRODUCTS LISTED	11184	11167	11291	11368
SINGLE SOURCE	2437	2428	2414	2428
	(21.8%)	(21.7%)	(21.4%)	(21.4%)
MULTISOURCE	8637	8630	8768	8851
	(77.2%)	(77.3%)	(77.7%)	(77.9%)
THERAPEUTICALLY	8428	8421	8558	8642
EQUIVALENT	(75.4%)	(75.4%)	(75.8%)	(76.0%)
NOT THERAPEUTICALLY	209	209	210	209
EQUIVALENT	(1.9%)	(1.9%)	(1.9%)	(1.8%)
EXCEPTIONS <sup>1</sup>	110	109	109	89
	(1.0%)	(1.0%)	(1.0%)	(0.8%)
NEW MOLECULAR ENTITIES				
APPROVED	2	4	4	11
NUMBER OF APPLICANTS	631	627	624	628

<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 1 - January 2006

1-1

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL  
BUTAPAP

>D>	AB	MIKART	650MG;50MG	N89988 001	Oct 26, 1992	Jan	CRLD
>A>	AB	+	650MG;50MG	N89988 001	Oct 26, 1992	Jan	CRLD
>D>		SEDAPAP					
>D>	AB	+	MAYRAND	650MG;50MG	N88944 001	Oct 17, 1985	Jan DISC
>A>		@	650MG;50MG	N88944 001	Oct 17, 1985	Jan	DISC

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION; ORAL  
ACETAMINOPHEN AND CODEINE PHOSPHATE

>D>	AA	CLONMEL	120MG/5ML;12MG/5ML	N40098 001	Sep 20, 1996	Jan	DISC
>A>		@	120MG/5ML;12MG/5ML	N40098 001	Sep 20, 1996	Jan	DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL  
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>A>		MIKART	300MG;5MG	N40658 001	Jan 19, 2006	Jan	NEWA
>A>	AA	VINTAGE PHARMS	325MG;5MG	N40655 001	Jan 19, 2006	Jan	NEWA
>A>	AA		325MG;7.5MG	N40656 001	Jan 19, 2006	Jan	NEWA

ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION/DROPS; OTIC  
HYDROCORTISONE AND ACETIC ACID

>A>	AT	VINTAGE	2%;1%	N40609 001	Feb 06, 2006	Jan	NEWA
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ALPHA-TOCOPHEROL ACETATE; ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN;  
DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE  
SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE; VITAMIN K

INJECTABLE; INJECTION  
INFUVITE ADULT

>D>	+	SABEX 2002	2 IU/ML;40MG/ML;12UGM/ML;40 IU/ML;1UGM/ML;3MG/ML;120UGM/ML;8M G/ML;1.2MG/ML;0.72MG/ML;1.2MG/ML; 660 IU/ML;0.03MG/ML	N21163 001	May 18, 2000	Jan	CAHN
>A>	+	SANDOZ	2 IU/ML;40MG/ML;12UGM/ML;40 IU/ML;1UGM/ML;3MG/ML;120UGM/ML;8M G/ML;1.2MG/ML;0.72MG/ML;1.2MG/ML; 660 IU/ML;0.03MG/ML	N21163 001	May 18, 2000	Jan	CAHN

INJECTABLE; IV (INFUSION)  
INFUVITE ADULT

>D>	+	SABEX 2002	2 IU/ML;40MG/ML;12UGM/ML;40 IU/ML;1UGM/ML;3MG/ML;120UGM/ML;8M G/ML;1.2MG/ML;0.72MG/ML;1.2MG/ML; 660 IU/ML;30UGM/ML	N21559 001	Jun 16, 2003	Jan	CAHN
>A>	+	SANDOZ	2 IU/ML;40MG/ML;12UGM/ML;40 IU/ML;1UGM/ML;3MG/ML;120UGM/ML;8M G/ML;1.2MG/ML;0.72MG/ML;1.2MG/ML; 660 IU/ML;30UGM/ML	N21559 001	Jun 16, 2003	Jan	CAHN

ALPRAZOLAM

TABLET, EXTENDED RELEASE; ORAL  
ALPRAZOLAM

>A>	AB	MYLAN	0.5MG	N77391 002	Jan 26, 2006	Jan	NEWA
>A>	AB		1MG	N77391 003	Jan 26, 2006	Jan	NEWA
>A>	AB		2MG	N77391 004	Jan 26, 2006	Jan	NEWA
>A>	AB		3MG	N77391 001	Jan 26, 2006	Jan	NEWA

## TABLET, EXTENDED RELEASE; ORAL

## XANAX XR

>D>		PHARMACIA AND UPJOHN	0.5MG	N21434 001	Jan 17, 2003	Jan	CFTG
>A>	AB		0.5MG	N21434 001	Jan 17, 2003	Jan	CFTG
>D>			1MG	N21434 002	Jan 17, 2003	Jan	CFTG
>A>	AB		1MG	N21434 002	Jan 17, 2003	Jan	CFTG
>D>			2MG	N21434 003	Jan 17, 2003	Jan	CFTG
>A>	AB		2MG	N21434 003	Jan 17, 2003	Jan	CFTG
>D>		+	3MG	N21434 004	Jan 17, 2003	Jan	CFTG
>A>	AB	+	3MG	N21434 004	Jan 17, 2003	Jan	CFTG

AMMONIUM LACTATE

## CREAM; TOPICAL

## AMMONIUM LACTATE

>A>	AB	PADDOCK	EQ 12% BASE	N76829 001	Feb 07, 2006	Jan	NEWA
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AMOXICILLIN

## CAPSULE; ORAL

## AMOXICILLIN

>A>	AB	AM ANTIBIOTICS	250MG	N62058 001		Jan	CAHN
>A>	AB		500MG	N62058 002		Jan	CAHN
>D>	AB	CONSOLIDATED PHARM	250MG	N62058 001		Jan	CAHN
>D>	AB		500MG	N62058 002		Jan	CAHN

## FOR SUSPENSION; ORAL

## AMOXICILLIN

>A>	AB	AM ANTIBIOTICS	125MG/5ML	N62059 001		Jan	CAHN
>A>	AB		250MG/5ML	N62059 002		Jan	CAHN
>D>	AB	CONSOLIDATED PHARM	125MG/5ML	N62059 001		Jan	CAHN
>D>	AB		250MG/5ML	N62059 002		Jan	CAHN

AMPICILLIN/AMPICILLIN TRIHYDRATE

## CAPSULE; ORAL

## AMPICILLIN TRIHYDRATE

>A>		@ AM ANTIBIOTICS	EQ 250MG BASE	N61602 001		Jan	CAHN
>A>		@	EQ 500MG BASE	N61602 002		Jan	CAHN
>D>		@ CONSOLIDATED PHARM	EQ 250MG BASE	N61602 001		Jan	CAHN
>D>		@	EQ 500MG BASE	N61602 002		Jan	CAHN

## FOR SUSPENSION; ORAL

## AMPICILLIN TRIHYDRATE

>A>		@ AM ANTIBIOTICS	EQ 125MG BASE/5ML	N61601 001		Jan	CAHN
>A>		@	EQ 250MG BASE/5ML	N61601 002		Jan	CAHN
>D>		@ CONSOLIDATED PHARM	EQ 125MG BASE/5ML	N61601 001		Jan	CAHN
>D>		@	EQ 250MG BASE/5ML	N61601 002		Jan	CAHN

>D> ANISINDIONE

## &gt;D&gt; TABLET; ORAL

## &gt;D&gt; MIRADON

>D>		+ SCHERING	50MG	N10909 003		Jan	DISC
>A>		@	50MG	N10909 003		Jan	DISC

ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID;  
NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K

## INJECTABLE; IV (INFUSION)

## INFUVITE PEDIATRIC

>D>	+	SABEX 2002	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.1 4MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG /VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N21265 001	Feb 21, 2001	Jan	CAHN
>A>	+	SANDOZ	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.1 4MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG /VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N21265 001	Feb 21, 2001	Jan	CAHN
INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE)							
>D>	+	SABEX 2002	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.1 4MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG /VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N21646 001	Jan 29, 2004	Jan	CAHN
>A>	+	SANDOZ	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.1 4MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG /VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N21646 001	Jan 29, 2004	Jan	CAHN

BENAZEPRIL HYDROCHLORIDE

## TABLET; ORAL

## BENAZEPRIL HYDROCHLORIDE

>A>	AB	BIOKEY	5MG	N76820 001	Feb 03, 2006	Jan	NEWA
>A>	AB		10MG	N76820 002	Feb 03, 2006	Jan	NEWA
>A>	AB		20MG	N76820 003	Feb 03, 2006	Jan	NEWA
>A>	AB		40MG	N76820 004	Feb 03, 2006	Jan	NEWA

BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE

## &gt;A&gt; OINTMENT; TOPICAL

## &gt;A&gt; TACLONEX

>A>	+	LEO PHARM PRODS	0.064%;0.005%	N21852 001	Jan 09, 2006	Jan	NEWA
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BUPROPION HYDROCHLORIDE

## TABLET; ORAL

## BUPROPION HYDROCHLORIDE

>A>	AB	APOTEX INC	75MG	N76143 001	Jan 17, 2006	Jan	NEWA
>A>	AB		100MG	N76143 002	Jan 17, 2006	Jan	NEWA

BUSULFAN

## INJECTABLE; INJECTION

## BUSULFEX

>D>	+	ESP PHARMA	6MG/ML	N20954 001	Feb 04, 1999	Jan	CAHN
>A>	+	PDL BIOPHARMA INC	6MG/ML	N20954 001	Feb 04, 1999	Jan	CAHN

CALCITONIN, SALMON

## INJECTABLE; INJECTION

## MIACALCIN

>D>	AP	+	NOVARTIS	200 IU/ML	N17808 002	Mar 29, 1991	Jan	CTEC
>A>		+		200 IU/ML	N17808 002	Mar 29, 1991	Jan	CTEC

CALCITRIOL

INJECTABLE; INJECTION  
CALCITRIOL

>A>	AP	GENIX THERAP	0.001MG/ML	N77102 001	Feb 08, 2006	Jan	NEWA
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CAPTOPRIL

TABLET; ORAL  
CAPTOPRIL

>D>	AB	CLONMEL HLTHCARE	12.5MG	N74423 001	Feb 13, 1996	Jan	DISC
>A>		@	12.5MG	N74423 001	Feb 13, 1996	Jan	DISC
>D>	AB		25MG	N74423 002	Feb 13, 1996	Jan	DISC
>A>		@	25MG	N74423 002	Feb 13, 1996	Jan	DISC
>D>	AB		50MG	N74423 003	Feb 13, 1996	Jan	DISC
>A>		@	50MG	N74423 003	Feb 13, 1996	Jan	DISC
>D>	AB		100MG	N74423 004	Feb 13, 1996	Jan	DISC
>A>		@	100MG	N74423 004	Feb 13, 1996	Jan	DISC

CARBOPLATIN

INJECTABLE; INJECTION  
CARBOPLATIN

>A>	AP	WATSON LABS	50MG/VIAL	N77383 001	Jan 27, 2006	Jan	NEWA
>A>	AP		150MG/VIAL	N77383 002	Jan 27, 2006	Jan	NEWA
>A>	AP		450MG/VIAL	N77383 003	Jan 27, 2006	Jan	NEWA

INJECTABLE; IV (INFUSION)  
CARBOPLATIN

>A>	AP	AM PHARM	EQ 50MG/5ML (10MG/ML)	N77266 001	Feb 15, 2006	Jan	NEWA
>A>	AP		EQ 150MG/15ML (10MG/ML)	N77266 002	Feb 15, 2006	Jan	NEWA
>A>	AP		EQ 450MG/45ML (10MG/ML)	N77266 003	Feb 15, 2006	Jan	NEWA
>A>	AP		EQ 600MG/60ML (10MG/ML)	N77266 004	Feb 15, 2006	Jan	NEWA
>A>	AP	BEDFORD LABS	EQ 600MG/60ML (10MG/ML)	N77244 004	Jan 20, 2006	Jan	NEWA

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL  
CEFADROXIL

>A>	AB	TEVA PHARMS	EQ 500MG BASE	N65282 001	Jan 20, 2006	Jan	NEWA
>A>	AB	WESTWARD	EQ 500MG BASE	N65311 001	Feb 07, 2006	Jan	NEWA
>D>		DURICEF					
>D>	AB	+ WARNER CHILCOTT	EQ 500MG BASE	N50512 001		Jan	DISC
>A>		@	EQ 500MG BASE	N50512 001		Jan	DISC

FOR SUSPENSION; ORAL  
CEFADROXIL

>A>	AB	TEVA PHARMS	EQ 250MG BASE/5ML	N65278 001	Jan 20, 2006	Jan	NEWA
>A>	AB		EQ 500MG BASE/5ML	N65278 002	Jan 20, 2006	Jan	NEWA

TABLET; ORAL  
DURICEF

>D>	AB	+ WARNER CHILCOTT	EQ 1GM BASE	N50528 001		Jan	DISC
>A>		@	EQ 1GM BASE	N50528 001		Jan	DISC

CEFOXITIN SODIUM

INJECTABLE; INJECTION  
CEFOXITIN

>A>	AP	ORCHID HLTHCARE	EQ 1GM BASE/VIAL	N65313 001	Jan 23, 2006	Jan	NEWA
>A>	AP		EQ 2GM BASE/VIAL	N65313 002	Jan 23, 2006	Jan	NEWA
>A>	AP		EQ 10GM BASE/VIAL	N65312 001	Feb 13, 2006	Jan	NEWA

CEFTRIAZONE SODIUM

INJECTABLE; IM-IV

CEFTRIAZONE

>A>	AP	AM PHARM PARTNERS	EQ 250MG BASE/VIAL	N65245 001	Feb 15, 2006	Jan	NEWA
>A>	AP		EQ 500MG BASE/VIAL	N65245 002	Feb 15, 2006	Jan	NEWA
>A>	AP		EQ 1GM BASE/VIAL	N65245 003	Feb 15, 2006	Jan	NEWA
>A>	AP		EQ 2GM BASE/VIAL	N65245 004	Feb 15, 2006	Jan	NEWA

INJECTABLE; INJECTION

CEFTRIAZONE

>A>	AP	AM PHARM	EQ 10GM BASE/VIAL	N65252 001	Feb 15, 2006	Jan	NEWA
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CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

>A>	AB	HIKMA	EQ 250MG BASE	N65215 001	Jan 24, 2006	Jan	NEWA
>A>	AB		EQ 500MG BASE	N65215 002	Jan 24, 2006	Jan	NEWA

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL

CLINDAMYCIN PHOSPHATE

>A>	AT	ALTANA	EQ 1% BASE	N65254 001	Feb 14, 2006	Jan	NEWA
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CLOPIDOGREL BISULFATE

TABLET; ORAL

CLOPIDOGREL BISULFATE

>A>	AB	APOTEX	EQ 75MG BASE	N76274 001	Jan 20, 2006	Jan	NEWA
>D>	+	SANOFI SYNTHELABO	EQ 75MG BASE	N20839 001	Nov 17, 1997	Jan	CFTG
>A>	AB	+	EQ 75MG BASE	N20839 001	Nov 17, 1997	Jan	CFTG

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETH VC W/ CODEINE

>D>	AA	+	ALPHARMA US PHARMS	10MG/5ML;5MG/5ML;.25MG/5ML	N88764 001	Oct 31, 1984	Jan	CTEC
>A>		+		10MG/5ML;5MG/5ML;.25MG/5ML	N88764 001	Oct 31, 1984	Jan	CTEC
>D>			PROMETHAZINE VC W/ CODEINE					
>D>	AA		MORTON GROVE	10MG/5ML;5MG/5ML;.25MG/5ML	N88896 001	Jan 04, 1985	Jan	DISC
>A>		@		10MG/5ML;5MG/5ML;.25MG/5ML	N88896 001	Jan 04, 1985	Jan	DISC

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE WITH CODEINE SYRUP

>A>	AA	VINTAGE	10MG/5ML;6.25MG/5ML	N40650 001	Jan 31, 2006	Jan	NEWA
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CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

CYCLOBENZAPRINE HYDROCHLORIDE

>A>	AB	AMIDE PHARM	5MG	N77291 001	Feb 03, 2006	Jan	NEWA	
>A>	AB	MYLAN	5MG	N73144 002	Feb 03, 2006	Jan	NEWA	
>A>	AB	SANDOZ	5MG	N72854 002	Feb 03, 2006	Jan	NEWA	
>A>	AB	WATSON LABS	5MG	N71611 002	Feb 03, 2006	Jan	NEWA	
>A>			7.5MG	N71611 003	Feb 03, 2006	Jan	NEWA	
>D>			FLEXERIL					
>D>			MCNEIL CONS SPECLT	5MG	N17821 001		Jan	CFTG

TABLET; ORAL

FLEXERIL

>A> AB MCNEIL CONS SPECLT 5MG N17821 001 Jan CFTG

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION

DESMOPRESSIN ACETATE

>D> AP BEDFORD 0.004MG/ML N74575 001 Feb 18, 2000 Jan DISC

>A> @ 0.004MG/ML N74575 001 Feb 18, 2000 Jan DISC

>D> DESMOPRESSIN ACETATE PRESERVATIVE FREE

>D> AP BEDFORD 0.004MG/ML N74574 001 Feb 18, 2000 Jan DISC

>A> @ 0.004MG/ML N74574 001 Feb 18, 2000 Jan DISC

TABLET; ORAL

DESMOPRESSIN ACETATE

>A> AB TEVA PHARMS 0.1MG N77122 001 Jan 25, 2006 Jan NEWA

>A> AB 0.2MG N77122 002 Jan 25, 2006 Jan NEWA

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE DM

>A> AA VINTAGE 15MG/5ML;6.25MG/5ML N40649 001 Feb 14, 2006 Jan NEWA

DIFLORASONE DIACETATE

CREAM; TOPICAL

DIFLORASONE DIACETATE

>D> AB2 ALTANA 0.05% N76263 001 Dec 20, 2002 Jan CRLD

>A> BX + 0.05% N76263 001 Dec 20, 2002 Jan CRLD

>D> FLORONE

>D> BX + PHARMACIA AND UPJOHN 0.05% N17741 001 Jan DISC

>A> @ 0.05% N17741 001 Jan DISC

>D> FLORONE E

>D> AB2 + PHARMACIA AND UPJOHN 0.05% N19259 001 Aug 28, 1985 Jan DISC

>A> @ 0.05% N19259 001 Aug 28, 1985 Jan DISC

OINTMENT; TOPICAL

DIFLORASONE DIACETATE

>D> AB TARO 0.05% N75331 001 May 14, 1999 Jan CRLD

>A> AB + 0.05% N75331 001 May 14, 1999 Jan CRLD

>D> FLORONE

>D> + PHARMACIA AND UPJOHN 0.05% N17994 001 Jan DISC

>A> @ 0.05% N17994 001 Jan DISC

>D> PSORCON

>D> AB + PHARMACIA AND UPJOHN 0.05% N19260 001 Aug 28, 1985 Jan DISC

>A> @ 0.05% N19260 001 Aug 28, 1985 Jan DISC

DIGOXIN

INJECTABLE; INJECTION

DIGOXIN

>D> AP SABEX 2002 0.25MG/ML N40481 001 Aug 21, 2003 Jan CAHN

>A> AP SANDOZ 0.25MG/ML N40481 001 Aug 21, 2003 Jan CAHN

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

DILTZAC

>A> AB4 APOTEX INC 120MG N76395 001 Feb 01, 2006 Jan NEWA

>A> AB4 180MG N76395 002 Feb 01, 2006 Jan NEWA

CAPSULE, EXTENDED RELEASE; ORAL

>A>		DILTZAC							
>A>	AB4	APOTEX INC	240MG	N76395	003	Feb 01,	2006	Jan	NEWA
>A>	AB4		300MG	N76395	004	Feb 01,	2006	Jan	NEWA
>A>	AB4		360MG	N76395	005	Feb 01,	2006	Jan	NEWA

DISOPYRAMIDE PHOSPHATE

## CAPSULE; ORAL

## DISOPYRAMIDE PHOSPHATE

>D>	AB	IVAX PHARMS	EQ 100MG BASE	N70186	001	Nov 18,	1985	Jan	DISC
>A>		@	EQ 100MG BASE	N70186	001	Nov 18,	1985	Jan	DISC
>D>	AB		EQ 150MG BASE	N70187	001	Nov 18,	1985	Jan	DISC
>A>		@	EQ 150MG BASE	N70187	001	Nov 18,	1985	Jan	DISC
>D>	AB	SANDOZ	EQ 100MG BASE	N70470	001	Dec 10,	1985	Jan	DISC
>A>		@	EQ 100MG BASE	N70470	001	Dec 10,	1985	Jan	DISC
>D>	AB		EQ 150MG BASE	N70471	001	Dec 10,	1985	Jan	DISC
>A>		@	EQ 150MG BASE	N70471	001	Dec 10,	1985	Jan	DISC

ESTRADIOL

## GEL; TOPICAL

## ESTROGEL

>A>		@ ASCEND	0.06%	N21166	001	Feb 09,	2004	Jan	CAHN
>D>		@ SOLVAY	0.06%	N21166	001	Feb 09,	2004	Jan	CAHN

## GEL, METERED; TOPICAL

## ESTROGEL

>A>	+	ASCEND	0.06%	N21166	002	Feb 09,	2004	Jan	CAHN
>D>	+	SOLVAY	0.06%	N21166	002	Feb 09,	2004	Jan	CAHN

FENOFIBRATE

## CAPSULE; ORAL

## LIPOFEN

>A>		CIPHER	50MG	N21612	001	Jan 11,	2006	Jan	NEWA
>A>			100MG	N21612	002	Jan 11,	2006	Jan	NEWA
>A>	+		150MG	N21612	003	Jan 11,	2006	Jan	NEWA

## TABLET; ORAL

## FENOFIBRATE

>D>	AB	TEVA	160MG	N76433	002	May 13,	2005	Jan	CRLD
>A>	AB	+	160MG	N76433	002	May 13,	2005	Jan	CRLD
>D>	AB	ABBOTT	54MG	N21203	001	Sep 04,	2001	Jan	DISC
>A>		@	54MG	N21203	001	Sep 04,	2001	Jan	DISC
>D>	AB	+	160MG	N21203	003	Sep 04,	2001	Jan	DISC
>A>		@	160MG	N21203	003	Sep 04,	2001	Jan	DISC

FENOLDOPAM MESYLATE

## INJECTABLE; INJECTION

## FENOLDOPAM MESYLATE

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

FENOPROFEN CALCIUM

## TABLET; ORAL

## FENOPROFEN CALCIUM

>D>	AB	CLONMEL HLTHCARE	EQ 600MG BASE	N72326	001	Aug 17,	1988	Jan	DISC
>A>		@	EQ 600MG BASE	N72326	001	Aug 17,	1988	Jan	DISC



FLUCONAZOLE

TABLET; ORAL

FLUCONAZOLE

>A>	AB	GLENMARK PHARMA	50MG	N77253 001	Jan 25, 2006	Jan	NEWA
>A>	AB		100MG	N77253 002	Jan 25, 2006	Jan	NEWA
>A>	AB		150MG	N77253 003	Jan 25, 2006	Jan	NEWA
>A>	AB		200MG	N77253 004	Jan 25, 2006	Jan	NEWA

FLUMAZENIL

INJECTABLE; INJECTION

FLUMAZENIL

>D>	AP	SABEX 2002	1MG/10ML (0.1MG/ML)	N77071 002	May 03, 2005	Jan	CAHN
>D>	AP		0.5MG/5ML (0.1MG/ML)	N77071 001	May 03, 2005	Jan	CAHN
>A>	AP	SANDOZ	0.5MG/5ML (0.1MG/ML)	N77071 001	May 03, 2005	Jan	CAHN
>A>	AP		1MG/10ML (0.1MG/ML)	N77071 002	May 03, 2005	Jan	CAHN

FLUNISOLIDE

AEROSOL, METERED; INHALATION

>A>		AEROSPAN HFA					
>A>	+	FOREST LABS	EQ 78UGM BASE/INH	N21247 001	Jan 27, 2006	Jan	NEWA

GABAPENTIN

CAPSULE; ORAL

GABAPENTIN

>A>	AB	SANDOZ	100MG	N75428 001	Jan 24, 2006	Jan	NEWA
>A>	AB		300MG	N75428 002	Jan 24, 2006	Jan	NEWA
>A>	AB		400MG	N75428 003	Jan 24, 2006	Jan	NEWA

TABLET; ORAL

GABAPENTIN

>A>	AB	SANDOZ	600MG	N76120 001	Jan 27, 2006	Jan	NEWA
>A>	AB		800MG	N76120 002	Jan 27, 2006	Jan	NEWA

GADOVERSETAMIDE

INJECTABLE; INJECTION

OPTIMARK

>D>	+	MALLINCKRODT	330.9MG/ML	N20937 001	Dec 08, 1999	Jan	CPOT
>A>	+		1654.5MG/5ML (330.9MG/ML)	N20937 001	Dec 08, 1999	Jan	CPOT
>A>	+		3309MG/10ML (330.9MG/ML)	N20937 002	Dec 08, 1999	Jan	NEWA
>A>	+		4963.5MG/15ML (330.9MG/ML)	N20937 003	Dec 08, 1999	Jan	NEWA
>A>	+		6618MG/20ML (330.9MG/ML)	N20937 004	Dec 08, 1999	Jan	NEWA
>D>	+		330.9MG/ML	N20975 001	Dec 08, 1999	Jan	CPOT
>A>	+		16.545GM/50ML (330.9MG/ML)	N20975 001	Dec 08, 1999	Jan	CPOT

OPTIMARK IN PLASTIC CONTAINER

>D>	+	MALLINCKRODT	330.9MG/ML	N20976 001	Dec 08, 1999	Jan	CPOT
>A>	+		1654.5MG/5ML (330.9MG/ML)	N20976 001	Dec 08, 1999	Jan	CPOT
>A>	+		3309MG/10ML (330.9MG/ML)	N20976 002	Dec 08, 1999	Jan	NEWA
>A>	+		4963.5MG/15ML (330.9MG/ML)	N20976 003	Dec 08, 1999	Jan	NEWA
>A>	+		6618MG/20ML (330.9MG/ML)	N20976 004	Dec 08, 1999	Jan	NEWA

GLIMEPIRIDE

TABLET; ORAL

GLIMEPIRIDE

>A>	AB	COBALT	1MG	N77280 001	Feb 03, 2006	Jan	NEWA
>A>	AB		2MG	N77280 002	Feb 03, 2006	Jan	NEWA

TABLET; ORALGLIMEPIRIDE

>A>	AB	COBALT	4MG	N77280 003	Feb 03, 2006	Jan	NEWA
>A>	AB	GENPHARM	1MG	N77486 001	Feb 10, 2006	Jan	NEWA
>A>	AB		2MG	N77486 002	Feb 10, 2006	Jan	NEWA
>A>	AB		4MG	N77486 003	Feb 10, 2006	Jan	NEWA

HALOPERIDOL DECANOATEINJECTABLE; INJECTIONHALOPERIDOL DECANOATE

>D>	AO	SABEX 2002	EQ 50MG BASE/ML	N76463 001	Jun 24, 2005	Jan	CAHN
>D>	AO		EQ 100MG BASE/ML	N76463 002	Jun 24, 2005	Jan	CAHN
>A>	AO	SANDOZ	EQ 50MG BASE/ML	N76463 001	Jun 24, 2005	Jan	CAHN
>A>	AO		EQ 100MG BASE/ML	N76463 002	Jun 24, 2005	Jan	CAHN

HALOPERIDOL LACTATEINJECTABLE; INJECTIONHALOPERIDOL

>D>	AP	SABEX 2002	EQ 5MG BASE/ML	N76464 001	Sep 29, 2004	Jan	CAHN
>A>	AP	SANDOZ	EQ 5MG BASE/ML	N76464 001	Sep 29, 2004	Jan	CAHN

IBANDRONATE SODIUM

>A>		INJECTABLE; INTRAVENOUS					
>A>		BONIVA					
>A>	+	ROCHE	EQ 3MG BASE/3ML	N21858 001	Jan 06, 2006	Jan	NEWA

INSULIN RECOMBINANT HUMAN

>A>		POWDER; INHALATION					
>A>		EXUBERA					
>A>		PFIZER	1MG/INH	N21868 001	Jan 27, 2006	Jan	NEWA
>A>	+		3MG/INH	N21868 002	Jan 27, 2006	Jan	NEWA

ISONIAZIDINJECTABLE; INJECTIONISONIAZID

>D>	AP	SABEX 2002	100MG/ML	N40648 001	Jul 05, 2005	Jan	CAHN
>A>	AP	SANDOZ	100MG/ML	N40648 001	Jul 05, 2005	Jan	CAHN

KETOROLAC TROMETHAMINEINJECTABLE; INJECTIONKETOROLAC TROMETHAMINE

>D>	AP	SABEX 2002	15MG/ML	N76271 001	Oct 06, 2004	Jan	CAHN
>D>	AP		30MG/ML	N76271 002	Oct 06, 2004	Jan	CAHN
>A>	AP	SANDOZ	15MG/ML	N76271 001	Oct 06, 2004	Jan	CAHN
>A>	AP		30MG/ML	N76271 002	Oct 06, 2004	Jan	CAHN

LIDOCAINE HYDROCHLORIDE

>A>		JELLY; TOPICAL					
>A>		ANESTACON					
>A>	AT	+ POLYMEDICA	2%	N80429 001		Jan	CDFR
>D>		SOLUTION; TOPICAL					
>D>		ANESTACON					
>D>	AT	+ POLYMEDICA	2%	N80429 001		Jan	CDFR

>A> LUBIPROSTONE  
 >A> CAPSULE; ORAL  
 >A> AMITIZA  
 >A> + SUCAMPO PHARMS 24UGM N21908 001 Jan 31, 2006 Jan NEWA

MEDROXYPROGESTERONE ACETATE

INJECTABLE; SUBCUTANEOUS  
 DEPO-SUBQ PROVERA 104  
 >D> + PFIZER 104MG/0.65ML N21583 001 Dec 17, 2004 Jan CAHN  
 >A> + PHARMACIA AND UPJOHN 104MG/0.65ML N21583 001 Dec 17, 2004 Jan CAHN

MEGESTROL ACETATE

SUSPENSION; ORAL  
 MEGESTROL ACETATE  
 >A> AB APOTEX 40MG/ML N77404 001 Feb 16, 2006 Jan NEWA

MEPROBAMATE

TABLET; ORAL  
 MeproBamate  
 >D> + ROXANE 600MG N84332 001 Jan DISC  
 >A> @ 600MG N84332 001 Jan DISC  
 >D> AA SANDOZ 200MG N14547 002 Jan DISC  
 >A> @ 200MG N14547 002 Jan DISC  
 >D> AA 400MG N14547 001 Jan DISC  
 >A> @ 400MG N14547 001 Jan DISC  
 >D> AA 400MG N80655 001 Jan DISC  
 >A> @ 400MG N80655 001 Jan DISC  
 >D> AA SCHERER LABS 400MG N83343 001 Jan DISC  
 >A> @ 400MG N83343 001 Jan DISC  
 >D> AA TABLICAPS 400MG N83494 001 Jan DISC  
 >A> @ 400MG N83494 001 Jan DISC  
 >D> AA WATSON LABS 200MG N83304 001 Jan CRLD  
 >A> AA + 200MG N83304 001 Jan CRLD  
 >D> AA 200MG N85720 001 Jan DISC  
 >A> @ 200MG N85720 001 Jan DISC  
 >D> AA 400MG N83308 001 Jan CRLD  
 >A> + 400MG N83308 001 Jan CRLD  
 >D> AA 400MG N85721 001 Jan DISC  
 >A> @ 400MG N85721 001 Jan DISC  
 >D> MILTOWN  
 >D> AA + MEDPOINTE PHARM HLC 200MG N09698 004 Jan DISC  
 >A> @ 200MG N09698 004 Jan DISC  
 >D> AA + 400MG N09698 002 Jan DISC  
 >A> @ 400MG N09698 002 Jan DISC  
 >D> TRANMEP  
 >D> AA SOLVAY 400MG N16249 001 Jan DISC  
 >A> @ 400MG N16249 001 Jan DISC

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL  
 GLUMETZA  
 >D> BX BIOVAIL 500MG N21748 001 Jun 03, 2005 Jan CAHN  
 >D> BX 1GM N21748 002 Jun 03, 2005 Jan CAHN  
 >A> BX DEPOMED INC 500MG N21748 001 Jun 03, 2005 Jan CAHN

TABLET, EXTENDED RELEASE; ORAL

GLUMETZA

>A>	BX	DEPOMED INC	1GM	N21748 002	Jun 03, 2005	Jan	CAHN
METFORMIN HYDROCHLORIDE							
>A>	AB	SUN PHARM INDS (IN)	500MG	N77336 001	Feb 09, 2006	Jan	NEWA
>A>	AB		750MG	N77336 002	Feb 09, 2006	Jan	NEWA

NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION; IRRIGATION

NEOSPORIN AND POLYMYXIN B SULFATE							
>A>	AT	X GEN PHARMS	EQ 40MG BASE/ML;200,000 UNITS/ML	N65106 001	Jan 31, 2006	Jan	NEWA
>A>	AT		EQ 800MG BASE/20ML;4,000,000 UNITS/20ML (EQ 40MG BASE/ML;200,000 UNITS/ML)	N65108 001	Jan 31, 2006	Jan	NEWA
NEOSPORIN G.U. IRRIGANT							
>D>	+	MONARCH PHARMS	EQ 40MG BASE/ML;200,000 UNITS/ML	N60707 001		Jan	CTEC
>A>	AT	+	EQ 40MG BASE/ML;200,000 UNITS/ML	N60707 001		Jan	CTEC
>A>	AT	+	EQ 800MG BASE/20ML;4,000,000 UNITS/20ML (EQ 40MG BASE/ML;200,000 UNITS/ML)	N60707 002		Jan	NEWA

NICARDIPINE HYDROCHLORIDE

INJECTABLE; INJECTION

CARDENE

>D>	+	ESP PHARMA	2.5MG/ML	N19734 001	Jan 30, 1992	Jan	CAHN
>A>	+	PDL BIOPHARMA INC	2.5MG/ML	N19734 001	Jan 30, 1992	Jan	CAHN

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

AFEDITAB CR

>A>	AB1	WATSON LABS	30MG	N75128 001	Mar 10, 2000	Jan	CAHN
>A>	AB1		60MG	N75659 001	Oct 26, 2001	Jan	CAHN

NIFEDIPINE

>D>	AB1	ELAN PHARM	30MG	N75128 001	Mar 10, 2000	Jan	CAHN
>D>	AB1		60MG	N75659 001	Oct 26, 2001	Jan	CAHN

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

OCTREOTIDE ACETATE

>A>	AP	AM PHARM	EQ 0.2MG BASE/ML	N77450 001	Feb 10, 2006	Jan	NEWA
>A>	AP		EQ 1MG BASE/ML	N77450 002	Feb 10, 2006	Jan	NEWA
OCTREOTIDE ACETATE (PRESERVATIVE FREE)							
>A>	AP	AM PHARM	EQ 0.05MG BASE/ML	N77457 001	Feb 10, 2006	Jan	NEWA
>A>	AP		EQ 0.1MG BASE/ML	N77457 002	Feb 10, 2006	Jan	NEWA
>A>	AP		EQ 0.5MG BASE/ML	N77457 003	Feb 10, 2006	Jan	NEWA

OFLOXACIN

TABLET; ORAL

OFLOXACIN

>A>	AB	DR REDDYS LABS LTD	200MG	N77098 001	Feb 10, 2006	Jan	NEWA
>A>	AB		300MG	N77098 002	Feb 10, 2006	Jan	NEWA
>A>	AB		400MG	N77098 003	Feb 10, 2006	Jan	NEWA

PENICILLIN V POTASSIUM

FOR SOLUTION; ORAL

PENICILLIN V POTASSIUM

>A>	AA	AM ANTIBIOTICS	EQ 125MG BASE/5ML	N61529 001		Jan	CAHN
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## FOR SOLUTION; ORAL

## PENICILLIN V POTASSIUM

>A>	AA	AM ANTIBIOTICS	EQ 250MG BASE/5ML	N61529 002		Jan	CAHN
>D>	AA	CONSOLIDATED PHARM	EQ 125MG BASE/5ML	N61529 001		Jan	CAHN
>D>	AA		EQ 250MG BASE/5ML	N61529 002		Jan	CAHN

## TABLET; ORAL

## PENICILLIN V POTASSIUM

>A>	@	AM ANTIBIOTICS	EQ 250MG BASE	N61528 001		Jan	CAHN
>A>	@		EQ 500MG BASE	N61528 002		Jan	CAHN
>D>	@	CONSOLIDATED PHARM	EQ 250MG BASE	N61528 001		Jan	CAHN
>D>	@		EQ 500MG BASE	N61528 002		Jan	CAHN

PERGOLIDE MESYLATE

## TABLET; ORAL

## PERMAX

>D>	AB	+ VALEANT	EQ 0.05MG BASE	N19385 001	Dec 30, 1988	Jan	CRLD
>A>	AB		EQ 0.05MG BASE	N19385 001	Dec 30, 1988	Jan	CRLD
>D>	AB		EQ 0.25MG BASE	N19385 002	Dec 30, 1988	Jan	CRLD
>A>	AB	+	EQ 0.25MG BASE	N19385 002	Dec 30, 1988	Jan	CRLD

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

## SYRUP; ORAL

## PROMETH VC PLAIN

>D>	AA	+ ALPHARMA US PHARMS	5MG/5ML; 6.25MG/5ML	N88761 001	Nov 08, 1984	Jan	CTEC
>A>	+		5MG/5ML; 6.25MG/5ML	N88761 001	Nov 08, 1984	Jan	CTEC
>D>		PROMETHAZINE VC PLAIN					
>D>	AA	MORTON GROVE	5MG/5ML; 6.25MG/5ML	N88897 001	Jan 04, 1985	Jan	DISC
>A>	@		5MG/5ML; 6.25MG/5ML	N88897 001	Jan 04, 1985	Jan	DISC

POTASSIUM CHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## KLOR-CON

>D>	AB	+ UPSHER SMITH	8MEQ	N19123 001	Apr 17, 1986	Jan	CRLD
>A>	AB		8MEQ	N19123 001	Apr 17, 1986	Jan	CRLD
>D>		POTASSIUM CHLORIDE					
>D>	AB	COPLEY PHARM	8MEQ	N70618 001	Sep 09, 1987	Jan	CRLD
>A>	AB	+	8MEQ	N70618 001	Sep 09, 1987	Jan	CRLD

PRAZOSIN HYDROCHLORIDE

## CAPSULE; ORAL

## PRAZOSIN HCL

>D>	AB	CLONMEL HLTHCARE	EQ 1MG BASE	N72705 001	May 16, 1989	Jan	DISC
>D>	AB		EQ 5MG BASE	N72707 001	May 16, 1989	Jan	DISC
>A>		PRAZOSIN HYDROCHLORIDE					
>A>	@	CLONMEL HLTHCARE	EQ 1MG BASE	N72705 001	May 16, 1989	Jan	DISC
>A>	@		EQ 5MG BASE	N72707 001	May 16, 1989	Jan	DISC

PROMETHAZINE HYDROCHLORIDE

## SUPPOSITORY; RECTAL

## PROMETHEGAN

>D>		G AND W LABS	50MG	N87165 001	Aug 14, 1987	Jan	CRLD
>A>	+		50MG	N87165 001	Aug 14, 1987	Jan	CRLD

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

PROPRANOLOL HYDROCHLORIDE

>D>	AP	SABEX 2002	1MG/ML	N76400 001	Feb 26, 2003	Jan	CAHN
>A>	AP	SANDOZ	1MG/ML	N76400 001	Feb 26, 2003	Jan	CAHN

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

REGONOL

>D>	AP	SABEX 2002	5MG/ML	N17398 001		Jan	CAHN
>A>	AP	SANDOZ	5MG/ML	N17398 001		Jan	CAHN

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

QUINAPRIL HYDROCHLORIDE

>A>	AB	TORPHARM	EQ 5MG BASE	N76240 001	Jan 26, 2006	Jan	NEWA
>A>	AB		EQ 10MG BASE	N76240 002	Jan 26, 2006	Jan	NEWA
>A>	AB		EQ 20MG BASE	N76240 003	Jan 26, 2006	Jan	NEWA
>A>	AB		EQ 40MG BASE	N76240 004	Jan 26, 2006	Jan	NEWA

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL

QUINIDINE GLUCONATE

>D>		+ MUTUAL PHARM	324MG	N89338 001	Feb 11, 1987	Jan	CTEC
>A>	BX	+	324MG	N89338 001	Feb 11, 1987	Jan	CTEC
>D>		@ WATSON LABS	324MG	N87810 001	Sep 29, 1982	Jan	CMFD
>A>	BX		324MG	N87810 001	Sep 29, 1982	Jan	CMFD

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

>D>	AB	CLONMEL HLTHCARE	200MG	N87011 001		Jan	DISC
>A>		@	200MG	N87011 001		Jan	DISC
>D>	AB	LANNETT	200MG	N83743 001		Jan	DISC
>A>		@	200MG	N83743 001		Jan	DISC
>D>	AB	MUTUAL PHARM	100MG	N81029 001	Apr 14, 1989	Jan	DISC
>A>		@	100MG	N81029 001	Apr 14, 1989	Jan	DISC
>D>	AB	PHARM FORM	200MG	N83808 001		Jan	DISC
>A>		@	200MG	N83808 001		Jan	DISC
>D>	AB	SANDOZ	200MG	N84631 001		Jan	DISC
>A>		@	200MG	N84631 001		Jan	DISC
>D>	AB		200MG	N84914 001		Jan	DISC
>A>		@	200MG	N84914 001		Jan	DISC
>A>	AB		200MG	N88072 002		Jan	NEWA
>D>	AB		300MG	N89839 001	Sep 29, 1988	Jan	DISC
>A>		@	300MG	N89839 001	Sep 29, 1988	Jan	DISC
>D>	AB	WATSON LABS	200MG	N83288 001		Jan	DISC
>A>		@	200MG	N83288 001		Jan	DISC
>D>	AB		200MG	N85140 002		Jan	DISC
>A>		@	200MG	N85140 002		Jan	DISC

>A> RANOLAZINE  
 >A> TABLET, EXTENDED RELEASE; ORAL  
 >A> RANEXA  
 >A> + CV THERAP 500MG N21526 002 Jan 27, 2006 Jan NEWA

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION  
 ANECTINE  
 >D> AP + SABEX 2002 20MG/ML N08453 002 Jan CAHN  
 >D> @ 50MG/ML N08453 003 Jan CAHN  
 >D> @ 500MG/VIAL N08453 001 Jan CAHN  
 >D> @ 1GM/VIAL N08453 004 Jan CAHN  
 >A> AP + SANDOZ 20MG/ML N08453 002 Jan CAHN  
 >A> @ 50MG/ML N08453 003 Jan CAHN  
 >A> @ 500MG/VIAL N08453 001 Jan CAHN  
 >A> @ 1GM/VIAL N08453 004 Jan CAHN

>A> SUNITINIB MALATE

>A> CAPSULE; ORAL  
 >A> SUTENT  
 >A> PFIZER 12.5MG N21938 001 Jan 26, 2006 Jan NEWA  
 >A> 25MG N21938 002 Jan 26, 2006 Jan NEWA  
 >A> + 50MG N21938 003 Jan 26, 2006 Jan NEWA

TESTOSTERONE

GEL; TRANSDERMAL  
 ANDROGEL  
 >D> BX + UNIMED PHARMS 1% N21015 001 Feb 28, 2000 Jan CTEC  
 >A> AB + 1% N21015 001 Feb 28, 2000 Jan CTEC  
 >A> TESTOSTERONE  
 >A> AB WATSON LABS 1% N76737 001 Jan 27, 2006 Jan NEWA

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION  
 DELATESTRYL  
 >A> AO + INDEVUS PHARMS 200MG/ML N09165 003 Jan CAHN  
 >A> @ 200MG/ML N09165 001 Jan CAHN  
 >D> @ SAVIENT PHARMS 200MG/ML N09165 001 Jan CAHN  
 >D> AO + 200MG/ML N09165 003 Jan CAHN

TINIDAZOLE

TABLET; ORAL  
 TINDAMAX  
 >A> MISSION PHARMA 250MG N21618 001 May 17, 2004 Jan CAHN  
 >A> + 500MG N21618 002 May 17, 2004 Jan CAHN  
 >D> PRESUTTI LABS 250MG N21618 001 May 17, 2004 Jan CAHN  
 >D> + 500MG N21618 002 May 17, 2004 Jan CAHN

TRAMADOL HYDROCHLORIDE

TABLET; ORAL  
 TRAMADOL HYDROCHLORIDE  
 >D> AB IVAX PHARMS 50MG N75963 001 Jul 03, 2002 Jan DISC  
 >A> @ 50MG N75963 001 Jul 03, 2002 Jan DISC

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION  
ARISTOCORT

>D>	@	SABEX 2002	25MG/ML	N11685 003	Jan	CAHN
>D>	@		40MG/ML	N12802 001	Jan	CAHN
>A>	@	SANDOZ	25MG/ML	N11685 003	Jan	CAHN
>A>	@		40MG/ML	N12802 001	Jan	CAHN

TRIAMCINOLONE HEXACETONIDE

INJECTABLE; INJECTION  
ARISTOSPAN

>D>	+	SABEX 2002	5MG/ML	N16466 001	Jan	CAHN
>D>	+		20MG/ML	N16466 002	Jan	CAHN
>A>	+	SANDOZ	5MG/ML	N16466 001	Jan	CAHN
>A>	+		20MG/ML	N16466 002	Jan	CAHN

>D> TRIPLENNAMINE HYDROCHLORIDE

TABLET; ORAL  
PBZ

>D>	+	NOVARTIS	50MG	N05914 002	Jan	DISC
>A>	@		50MG	N05914 002	Jan	DISC

VECURONIUM BROMIDE

INJECTABLE; INJECTION  
VECURONIUM BROMIDE

>D>	AP	BEDFORD	20MG/VIAL	N75549 002	Jun 13, 2000	Jan	CRLD
>A>	AP	+	20MG/VIAL	N75549 002	Jun 13, 2000	Jan	CRLD

ZONISAMIDE

CAPSULE; ORAL  
ZONISAMIDE

>A>	AB	GLENMARK PHARMS	25MG	N77651 001	Jan 30, 2006	Jan	NEWA
>A>	AB		50MG	N77651 002	Jan 30, 2006	Jan	NEWA
>A>	AB		100MG	N77651 003	Jan 30, 2006	Jan	NEWA



OTC DRUG PRODUCT LIST - 25TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 1 - January 2006

2-1

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SPONGE; TOPICAL

CHLORAPREP WITH TINT

>A> + MEDI FLEX INC 2%;70% (10.5ML) N20832 005 Dec 27, 2005 Jan NEWA

CROMOLYN SODIUM

SPRAY, METERED; NASAL

CROMOLYN SODIUM

>D> ALPHARMA US PHARMS 5.2MG/INH N74800 001 Jul 26, 2001 Jan CPOT

>A> 5.2MG/SPRAY N74800 001 Jul 26, 2001 Jan CPOT

>D> BAUSCH AND LOMB 5.2MG/SPRAY N75702 001 Jul 03, 2001 Jan CRLD

>A> + 5.2MG/SPRAY N75702 001 Jul 03, 2001 Jan CRLD

>D> NASALCROM

>D> + PHARMACIA UPJOHN 5.2MG/SPRAY N20463 001 Jan 03, 1997 Jan DISC

>A> @ 5.2MG/SPRAY N20463 001 Jan 03, 1997 Jan DISC

LORATADINE

TABLET; ORAL

LORATADINE

>A> APOTEX 10MG N76471 001 Feb 14, 2006 Jan NEWA

MINOXIDIL

>A> AEROSOL, FOAM; TOPICAL

>A> MEN'S ROGAINE

>A> + PHARMACIA AND UPJOHN 5% N21812 001 Jan 20, 2006 Jan NEWA

NICOTINE POLACRILEX

TROCHE/LOZENGE; ORAL

>A> NICOTINE POLACRILEX

>A> PERRIGO R AND D EQ 2MG BASE N77007 001 Jan 31, 2006 Jan NEWA

>A> EQ 4MG BASE N77007 002 Jan 31, 2006 Jan 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 JANUARY 2006**

NO JANUARY 2006 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 2006 ADDITIONS

**PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA**

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ALENDRONATE SODIUM; CHOLECALCIFEROL - FOSAMAX PLUS D</u>					
021762 001				>A> NC	Apr 07, 2008
<u>APREPITANT - EMEND</u>					
021549 001	>A> 5145684	Jan 25, 2011	DP		
<u>APREPITANT - EMEND</u>					
021549 002	>A> 5145684	Jan 25, 2011	DP		
<u>ARIPIPIRAZOLE - ABILIFY</u>					
021713 001	>A> 6977257	Apr 24, 2022	DS DP		
<u>BIVALIRUDIN - ANGIOMAX</u>					
020873 001				>A> I-486	Nov 30, 2008
<u>BORTEZOMIB - VELCADE</u>					
021602 001				>A> ODE	Mar 25, 2012
<u>BRIMONIDINE TARTRATE - ALPHAGAN P</u>					
021770 001	>A> 5424078	Jun 13, 2012	DP		
	>A> 5424078*PED	Dec 13, 2012			
	>A> 6562873	Jul 10, 2021	DP		
	>A> 6562873*PED	Jan 10, 2022			
	>A> 6627210	Jul 18, 2021	DP		
	>A> 6627210*PED	Jan 18, 2022			
	>A> 6641834	Jul 28, 2021	DP		
	>A> 6641834*PED	Jan 28, 2022			
	>A> 6673337	Jul 26, 2021	DP		
	>A> 6673337*PED	Jan 26, 2022			
<u>BROMFENAC SODIUM - XIBROM</u>					
021664 001				>A> I-485	Jan 27, 2009
<u>BUDESONIDE - RHINOCORT</u>					
020746 001	>A> 6986904	Apr 29, 2017			
<u>CALCIUM CARBONATE; RISEDRONATE SODIUM - ACTONEL WITH CALCIUM (COPACKAGED)</u>					
021823 001				>A> M-52	Jan 24, 2009
<u>CONIVAPTAN HYDROCHLORIDE - VAPRISOL</u>					
021697 001	>A> 5723606	Mar 03, 2015	DS DP	U-698	
<u>DESFLURANE - SUPRANE</u>					
020118 001	>A> 5617906	Apr 08, 2014	DP		
<u>DESGLORATADINE; PSEUDOEPHEDRINE SULFATE - CLARINEX D 24 HOUR</u>					
021605 001	>A> 6979463	Mar 28, 2022	DP		
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>					
021153 001				>A> I-484	Nov 24, 2007
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>					
021153 002				>A> I-484	Nov 24, 2007
<u>FENOFIBRATE - FENOFIBRATE</u>					
076433 001				>A> PC	May 22, 2006
<u>FENOFIBRATE - FENOFIBRATE</u>					
076433 002				>A> PC	May 22, 2006
<u>FLUNISOLIDE - AEROSPAN HFA</u>					
021247 001				>A> NP	Jan 27, 2009
<u>FULVESTRANT - FASLODEX</u>					
021344 001	>A> 4659516	Oct 01, 2006			
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 001	>A> 5002953	Sep 17, 2011	DS DP	U-690	
	>A> 5002953*PED	Mar 17, 2012			
	>A> 5741803	Apr 21, 2015	DS DP	U-690	
	>A> 5741803*PED	Oct 21, 2015			
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 002	>A> 5002953	Sep 17, 2011	DS DP	U-690	
	>A> 5002953*PED	Mar 17, 2012			
	>A> 5741803	Apr 21, 2015	DS DP	U-690	
	>A> 5741803*PED	Oct 21, 2015			

**PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA**

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 003	>A> 5002953	Sep 17, 2011	DS DP	U-690	
	>A> 5002953*PED	Mar 17, 2012			
	>A> 5741803	Apr 21, 2015	DS DP	U-690	
	>A> 5741803*PED	Oct 21, 2015			
<u>HYALURONIDASE RECOMBINANT HUMAN - HYLENEX RECOMBINANT</u>					
021859 001				>A> NCE	Dec 02, 2010
<u>IBANDRONATE SODIUM - BONIVA</u>					
021455 001	>A> 4927814	Jul 09, 2007	DS DP	U-642	
	>A> 6143326	Apr 21, 2017		U-642	
<u>IBANDRONATE SODIUM - BONIVA</u>					
021858 001				>A> NDF >A> NCE	Jan 06, 2009 May 16, 2008
<u>IPRATROPIUM BROMIDE - ATROVENT HFA</u>					
021527 001	>A> 6983743	May 26, 2020	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
020406 001	>A> 6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
020406 002	>A> 6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021281 001	>A> 6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021281 002	>A> 6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021428 001	>A> 6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021428 002	>A> 6749864	Feb 13, 2007	DP		
<u>LANTHANUM CARBONATE - FOSRENOL</u>					
021468 003	>A> 5968976	Mar 19, 2016	DP	U-613	
<u>LANTHANUM CARBONATE - FOSRENOL</u>					
021468 004	>A> 5968976	Mar 19, 2016	DP	U-613	
<u>LENALIDOMIDE - REVLIMID</u>					
021880 001	>A> 5635517	Jul 24, 2016	DS		>A> ODE
	>A> 6045501	Aug 28, 2018		U-694	
	>A> 6315720	Oct 23, 2020		U-694	
	>A> 6555554	Jul 24, 2016	DP		
	>A> 6561976	Aug 28, 2018		U-694	
	>A> 6561977	Oct 23, 2020		U-694	
	>A> 6755784	Oct 23, 2020		U-694	
	>A> 6908432	Aug 28, 2018		U-694	
<u>LENALIDOMIDE - REVLIMID</u>					
021880 002	>A> 5635517	Jul 24, 2016	DS		>A> ODE
	>A> 6045501	Aug 28, 2018		U-694	
	>A> 6315720	Oct 23, 2020		U-694	
	>A> 6555554	Jul 24, 2016	DP		
	>A> 6561976	Aug 28, 2018		U-694	
	>A> 6561977	Oct 23, 2020		U-694	
	>A> 6755784	Oct 23, 2020		U-694	
	>A> 6908432	Aug 28, 2018		U-694	

**PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA**

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>LOPINAVIR; RITONAVIR - KALETRA</u>					
021906 001	>A> 5541206	Jul 30, 2013	DS DP	U-688	
	>A> 5541206*PED	Jan 30, 2014			
	>A> 5635523	Jun 03, 2014		U-688	
	>A> 5635523*PED	Dec 03, 2014			
	>A> 5648497	Jul 15, 2014	DS DP		
	>A> 5648497*PED	Jan 15, 2015			
	>A> 5674882	Oct 07, 2014		U-688	
	>A> 5674882*PED	Apr 07, 2015			
	>A> 5846987	Dec 29, 2012		U-688	
	>A> 5846987*PED	Jun 29, 2013			
	>A> 5886036	Dec 29, 2012	DP		
	>A> 5886036*PED	Jun 29, 2013			
	>A> 6037157	Jun 26, 2016		U-688	
	>A> 6037157*PED	Dec 26, 2016			
	>A> 6703403	Jun 26, 2016		U-688	
	>A> 6703403*PED	Dec 26, 2016			
<u>LUBIPROSTONE - AMITIZA</u>					
021908 001				>A> NCE	Jan 31, 2011
<u>MECASERMIN RINFABATE RECOMBINANT - IPLEX</u>					
021884 001	>A> 5200509	Apr 06, 2010	DS		
	>A> 5681818	Oct 28, 2014		U-697	
<u>MELOXICAM - MOBIC</u>					
020938 001				>A> ODE	Aug 11, 2012
				>A> PED	Feb 11, 2013
<u>MELOXICAM - MOBIC</u>					
020938 002				>A> ODE	Aug 11, 2012
				>A> PED	Feb 11, 2013
<u>MELOXICAM - MOBIC</u>					
021530 001				>A> I-469	Aug 11, 2008
				>A> ODE	Aug 11, 2012
				>A> PED	Feb 11, 2013
				>A> PED	Feb 11, 2009
<u>MINOXIDIL - MEN'S ROGAINE</u>					
021812 001				>A> NDF	Jan 20, 2009
<u>MORPHINE SULFATE - KADIAN</u>					
020616 004	>A> 5378474	Mar 23, 2010			
<u>MORPHINE SULFATE - KADIAN</u>					
020616 005	>A> 5202128	Apr 13, 2010			
	>A> 5378474	Mar 23, 2010			
<u>NELARABINE - ARRANON</u>					
021877 001	>A> 5747472	Feb 20, 2013		U-696	
	>A> 5747472	Feb 20, 2013		U-695	
	>A> 5747472	Feb 20, 2013		U-689	
	>A> 5821236	Feb 20, 2013		U-695	
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 001	>A> 5753618	May 19, 2015			
	>A> 5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 002	>A> 5753618	May 19, 2015			
	>A> 5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 003	>A> 5753618	May 19, 2015			
	>A> 5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 004	>A> 5753618	May 19, 2015			
	>A> 5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 005	>A> 5753618	May 19, 2015			
	>A> 5753618*PED	Nov 19, 2015			

**PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA**

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>					
021008 001	>A> 5538739	Jul 23, 2013		>A> ODE	Nov 25, 2005
	>A> 5538739*PED	Jan 23, 2014		>A> PED	May 25, 2006
	>A> 5639480	Jun 17, 2014			
	>A> 5639480*PED	Dec 17, 2014			
	>A> 5688530	Nov 18, 2014	U-268		
	>A> 5688530*PED	May 18, 2015			
	>A> 5922338	Jul 13, 2016			
	>A> 5922338*PED	Jan 13, 2017			
	>A> 5922682	Jul 13, 2016			
	>A> 5922682*PED	Jan 13, 2017			
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>					
021008 002	>A> 5538739	Jul 23, 2013		>A> ODE	Nov 25, 2005
	>A> 5538739*PED	Jan 23, 2014		>A> PED	May 25, 2006
	>A> 5639480	Jun 17, 2014			
	>A> 5639480*PED	Dec 17, 2014			
	>A> 5688530	Nov 18, 2014	U-268		
	>A> 5688530*PED	May 18, 2015			
	>A> 5922338	Jul 13, 2016			
	>A> 5922338*PED	Jan 13, 2017			
	>A> 5922682	Jul 13, 2016			
	>A> 5922682*PED	Jan 13, 2017			
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>					
021008 003	>A> 5538739	Jul 23, 2013		>A> ODE	Nov 25, 2005
	>A> 5538739*PED	Jan 23, 2014		>A> PED	May 25, 2006
	>A> 5639480	Jun 17, 2014			
	>A> 5639480*PED	Dec 17, 2014			
	>A> 5688530	Nov 18, 2014	U-268		
	>A> 5688530*PED	May 18, 2015			
	>A> 5922338	Jul 13, 2016			
	>A> 5922338*PED	Jan 13, 2017			
	>A> 5922682	Jul 13, 2016			
	>A> 5922682*PED	Jan 13, 2017			
<u>OXALIPLATIN - ELOXATIN</u>					
021492 001	>A> 5420319	Aug 09, 2016	DS		
<u>OXALIPLATIN - ELOXATIN</u>					
021492 002	>A> 5420319	Aug 09, 2016	DS		
<u>OXALIPLATIN - ELOXATIN</u>					
021759 001	>A> 5420319	Aug 08, 2016	DS		
<u>OXALIPLATIN - ELOXATIN</u>					
021759 002	>A> 5420319	Aug 08, 2016	DS		
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 001	>A> 4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 002	>A> 4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 003	>A> 4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 004	>A> 4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 005	>A> 4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 006	>A> 4843086	Jun 27, 2006		U-231	
<u>QUETIAPINE FUMARATE - SEROQUEL</u>					
020639 006	>A> 4879288	Sep 26, 2011	DS DP	U-550	
<u>QUETIAPINE FUMARATE - SEROQUEL</u>					
020639 007	>A> 4879288	Sep 26, 2011	DS DP	U-550	
<u>RALOXIFENE HYDROCHLORIDE - EVISTA</u>					
020815 001	>A> RE38968	Jul 28, 2012		U-662	
	>A> RE38968	Jul 28, 2012		U-657	
<u>RANOLAZINE - RANEXA</u>					
021526 002				>A> NCE	Jan 27, 2011



**PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA**

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>RISEDRONATE SODIUM - ACTONEL</u> 020835 001				>A> M-52	Jan 24, 2009
<u>RISEDRONATE SODIUM - ACTONEL</u> 020835 002				>A> M-52	Jan 24, 2009
<u>RISEDRONATE SODIUM - ACTONEL</u> 020835 003				>A> M-52	Jan 24, 2009
<u>SORAFENIB TOSYLATE - NEXAVAR</u> 021923 001				>A> ODE	Dec 20, 2012
<u>SUNITINIB MALATE - SUTENT</u> 021938 001				>A> NCE	Jan 26, 2011
<u>SUNITINIB MALATE - SUTENT</u> 021938 002				>A> NCE	Jan 26, 2011
<u>SUNITINIB MALATE - SUTENT</u> 021938 003				>A> NCE	Jan 26, 2011
<u>TERIPARATIDE RECOMBINANT HUMAN - FORTEO</u> 021318 001	>A> 6977077	Aug 19, 2019	U-597		
<u>THYROTROPIN ALFA - THYROGEN</u> 020898 001				>A> M-53	Jan 23, 2009
<u>TREPROSTINIL SODIUM - REMODULIN</u> 021272 001	>A> 5153222	Oct 06, 2014	U-455		
<u>TREPROSTINIL SODIUM - REMODULIN</u> 021272 002	>A> 5153222	Oct 06, 2014	U-455		
<u>TREPROSTINIL SODIUM - REMODULIN</u> 021272 003	>A> 5153222	Oct 06, 2014	U-455		
<u>TREPROSTINIL SODIUM - REMODULIN</u> 021272 004	>A> 5153222	Oct 06, 2014	U-455		

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>