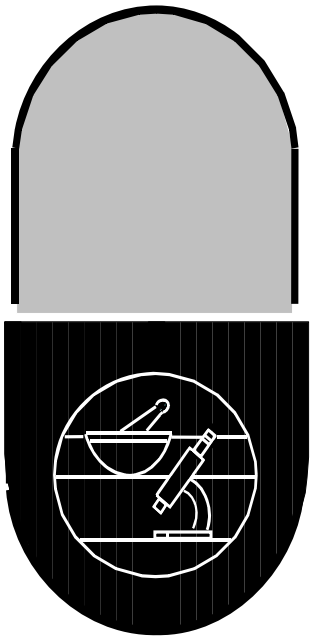
CUMULATIVE SUPPLEMENT 01
January 2006



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

26th 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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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 Previously, a first-time-generic approved early in the month would not be published in the CS for several weeks.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.

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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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)	PERRIGO NEW YORK INC (PERRIGO NEW YORK)
CLAY PARK LABS INC	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

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

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

1.5 CUMULATIVE SUPPLEMENT LEGEND

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

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The last two

columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

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

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

The change code and description:

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

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

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;8MG/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;8MG/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;8MG/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;8MG/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

>A> 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

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

>D> TABLET; ORAL
>D> 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;0.14MG/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;0.14MG/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;0.14MG/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;0.14MG/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

>A> BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE

>A> OINTMENT; TOPICAL

>A> TACLONEX

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

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

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

>D>			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

CEFTRIAXONE SODIUM

INJECTABLE; IM-IV

CEFTRIAXONE

>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

CEFTRIAXONE

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

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

CLOPIDOGREL BISULFATE

TABLET; ORAL

>A>		CLOPIDOGREL BISULFATE						
>A>	AB	APOTEX	EQ 75MG BASE	N76274	001	Jan 20, 2006	Jan	NEWA

PLAVIX

>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;6.25MG/5ML	N88764	001	Oct 31, 1984	Jan	CTEC
>A>	+		10MG/5ML;5MG/5ML;6.25MG/5ML	N88764	001	Oct 31, 1984	Jan	CTEC

>D>		PROMETHAZINE VC W/ CODEINE						
>D>	AA	MORTON GROVE	10MG/5ML;5MG/5ML;6.25MG/5ML	N88896	001	Jan 04, 1985	Jan	DISC
>A>		@	10MG/5ML;5MG/5ML;6.25MG/5ML	N88896	001	Jan 04, 1985	Jan	DISC

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

>A>		PROMETHAZINE WITH CODEINE SYRUP						
>A>	AA	VINTAGE	10MG/5ML;6.25MG/5ML	N40650	001	Jan 31, 2006	Jan	NEWA

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

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
>A> 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
>A> 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

>A>		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

TRICOR

>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; ORAL
GLIMEPIRIDE

>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 DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL 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 LACTATE

INJECTABLE; INJECTION
HALOPERIDOL

>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

ISONIAZID

INJECTABLE; INJECTION
ISONIAZID

>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 TROMETHAMINE

INJECTABLE; INJECTION
KETOROLAC 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

>A> 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

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

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

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> TRIPELENNAMINE HYDROCHLORIDE

>D> TABLET; ORAL

>D>		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

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

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

AEROSOL, FOAM; TOPICAL

MEN'S ROGAINE

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

NICOTINE POLACRILEX

TROCHE/LOZENGE; ORAL

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 EXPIRATON DATE		PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ALENDRONATE SODIUM; CHOLECALCIFEROL - FOSAMAX PLUS D						
021762 001					**>A>** NC	Apr 07, 2008
APREPITANT - EMEND						
021549 001	**>A>** 5145684	Jan 25, 2011		DP		
APREPITANT - EMEND						
021549 002	**>A>** 5145684	Jan 25, 2011		DP		
ARIPIPRAZOLE - ABILIFY						
021713 001	**>A>** 6977257	Apr 24, 2022	DS	DP		
BIVALIRUDIN - ANGIOMAX						
020873 001					**>A>** I-486	Nov 30, 2008
BORTEZOMIB - VELCADE						
021602 001					**>A>** ODE	Mar 25, 2012
BRIMONIDINE TARTRATE - ALPHAGAN P						
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				
BROMFENAC SODIUM - XIBROM						
021664 001					**>A>** I-485	Jan 27, 2009
BUDESONIDE - RHINOCORT						
020746 001	**>A>** 6986904	Apr 29, 2017				
CALCIUM CARBONATE; RISEDRONATE SODIUM - ACTONEL WITH CALCIUM (COPACKAGED)						
021823 001					**>A>** M-52	Jan 24, 2009
CONIVAPTAN HYDROCHLORIDE - VAPRISOL						
021697 001	**>A>** 5723606	Mar 03, 2015	DS	DP U-698		
DESFLURANE - SUPRANE						
020118 001	**>A>** 5617906	Apr 08, 2014		DP		
DESLORATADINE; PSEUDOEPHEDRINE SULFATE - CLARINEX D 24 HOUR						
021605 001	**>A>** 6979463	Mar 28, 2022		DP		
ESOMEPRAZOLE MAGNESIUM - NEXIUM						
021153 001					**>A>** I-484	Nov 24, 2007
ESOMEPRAZOLE MAGNESIUM - NEXIUM						
021153 002					**>A>** I-484	Nov 24, 2007
FENOFIBRATE - FENOFIBRATE						
076433 001					**>A>** PC	May 22, 2006
FENOFIBRATE - FENOFIBRATE						
076433 002					**>A>** PC	May 22, 2006
FLUNISOLIDE - AEROSPAN HFA						
021247 001					**>A>** NP	Jan 27, 2009
FULVESTRANT - FASLODEX						
021344 001	**>A>** 4659516	Oct 01, 2006				
GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL						
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				
GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL						
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
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APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE	PATENT CODES		EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL						
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				
HYALURONIDASE RECOMBINANT HUMAN - HYLENEX RECOMBINANT						
021859 001					**>A>** NCE	Dec 02, 2010
IBANDRONATE SODIUM - BONIVA						
021455 001	**>A>** 4927814	Jul 09, 2007	DS	DP U-642		
	>A> 6143326	Apr 21, 2017		U-642		
IBANDRONATE SODIUM - BONIVA						
021858 001					**>A>** NDF	Jan 06, 2009
					>A> NCE	May 16, 2008
IPRATROPIUM BROMIDE - ATROVENT HFA						
021527 001	**>A>** 6983743	May 26, 2020		DP		
LANSOPRAZOLE - PREVACID						
020406 001	**>A>** 6749864	Feb 13, 2007		DP		
LANSOPRAZOLE - PREVACID						
020406 002	**>A>** 6749864	Feb 13, 2007		DP		
LANSOPRAZOLE - PREVACID						
021281 001	**>A>** 6749864	Feb 13, 2007		DP		
LANSOPRAZOLE - PREVACID						
021281 002	**>A>** 6749864	Feb 13, 2007		DP		
LANSOPRAZOLE - PREVACID						
021428 001	**>A>** 6749864	Feb 13, 2007		DP		
LANSOPRAZOLE - PREVACID						
021428 002	**>A>** 6749864	Feb 13, 2007		DP		
LANTHANUM CARBONATE - FOSRENOL						
021468 003	**>A>** 5968976	Mar 19, 2016		DP U-613		
LANTHANUM CARBONATE - FOSRENOL						
021468 004	**>A>** 5968976	Mar 19, 2016		DP U-613		
LENALIDOMIDE - REVLIMID						
021880 001	**>A>** 5635517	Jul 24, 2016	DS		**>A>** ODE	Dec 27, 2012
	>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		
LENALIDOMIDE - REVLIMID						
021880 002	**>A>** 5635517	Jul 24, 2016	DS		**>A>** ODE	Dec 27, 2012
	>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

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APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
LOPINAVIR; RITONAVIR - KALETRA					
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			
LUBIPROSTONE - AMITIZA					
021908 001				**>A>** NCE	Jan 31, 2011
MECASERMIN RINFABATE RECOMBINANT - IPLEX					
021884 001	**>A>** 5200509	Apr 06, 2010	DS		
	>A> 5681818	Oct 28, 2014	U-697		
MELOXICAM - MOBIC					
020938 001				**>A>** ODE	Aug 11, 2012
				>A> PED	Feb 11, 2013
MELOXICAM - MOBIC					
020938 002				**>A>** ODE	Aug 11, 2012
				>A> PED	Feb 11, 2013
MELOXICAM - MOBIC					
021530 001				**>A>** I-469	Aug 11, 2008
				>A> ODE	Aug 11, 2012
				>A> PED	Feb 11, 2013
				>A> PED	Feb 11, 2009
MINOXIDIL - MEN'S ROGAINE					
021812 001				**>A>** NDF	Jan 20, 2009
MORPHINE SULFATE - KADIAN					
020616 004	**>A>** 5378474	Mar 23, 2010			
MORPHINE SULFATE - KADIAN					
020616 005	**>A>** 5202128	Apr 13, 2010			
	>A> 5378474	Mar 23, 2010			
NELARABINE - ARRANON					
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		
OCTREOTIDE ACETATE - SANDOSTATIN					
019667 001	**>A>** 5753618	May 19, 2015			
	>A> 5753618*PED	Nov 19, 2015			
OCTREOTIDE ACETATE - SANDOSTATIN					
019667 002	**>A>** 5753618	May 19, 2015			
	>A> 5753618*PED	Nov 19, 2015			
OCTREOTIDE ACETATE - SANDOSTATIN					
019667 003	**>A>** 5753618	May 19, 2015			
	>A> 5753618*PED	Nov 19, 2015			
OCTREOTIDE ACETATE - SANDOSTATIN					
019667 004	**>A>** 5753618	May 19, 2015			
	>A> 5753618*PED	Nov 19, 2015			
OCTREOTIDE ACETATE - SANDOSTATIN					
019667 005	**>A>** 5753618	May 19, 2015			
	>A> 5753618*PED	Nov 19, 2015			

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

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APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
OCTREOTIDE ACETATE - SANDOSTATIN LAR					
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			
OCTREOTIDE ACETATE - SANDOSTATIN LAR					
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			
OCTREOTIDE ACETATE - SANDOSTATIN LAR					
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			
OXALIPLATIN - ELOXATIN					
021492 001	**>A>** 5420319	Aug 09, 2016	DS		
OXALIPLATIN - ELOXATIN					
021492 002	**>A>** 5420319	Aug 09, 2016	DS		
OXALIPLATIN - ELOXATIN					
021759 001	**>A>** 5420319	Aug 08, 2016	DS		
OXALIPLATIN - ELOXATIN					
021759 002	**>A>** 5420319	Aug 08, 2016	DS		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX					
020667 001	**>A>** 4843086	Jun 27, 2006	U-231		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX					
020667 002	**>A>** 4843086	Jun 27, 2006	U-231		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX					
020667 003	**>A>** 4843086	Jun 27, 2006	U-231		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX					
020667 004	**>A>** 4843086	Jun 27, 2006	U-231		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX					
020667 005	**>A>** 4843086	Jun 27, 2006	U-231		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX					
020667 006	**>A>** 4843086	Jun 27, 2006	U-231		
QUETIAPINE FUMARATE - SEROQUEL					
020639 006	**>A>** 4879288	Sep 26, 2011	DS DP	U-550	
QUETIAPINE FUMARATE - SEROQUEL					
020639 007	**>A>** 4879288	Sep 26, 2011	DS DP	U-550	
RALOXIFENE HYDROCHLORIDE - EVISTA					
020815 001	**>A>** RE38968	Jul 28, 2012		U-662	
	>A> RE38968	Jul 28, 2012		U-657	
RANOLAZINE - RANEXA					
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 EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
RISEDRONATE SODIUM - ACTONEL					
020835 001				**>A>** M-52	Jan 24, 2009
RISEDRONATE SODIUM - ACTONEL					
020835 002				**>A>** M-52	Jan 24, 2009
RISEDRONATE SODIUM - ACTONEL					
020835 003				**>A>** M-52	Jan 24, 2009
SORAFENIB TOSYLATE - NEXAVAR					
021923 001				**>A>** ODE	Dec 20, 2012
SUNITINIB MALATE - SUTENT					
021938 001				**>A>** NCE	Jan 26, 2011
SUNITINIB MALATE - SUTENT					
021938 002				**>A>** NCE	Jan 26, 2011
SUNITINIB MALATE - SUTENT					
021938 003				**>A>** NCE	Jan 26, 2011
TERIPARATIDE RECOMBINANT HUMAN - FORTEO					
021318 001	**>A>** 6977077	Aug 19, 2019	U-597		
THYROTROPIN ALFA - THYROGEN					
020898 001				**>A>** M-53	Jan 23, 2009
TREPROSTINIL SODIUM - REMODULIN					
021272 001	**>A>** 5153222	Oct 06, 2014	U-455		
TREPROSTINIL SODIUM - REMODULIN					
021272 002	**>A>** 5153222	Oct 06, 2014	U-455		
TREPROSTINIL SODIUM - REMODULIN					
021272 003	**>A>** 5153222	Oct 06, 2014	U-455		
TREPROSTINIL SODIUM - REMODULIN					
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, 25th Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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

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