

APPROVED DRUG PRODUCTS

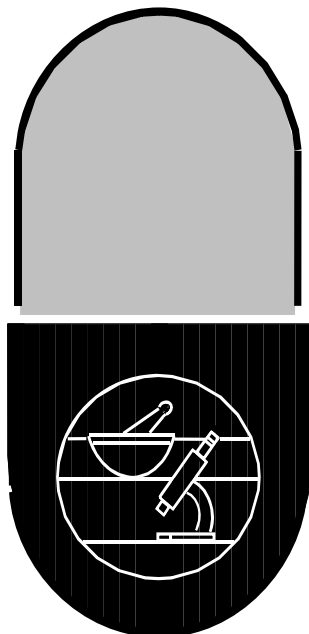
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**CUMULATIVE
SUPPLEMENT 02**
February 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

**APPROVED DRUG PRODUCTS
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26th EDITION

Cumulative Supplement 02

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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.

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 Previously, a first-time-generic approved early in the month would not be published in the CS for several weeks.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

**CUMULATIVE SUPPLEMENT 02
February 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, 25th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to mark to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement. Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 25th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 26th Edition. The current edition

Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. The Patent and Exclusivity 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)

AVENTIS PHARMACEUTICALS INC
(AVENTIS)
AVENTIS PHARMACEUTICAL PRODUCTS INC
(AVENTIS PHARMS)

SANOFI AVENTIS US LLC
(SANOFI AVENTIS US)
SANOFI AVENTIS US LLC
(SANOFI AVENTIS US)

DERMIK LABORATORIES DIV AVENTIS PHARMACEUTICALS INC (DERMIK LABS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
DERMIK LABORATORIES INC (DERMIK LABS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
DERMIK LABORATORIES INC SUB RORER (DERMIK LABS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
CLAY PARK LABORATORIES INC (CLAY PARK)	PERRIGO NEW YORK INC (PERRIGO NEW YORK)
CLAY PARK LABS INC (CLAY PARK)	PERRIGO NEW YORK INC (PERRIGO NEW YORK)
LOREX PHARMACEUTICALS (LOREX)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
MARTEC PHARMACEUTICALS (MARTEC)	MARTEC USA LLC (MARTEC USA LLC)
MARTEC SCIENTIFIC INC (MARTEC)	MARTEC USA LLC (MARTEC USA LLC)
SANOFI AVENTIS US INC (SANOFI AVENTIS US)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI-AVENTIS US INC (SANOFI AVENTIS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI INC (SANOFI)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI SYNTHELABO INC (SANOFI SYNTHELABO)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI SYNTHELABO RESEARCH DIV SANOFI SYNTHELABO INC (SANOFI SYN RES)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
UCB PHARMA INC (UCB PHARMA)	UCB INC (UCB INC)

1.3 AVAILABILITY OF THE EDITION

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements will not be available in a published paper version.

Since 1997, the Electronic Orange Book (EOB <http://www.fda.gov/cder/ob/default.htm>), has been available on the internet and has become the updated-every-month Orange Book.

The 25th 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.

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 (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

¹Amino 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 - 26TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2006

1-1

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL
BUTAPAP

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

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
@ CLONMEL

120MG/5ML;12MG/5ML N40098 001 Sep 20, 1996 Jan DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D>	AA	ENDO PHARMS	500MG;7.5MG	N40280	001	Sep 30, 1998	Feb	DISC
>A>		@	500MG;7.5MG	N40280	001	Sep 30, 1998	Feb	DISC
>D>	AA		650MG;7.5MG	N40280	002	Sep 30, 1998	Feb	DISC
>A>		@	650MG;7.5MG	N40280	002	Sep 30, 1998	Feb	DISC
>D>	AA		650MG;10MG	N40280	003	Sep 30, 1998	Feb	DISC
>A>		@	650MG;10MG	N40280	003	Sep 30, 1998	Feb	DISC
>D>	AA		750MG;7.5MG	N40281	002	Sep 30, 1998	Feb	DISC
>A>		@	750MG;7.5MG	N40281	002	Sep 30, 1998	Feb	DISC
		MIKART	300MG;5MG	N40658	001	Jan 19, 2006	Jan	NEWA
AA		VINTAGE PHARMS	325MG;5MG	N40655	001	Jan 19, 2006	Jan	NEWA
AA			325MG;7.5MG	N40656	001	Jan 19, 2006	Jan	NEWA

ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION/DROPS; OTIC
HYDROCORTISONE AND ACETIC ACID

AT		VINTAGE	2%;1%	N40609	001	Feb 06, 2006	Jan	NEWA
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ALBUTEROL

AEROSOL, METERED; INHALATION
ALBUTEROL

>D>	AB	GENPHARM	0.09MG/INH	N73045	001	Aug 19, 1997	Feb	DISC
>A>		@	0.09MG/INH	N73045	001	Aug 19, 1997	Feb	DISC
>D>	AB	PLIVA	0.09MG/INH	N74072	001	Aug 01, 1996	Feb	DISC
>A>		@	0.09MG/INH	N74072	001	Aug 01, 1996	Feb	DISC

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

+	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
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INJECTABLE; IV (INFUSION)
INFUVITE ADULT

+	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
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ALPRAZOLAM

TABLET, EXTENDED RELEASE; ORAL

ALPRAZOLAM

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

XANAX XR

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

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

AMANTADINE HYDROCHLORIDE

>A>	AB	AMIDE PHARM	100MG	N77659 001	Feb 23, 2006	Feb	NEWA
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AMMONIUM LACTATE

CREAM; TOPICAL

AMMONIUM LACTATE

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

CAPSULE; ORAL

AMOXICILLIN

AB	AM ANTIBIOTICS	250MG	N62058 001		Jan	CAHN
AB		500MG	N62058 002		Jan	CAHN

FOR SUSPENSION; ORAL

AMOXICILLIN

AB	AM ANTIBIOTICS	125MG/5ML	N62059 001		Jan	CAHN
AB		250MG/5ML	N62059 002		Jan	CAHN

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

AMPICILLIN TRIHYDRATE

@ AM ANTIBIOTICS EQ 250MG BASE

N61602 001 Jan CAHN

@ EQ 500MG BASE

N61602 002 Jan CAHN

FOR SUSPENSION; ORAL

AMPICILLIN TRIHYDRATE

@ AM ANTIBIOTICS EQ 125MG BASE/5ML

N61601 001 Jan CAHN

@ EQ 250MG BASE/5ML

N61601 002 Jan CAHN

>A> ANIDULAFUNGIN

>A> INJECTABLE; IV (INFUSION)

>A> ERAXIS

>A>	+	VICURON	50MG/VIAL	N21632 001	Feb 17, 2006	Feb	NEWA
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ANISINDIONE

TABLET; ORAL

MIRADON

@ SCHERING 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

+	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
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INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE)

+	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
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ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL

BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE

>D>	AB	ENDO PHARMS	325MG;50MG;40MG;30MG	N75351 001	Mar 05, 1999	Feb	DISC
>A>		@	325MG;50MG;40MG;30MG	N75351 001	Mar 05, 1999	Feb	DISC

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL

>D>		PERCODAN-DEMI					
>D>	AA	+ ENDO PHARMS	325MG;2.25MG;0.19MG	N07337 005		Feb	DISC
>A>		@	325MG;2.25MG;0.19MG	N07337 005		Feb	DISC

>D> BACAMPICILLIN HYDROCHLORIDE

>D> FOR SUSPENSION; ORAL

>D>		SPECTROBID					
>D>		+ PFIZER	125MG/5ML	N50556 001	Mar 23, 1982	Feb	DISC
>A>		@	125MG/5ML	N50556 001	Mar 23, 1982	Feb	DISC

>D> TABLET; ORAL

>D>		SPECTROBID					
>D>		+ PFIZER	400MG	N50520 001		Feb	DISC
>A>		@	400MG	N50520 001		Feb	DISC

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL

BENAZEPRIL HYDROCHLORIDE

>A>	AB	APOTEX INC	5MG	N77128 001	Mar 08, 2006	Feb	NEWA
>A>	AB		10MG	N77128 002	Mar 08, 2006	Feb	NEWA
>A>	AB		20MG	N77128 003	Mar 08, 2006	Feb	NEWA
>A>	AB		40MG	N77128 004	Mar 08, 2006	Feb	NEWA
	AB	BIOKEY	5MG	N76820 001	Feb 03, 2006	Jan	NEWA
	AB		10MG	N76820 002	Feb 03, 2006	Jan	NEWA
	AB		20MG	N76820 003	Feb 03, 2006	Jan	NEWA
	AB		40MG	N76820 004	Feb 03, 2006	Jan	NEWA

BETAINE, ANHYDROUS

FOR SOLUTION; ORAL

CYSTADANE

>A>		+ JAZZ	1GM/SC00PFUL	N20576 001	Oct 25, 1996	Feb	CAHN
>D>		+ ORPHAN MEDCL	1GM/SC00PFUL	N20576 001	Oct 25, 1996	Feb	CAHN

BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE

OINTMENT; TOPICAL

TACLONEX

+	LEO PHARM PRODS	0.064%;0.005%	N21852 001	Jan 09, 2006	Jan	NEWA
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BRIMONIDINE TARTRATE

SOLUTION/DROPS; OPHTHALMIC

BRIMONIDINE TARTRATE

>A>	AT	AKORN	0.2%	N76439 001	Mar 14, 2006	Feb	NEWA
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BRINZOLAMIDE

SUSPENSION/DROPS; OPHTHALMIC

AZOPT

>D>	+	ALCON	1%	N20816 001	Apr 01, 1998	Feb	CAHN
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>A>	+		1%	N20816 001	Apr 01, 1998	Feb	CAHN
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BUMETANIDE

INJECTABLE; INJECTION

BUMETANIDE

>D>	AP	BEDFORD	0.25MG/ML	N74441 001	Jan 27, 1995	Feb	CRLD
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>A>	AP	+	0.25MG/ML	N74441 001	Jan 27, 1995	Feb	CRLD
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>D>		BUMEX					
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>D>	AP	+	ROCHE	0.25MG/ML	N18226 001	Feb 28, 1983	Feb	DISC
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>A>		@	0.25MG/ML	N18226 001	Feb 28, 1983	Feb	DISC
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BUPROPION HYDROCHLORIDE

TABLET; ORAL

BUPROPION HYDROCHLORIDE

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

INJECTABLE; INJECTION

BUSULFEX

+	PDL BIOPHARMA INC	6MG/ML	N20954 001	Feb 04, 1999	Jan	CAHN
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CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL

CAFERGOT

>D>	BR	+	NOVARTIS	100MG;2MG	N09000 002		Feb	DISC
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>A>		@	100MG;2MG	N09000 002			Feb	DISC
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MIGERGOT

>D>	BR		G AND W LABS	100MG;2MG	N86557 001	Oct 04, 1983	Feb	CRLD
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>A>		+		100MG;2MG	N86557 001	Oct 04, 1983	Feb	CRLD
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CALCIPOTRIENE

CREAM; TOPICAL

DOVONEX

>D>	+	BRISTOL MYERS SQUIBB	0.005%	N20554 001	Jul 22, 1996	Feb	CAHN
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>A>	+	LEO PHARM	0.005%	N20554 001	Jul 22, 1996	Feb	CAHN
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OINTMENT; TOPICAL

DOVONEX

>D>	+	BRISTOL MYERS SQUIBB	0.005%	N20273 001	Dec 29, 1993	Feb	CAHN
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>A>	+	LEO PHARM	0.005%	N20273 001	Dec 29, 1993	Feb	CAHN
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SOLUTION; TOPICAL

DOVONEX

>D>	+	BRISTOL MYERS SQUIBB	0.005%	N20611 001	Mar 03, 1997	Feb	CAHN
>A>	+	LEO PHARM	0.005%	N20611 001	Mar 03, 1997	Feb	CAHN

CALCITONIN, SALMON

INJECTABLE; INJECTION

MIACALCIN

	+	NOVARTIS	200 IU/ML	N17808 002	Mar 29, 1991	Jan	CTEC
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CALCITRIOL

INJECTABLE; INJECTION

CALCITRIOL

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

TABLET; ORAL

CAPTOPRIL

		@ CLONMEL HLTHCARE	12.5MG	N74423 001	Feb 13, 1996	Jan	DISC
		@	25MG	N74423 002	Feb 13, 1996	Jan	DISC
		@	50MG	N74423 003	Feb 13, 1996	Jan	DISC
		@	100MG	N74423 004	Feb 13, 1996	Jan	DISC
>D>	AB	ENDO LABS	12.5MG	N74418 001	Feb 13, 1996	Feb	DISC
>A>		@	12.5MG	N74418 001	Feb 13, 1996	Feb	DISC
>D>	AB		25MG	N74418 002	Feb 13, 1996	Feb	DISC
>A>		@	25MG	N74418 002	Feb 13, 1996	Feb	DISC
>D>	AB		50MG	N74418 003	Feb 13, 1996	Feb	DISC
>A>		@	50MG	N74418 003	Feb 13, 1996	Feb	DISC
>D>	AB		100MG	N74418 004	Feb 13, 1996	Feb	DISC
>A>		@	100MG	N74418 004	Feb 13, 1996	Feb	DISC

CAPTOPRIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL

CAPTOPRIL AND HYDROCHLOROTHIAZIDE

>D>	AB	ENDO LABS	25MG;15MG	N74788 001	Dec 29, 1997	Feb	DISC
>A>		@	25MG;15MG	N74788 001	Dec 29, 1997	Feb	DISC
>D>	AB		25MG;25MG	N74788 002	Dec 29, 1997	Feb	DISC
>A>		@	25MG;25MG	N74788 002	Dec 29, 1997	Feb	DISC
>D>	AB		50MG;15MG	N74788 004	Dec 29, 1997	Feb	DISC
>A>		@	50MG;15MG	N74788 004	Dec 29, 1997	Feb	DISC
>D>	AB		50MG;25MG	N74788 003	Dec 29, 1997	Feb	DISC
>A>		@	50MG;25MG	N74788 003	Dec 29, 1997	Feb	DISC

CARBOPLATIN

INJECTABLE; INJECTION

CARBOPLATIN

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

INJECTABLE; IV (INFUSION)

CARBOPLATIN

>D>	AP	AM PHARM	EQ 50MG/5ML (10MG/ML)	N77247 001	Oct 21, 2004	Feb	DISC
>A>		@	EQ 50MG/5ML (10MG/ML)	N77247 001	Oct 21, 2004	Feb	DISC
	AP		EQ 50MG/5ML (10MG/ML)	N77266 001	Feb 15, 2006	Jan	NEWA
>D>	AP		EQ 150MG/15ML (10MG/ML)	N77247 002	Oct 21, 2004	Feb	DISC

INJECTABLE; IV (INFUSION)

CARBOPLATIN

>A>	@ AM PHARM	EQ 150MG/15ML (10MG/ML)	N77247 002	Oct 21, 2004	Feb	DISC
AP		EQ 150MG/15ML (10MG/ML)	N77266 002	Feb 15, 2006	Jan	NEWA
AP		EQ 450MG/45ML (10MG/ML)	N77266 003	Feb 15, 2006	Jan	NEWA
AP		EQ 600MG/60ML (10MG/ML)	N77266 004	Feb 15, 2006	Jan	NEWA
AP	BEDFORD LABS	EQ 600MG/60ML (10MG/ML)	N77244 004	Jan 20, 2006	Jan	NEWA

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL

AB	TEVA PHARMS	EQ 500MG BASE	N65282 001	Jan 20, 2006	Jan	NEWA
AB	WESTWARD	EQ 500MG BASE	N65311 001	Feb 07, 2006	Jan	NEWA

DURICEF

@ WARNER CHILCOTT

EQ 500MG BASE	N50512 001		Jan	DISC
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FOR SUSPENSION; ORAL

CEFADROXIL

>D>	AB	RANBAXY	EQ 125MG BASE/5ML	N65115 001	Mar 26, 2003	Feb	CTEC
>A>			EQ 125MG BASE/5ML	N65115 001	Mar 26, 2003	Feb	CTEC
	AB	TEVA PHARMS	EQ 250MG BASE/5ML	N65278 001	Jan 20, 2006	Jan	NEWA
	AB		EQ 500MG BASE/5ML	N65278 002	Jan 20, 2006	Jan	NEWA

DURICEF

>D>	AB	WARNER CHILCOTT	EQ 125MG BASE/5ML	N50527 002		Feb	DISC
>A>		@	EQ 125MG BASE/5ML	N50527 002		Feb	DISC

TABLET; ORAL

CEFADROXIL

>D>	AB	IVAX PHARMS	EQ 1GM BASE	N62774 001	Apr 08, 1987	Feb	CRLD
>A>	AB	+	EQ 1GM BASE	N62774 001	Apr 08, 1987	Feb	CRLD

DURICEF

@ WARNER CHILCOTT

EQ 1GM BASE	N50528 001		Jan	DISC
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CEFOXITIN SODIUM

INJECTABLE; INJECTION

CEFOXITIN

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

>A> CEFOXITIN AND DEXTROSE IN DUPLEX CONTAINER

>A>	AP	B BRAUN	EQ 1GM BASE/VIAL	N65214 001	Mar 10, 2006	Feb	NEWA
>A>	AP		EQ 2GM BASE/VIAL	N65214 002	Mar 10, 2006	Feb	NEWA

CEFTRIAZONE SODIUM

INJECTABLE; IM-IV

CEFTRIAZONE

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

INJECTABLE; INJECTION

CEFTRIAZONE

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

CAPSULE; ORAL

CEPHALEXIN

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

CICLOPIROX

CREAM; TOPICAL

CICLOPIROX

>A>	AB	PERRIGO NEW YORK	0.77%	N77364 001	Mar 03, 2006	Feb	NEWA
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CIMETIDINE

TABLET; ORAL

CIMETIDINE

>D>	AB	ENDO PHARMS	200MG	N74281 001	May 17, 1994	Feb	DISC
>A>		@	200MG	N74281 001	May 17, 1994	Feb	DISC
>D>	AB		300MG	N74281 002	May 17, 1994	Feb	DISC
>A>		@	300MG	N74281 002	May 17, 1994	Feb	DISC
>D>	AB		400MG	N74281 003	May 17, 1994	Feb	DISC
>A>		@	400MG	N74281 003	May 17, 1994	Feb	DISC
>D>	AB		800MG	N74329 001	May 17, 1994	Feb	DISC
>A>		@	800MG	N74329 001	May 17, 1994	Feb	DISC

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

CIMETIDINE HYDROCHLORIDE

>D>	AP	ENDO PHARMS	EQ 300MG BASE/2ML	N74005 001	Aug 31, 1994	Feb	DISC
>A>		@	EQ 300MG BASE/2ML	N74005 001	Aug 31, 1994	Feb	DISC

SOLUTION; ORAL

CIMETIDINE HYDROCHLORIDE

>D>	AA	ENDO PHARMS	EQ 300MG BASE/5ML	N74251 001	Dec 22, 1994	Feb	DISC
>A>		@	EQ 300MG BASE/5ML	N74251 001	Dec 22, 1994	Feb	DISC

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL

CLINDAMYCIN PHOSPHATE

AT	ALTANA	EQ 1% BASE	N65254 001	Feb 14, 2006	Jan	NEWA
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CLOBETASOL PROPIONATE

SPRAY; TOPICAL

CLOBEX

>D>	+	DOW PHARM SCI	0.05%	N21835 001	Oct 27, 2005	Feb	CAHN
>A>	+	GALDERMA LABS LP	0.05%	N21835 001	Oct 27, 2005	Feb	CAHN

CLOPIDOGREL BISULFATE

TABLET; ORAL

CLOPIDOGREL BISULFATE

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

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETH VC W/ CODEINE

+ ALPHARMA US PHARMS 10MG/5ML;5MG/5ML;6.25MG/5ML N88764 001 Oct 31, 1984 Jan CTEC

PROMETHAZINE VC W/ CODEINE

@ MORTON GROVE 10MG/5ML;5MG/5ML;6.25MG/5ML N88896 001 Jan 04, 1985 Jan DISC

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE WITH CODEINE SYRUP

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

CROMOLYN SODIUM

SOLUTION, CONCENTRATE; ORAL

GASTROCROM

>A> + AZUR PHARMA 100MG/5ML N20479 001 Feb 29, 1996 Feb CAHN

>D> + UCB INC 100MG/5ML N20479 001 Feb 29, 1996 Feb CAHN

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

CYCLOBENZAPRINE HYDROCHLORIDE

AB AMIDE PHARM 5MG N77291 001 Feb 03, 2006 Jan NEWA

AB MYLAN 5MG N73144 002 Feb 03, 2006 Jan NEWA

AB SANDOZ 5MG N72854 002 Feb 03, 2006 Jan NEWA

AB WATSON LABS 5MG N71611 002 Feb 03, 2006 Jan NEWA

7.5MG N71611 003 Feb 03, 2006 Jan NEWA

FLEXERIL

AB MCNEIL CONS SPECLT 5MG N17821 001 Jan CFTG

DEMECLOCYCLINE HYDROCHLORIDE

TABLET; ORAL

DECLOMYCIN

>D> @ ESP PHARMA 75MG N50261 001 Feb CAHN

>D> AB 150MG N50261 002 Feb CAHN

>D> AB + 300MG N50261 003 Feb CAHN

>A> @ PROTEIN DESIGN LABS 75MG N50261 001 Feb CAHN

>A> AB 150MG N50261 002 Feb CAHN

>A> AB + 300MG N50261 003 Feb CAHN

DESLOMATADINE; PSEUDOEPHEDRINE SULFATE

>A> TABLET, EXTENDED RELEASE; ORAL

>A> CLARINEX-D 12 HOUR

>A> + SCHERING 2.5MG;120MG N21313 001 Feb 01, 2006 Feb NEWA

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION

DESMOPRESSIN ACETATE

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

DESMOPRESSIN ACETATE PRESERVATIVE FREE

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

TABLET; ORAL

DESMOPRESSIN ACETATE

>A> AB APOTEX 0.1MG N77414 001 Mar 07, 2006 Feb NEWA

>A> AB 0.2MG N77414 002 Mar 07, 2006 Feb NEWA

TABLET; ORALDESMOPRESSIN ACETATE

AB	TEVA PHARMS	0.1MG	N77122 001	Jan 25, 2006	Jan	NEWA
AB		0.2MG	N77122 002	Jan 25, 2006	Jan	NEWA

DESOGESTREL; ETHINYL ESTRADIOLTABLET; ORAL-28MIRCETTE

>A>	AB	+	DURAMED	0.15MG, N/A; 0.02MG, 0.01MG	N20713 001	Apr 22, 1998	Feb	CAHN
>A>	AB	+		0.15MG, N/A; 0.02MG, 0.01MG	N20713 001	Apr 22, 1998	Feb	CAHN
>D>	AB	+	ORGANON USA INC	0.15MG, N/A; 0.02MG, 0.01MG	N20713 001	Apr 22, 1998	Feb	CAHN
>D>	AB	+		0.15MG, N/A; 0.02MG, 0.01MG	N20713 001	Apr 22, 1998	Feb	CAHN

DEXTROAMPHETAMINE SULFATETABLET; ORALDEXTROAMPHETAMINE SULFATE

>D>	AA		ENDO PHARMS	5MG	N40299 001	May 13, 1999	Feb	DISC
>A>			@	5MG	N40299 001	May 13, 1999	Feb	DISC

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDESYRUP; ORALPROMETHAZINE DM

AA	VINTAGE	15MG/5ML; 6.25MG/5ML	N40649 001	Feb 14, 2006	Jan	NEWA
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DIFLORASONE DIACETATECREAM; TOPICALDIFLORASONE DIACETATE

BX	+	ALTANA	0.05%	N76263 001	Dec 20, 2002	Jan	CRLD
		FLORONE					
		@ PHARMACIA AND UPJOHN	0.05%	N17741 001		Jan	DISC
		FLORONE E					
		@ PHARMACIA AND UPJOHN	0.05%	N19259 001	Aug 28, 1985	Jan	DISC

OINTMENT; TOPICALDIFLORASONE DIACETATE

AB	+	TARO	0.05%	N75331 001	May 14, 1999	Jan	CRLD
		FLORONE					
		@ PHARMACIA AND UPJOHN	0.05%	N17994 001		Jan	DISC
		PSORCON					
		@ PHARMACIA AND UPJOHN	0.05%	N19260 001	Aug 28, 1985	Jan	DISC

DIGOXININJECTABLE; INJECTIONDIGOXIN

AP	SANDOZ	0.25MG/ML	N40481 001	Aug 21, 2003	Jan	CAHN
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DILTIAZEM HYDROCHLORIDECAPSULE, EXTENDED RELEASE; ORALDILTIAZEM

AB4	APOTEX INC	120MG	N76395 001	Feb 01, 2006	Jan	NEWA
AB4		180MG	N76395 002	Feb 01, 2006	Jan	NEWA
AB4		240MG	N76395 003	Feb 01, 2006	Jan	NEWA
AB4		300MG	N76395 004	Feb 01, 2006	Jan	NEWA
AB4		360MG	N76395 005	Feb 01, 2006	Jan	NEWA

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

@ IVAX PHARMS

EQ 100MG BASE

N70186 001 Nov 18, 1985 Jan DISC

@

EQ 150MG BASE

N70187 001 Nov 18, 1985 Jan DISC

@ SANDOZ

EQ 100MG BASE

N70470 001 Dec 10, 1985 Jan DISC

@

EQ 150MG BASE

N70471 001 Dec 10, 1985 Jan DISC

DOXYCYCLINE HYCLATE

TABLET; ORAL

DOXYCYCLINE HYCLATE

>A> AB

PAR PHARM

EQ 20MG BASE

N65287 001 Feb 28, 2006 Feb NEWA

ERYTHROMYCIN

SOLUTION; TOPICAL

A/T/S

>D> AT

AVENTIS PHARMS

2%

N62405 001 Nov 18, 1982 Feb CAHN

>A> AT

TARO PHARMS NORTH

2%

N62405 001 Nov 18, 1982 Feb CAHN

ESTRADIOL

GEL; TOPICAL

ESTROGEL

@ ASCEND

0.06%

N21166 001 Feb 09, 2004 Jan CAHN

GEL, METERED; TOPICAL

ESTROGEL

+ ASCEND

0.06%

N21166 002 Feb 09, 2004 Jan CAHN

ESTRADIOL HEMIHYDRATE

EMULSION; TOPICAL

ESTRASORB

>A>

+ ESPRIT PHARMA

0.25%

N21371 001 Oct 09, 2003 Feb CAHN

>D>

+ NOVAVAX

0.25%

N21371 001 Oct 09, 2003 Feb CAHN

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

LOESTRIN 24 FE

>A>

+ WARNER CHILCOTT

0.02MG;1MG

N21871 001 Feb 17, 2006 Feb NEWA

ETODOLAC

CAPSULE; ORAL

ETODOLAC

>D> AB

ENDO PHARMS

200MG

N74842 001 Jul 17, 1997 Feb DISC

>A>

@

200MG

N74842 001 Jul 17, 1997 Feb DISC

>D> AB

300MG

N74842 002 Jul 17, 1997 Feb DISC

>A>

@

300MG

N74842 002 Jul 17, 1997 Feb DISC

TABLET; ORAL

ETODOLAC

>D> AB

ENDO PHARMS

400MG

N74841 001 Jun 27, 1997 Feb DISC

>A>

@

400MG

N74841 001 Jun 27, 1997 Feb DISC

FENOFIBRATE

CAPSULE; ORAL

LIPOFEN

CIPHER

50MG

N21612 001 Jan 11, 2006 Jan NEWA

CAPSULE; ORAL

LIPOFEN

CIPHER

100MG

N21612 002 Jan 11, 2006 Jan NEWA

+

150MG

N21612 003 Jan 11, 2006 Jan NEWA

TABLET; ORAL

FENOFIBRATE

AB

+

TEVA

160MG

N76433 002 May 13, 2005 Jan CRLD

TRICOR

@ ABBOTT

54MG

N21203 001 Sep 04, 2001 Jan DISC

@

160MG

N21203 003 Sep 04, 2001 Jan DISC

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION

FENOLDOPAM MESYLATE

AP

SANDOZ

EQ 10MG BASE/ML

N77155 001 Feb 15, 2005 Jan CAHN

FENOPROFEN CALCIUM

TABLET; ORAL

FENOPROFEN CALCIUM

@ CLONMEL HLTHCARE

EQ 600MG BASE

N72326 001 Aug 17, 1988 Jan DISC

FLUCONAZOLE

TABLET; ORAL

FLUCONAZOLE

AB

GLENMARK PHARMA

50MG

N77253 001 Jan 25, 2006 Jan NEWA

AB

100MG

N77253 002 Jan 25, 2006 Jan NEWA

AB

150MG

N77253 003 Jan 25, 2006 Jan NEWA

AB

200MG

N77253 004 Jan 25, 2006 Jan NEWA

FLUMAZENIL

INJECTABLE; INJECTION

FLUMAZENIL

AP

SANDOZ

1MG/10ML (0.1MG/ML)

N77071 002 May 03, 2005 Jan CAHN

AP

0.5MG/5ML (0.1MG/ML)

N77071 001 May 03, 2005 Jan CAHN

FLUNISOLIDE

AEROSOL, METERED; INHALATION

AEROSPAN HFA

+

FOREST LABS

EQ 78UGM BASE/INH

N21247 001 Jan 27, 2006 Jan NEWA

FLUTICASONE PROPIONATE

OINTMENT; TOPICAL

FLUTICASONE PROPIONATE

>A>

AB

G AND W LABS

0.005%

N77168 001 Mar 03, 2006 Feb NEWA

SPRAY, METERED; NASAL

FLONASE

>D>

+

GLAXOSMITHKLINE

0.05MG/SPRAY

N20121 001 Oct 19, 1994 Feb CFTG

>A>

AB

+

FLONASE

0.05MG/SPRAY

N20121 001 Oct 19, 1994 Feb CFTG

>A>

FLUTICASONE PROPIONATE

>A>

AB

ROXANE

0.05MG/SPRAY

N76504 001 Feb 22, 2006 Feb NEWA

FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATE

>A>

AB

CARACO

25MG

N75900 001 Feb 23, 2006 Feb NEWA

TABLET; ORAL

FLUVOXAMINE MALEATE

>A>	AB	CARACO	50MG	N75900 002	Feb 23, 2006	Feb	NEWA
>A>	AB		100MG	N75900 003	Feb 23, 2006	Feb	NEWA

FOSCARNET SODIUM

INJECTABLE; INJECTION

FOSCARNET SODIUM

>A>	AP	HOSPIRA	2.4GM/100ML	N77174 001	May 31, 2005	Feb	CAHN
>D>	AP	PHARMAFORCE	2.4GM/100ML	N77174 001	May 31, 2005	Feb	CAHN

GABAPENTIN

CAPSULE; ORAL

GABAPENTIN

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

TABLET; ORAL

GABAPENTIN

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

GADOVERSETAMIDE

INJECTABLE; INJECTION

OPTIMARK

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

OPTIMARK IN PLASTIC CONTAINER

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

GLIMEPIRIDE

TABLET; ORAL

GLIMEPIRIDE

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

GLIPIZIDE

TABLET; ORAL

GLIPIZIDE

>D>	AB	ENDO PHARMS	5MG	N74378 001	Nov 28, 1994	Feb	DISC
>A>		@	5MG	N74378 001	Nov 28, 1994	Feb	DISC
>D>	AB		10MG	N74378 002	Nov 28, 1994	Feb	DISC
>A>		@	10MG	N74378 002	Nov 28, 1994	Feb	DISC

GLYBURIDE

TABLET; ORAL

DIABETA

>D>	BX	AVENTIS PHARMS	5MG	N17532 003	May 01, 1984	Feb	CRLD
>A>	BX +	SANOFI AVENTIS US	5MG	N17532 003	May 01, 1984	Feb	CRLD

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALOPERIDOL DECANOATE

AO	SANDOZ	EQ 50MG BASE/ML	N76463 001	Jun 24, 2005	Jan	CAHN
AO		EQ 100MG BASE/ML	N76463 002	Jun 24, 2005	Jan	CAHN

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALOPERIDOL

AP	SANDOZ	EQ 5MG BASE/ML	N76464 001	Sep 29, 2004	Jan	CAHN
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HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

APRESOLINE

>D>	AA +	NOVARTIS	10MG	N08303 004		Feb	DISC
>A>	@		10MG	N08303 004		Feb	DISC
>D>	AA +		25MG	N08303 001		Feb	DISC
>A>	@		25MG	N08303 001		Feb	DISC
>D>	AA +		50MG	N08303 002		Feb	DISC
>A>	@		50MG	N08303 002		Feb	DISC
>D>	AA +		100MG	N08303 005		Feb	DISC
>A>	@		100MG	N08303 005		Feb	DISC

HYDRALAZINE HYDROCHLORIDE

>D>	AA	PLIVA	10MG	N89097 001	Dec 18, 1985	Feb	CRLD
>A>	AA +		10MG	N89097 001	Dec 18, 1985	Feb	CRLD
>D>	AA		25MG	N88467 001	May 01, 1984	Feb	CRLD
>A>	AA +		25MG	N88467 001	May 01, 1984	Feb	CRLD
>D>	AA		50MG	N88468 001	May 01, 1984	Feb	CRLD
>A>	AA +		50MG	N88468 001	May 01, 1984	Feb	CRLD
>D>	AA		100MG	N89098 001	Dec 18, 1985	Feb	CRLD
>A>	AA +		100MG	N89098 001	Dec 18, 1985	Feb	CRLD

HYDROCHLOROTHIAZIDE; LISINAPRIL

TABLET; ORAL

LISINAPRIL AND HYDROCHLOROTHIAZIDE

>A>	AB	AUROBINDO	12.5MG;10MG	N77606 001	Mar 14, 2006	Feb	NEWA
>A>	AB		12.5MG;20MG	N77606 002	Mar 14, 2006	Feb	NEWA
>A>	AB		25MG;20MG	N77606 003	Mar 14, 2006	Feb	NEWA

IBANDRONATE SODIUM

INJECTABLE; INTRAVENOUS

BONIVA

+	ROCHE	EQ 3MG BASE/3ML	N21858 001	Jan 06, 2006	Jan	NEWA
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INSULIN RECOMBINANT HUMAN

POWDER; INHALATION

EXUBERA

	PFIZER	1MG/INH	N21868 001	Jan 27, 2006	Jan	NEWA
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POWDER; INHALATION

EXUBERA

+	PFIZER	3MG/INH	N21868 002	Jan 27, 2006	Jan	NEWA
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ISONIAZID

INJECTABLE; INJECTION

ISONIAZID

AP	SANDOZ	100MG/ML	N40648 001	Jul 05, 2005	Jan	CAHN
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KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

KETOROLAC TROMETHAMINE

AP	SANDOZ	15MG/ML	N76271 001	Oct 06, 2004	Jan	CAHN
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AP		30MG/ML	N76271 002	Oct 06, 2004	Jan	CAHN
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LANSOPRAZOLE; NAPROXEN

CAPSULE, DELAYED REL PELLETS, TABLET; ORAL

>D>	NAPRAPAC 250 (COPACKAGED)					
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>D>	TAP PHARM	15MG, N/A; N/A, 250MG	N21507 002	Nov 14, 2003	Feb	CTNA
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>D>	NAPRAPAC 375 (COPACKAGED)					
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>D>	TAP PHARM	15MG, N/A; N/A, 375MG	N21507 003	Nov 14, 2003	Feb	CTNA
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>D>	NAPRAPAC 500 (COPACKAGED)					
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>D>	+ TAP PHARM	15MG, N/A; N/A, 500MG	N21507 004	Nov 14, 2003	Feb	CTNA
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>A>	PREVACID NAPRAPAC 250 (COPACKAGED)					
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>A>	TAP PHARM	15MG, N/A; N/A, 250MG	N21507 002	Nov 14, 2003	Feb	CTNA
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>A>	PREVACID NAPRAPAC 375 (COPACKAGED)					
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>A>	TAP PHARM	15MG, N/A; N/A, 375MG	N21507 003	Nov 14, 2003	Feb	CTNA
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>A>	PREVACID NAPRAPAC 500 (COPACKAGED)					
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>A>	+ TAP PHARM	15MG, N/A; N/A, 500MG	N21507 004	Nov 14, 2003	Feb	CTNA
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LEVOBETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC

BETAXON

>D>	@ ALCON	EQ 0.5% BASE	N21114 001	Feb 23, 2000	Feb	CAHN
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>A>	@	EQ 0.5% BASE	N21114 001	Feb 23, 2000	Feb	CAHN
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LIDOCAINE HYDROCHLORIDE

JELLY; TOPICAL

ANESTACON

AT	+ POLYMEDICA	2%	N80429 001		Jan	CDFR
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LIDOCAINE; TETRACAINE

PATCH; TOPICAL

SYNERA

>A>	+ ENDO PHARMS	70MG; 70MG	N21623 001	Jun 23, 2005	Feb	CAHN
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>D>	+ ZARS	70MG; 70MG	N21623 001	Jun 23, 2005	Feb	CAHN
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LISINAPRIL

TABLET; ORAL

LISINAPRIL

>A>	AB AUROBINDO	2.5MG	N77622 001	Feb 22, 2006	Feb	NEWA
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>A>	AB	5MG	N77622 002	Feb 22, 2006	Feb	NEWA
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>A>	AB	10MG	N77622 003	Feb 22, 2006	Feb	NEWA
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>A>	AB	20MG	N77622 004	Feb 22, 2006	Feb	NEWA
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>A>	AB	30MG	N77622 005	Feb 22, 2006	Feb	NEWA
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		TABLET; ORAL							
		LISINOPRIL							
>A>	AB	AUROBINDO	40MG	N77622	006	Feb 22, 2006	Feb	NEWA	
		<u>LOVASTATIN; NIACIN</u>							
		TABLET, EXTENDED RELEASE; ORAL							
		ADVICOR							
>D>		@ KOS LIFE	20MG;750MG	N21249	002	Dec 17, 2001	Feb	CMFD	
>A>		+	20MG;750MG	N21249	002	Dec 17, 2001	Feb	CMFD	
		<u>LUBIPROSTONE</u>							
		CAPSULE; ORAL							
		AMITIZA							
		+ SUCAMPO PHARMS	24UGM	N21908	001	Jan 31, 2006	Jan	NEWA	
		<u>MEDROXYPROGESTERONE ACETATE</u>							
		INJECTABLE; SUBCUTANEOUS							
		DEPO-SUBQ PROVERA 104							
		+ PHARMACIA AND UPJOHN	104MG/0.65ML	N21583	001	Dec 17, 2004	Jan	CAHN	
		<u>MEGESTROL ACETATE</u>							
		SUSPENSION; ORAL							
		MEGESTROL ACETATE							
	AB	APOTEX	40MG/ML	N77404	001	Feb 16, 2006	Jan	NEWA	
		<u>MEPROBAMATE</u>							
		TABLET; ORAL							
		MEPROBAMATE							
		@ ROXANE	600MG	N84332	001		Jan	DISC	
		@ SANDOZ	200MG	N14547	002		Jan	DISC	
		@	400MG	N14547	001		Jan	DISC	
		@	400MG	N80655	001		Jan	DISC	
		@ SCHERER LABS	400MG	N83343	001		Jan	DISC	
		@ TABLICAPS	400MG	N83494	001		Jan	DISC	
	AA	+ WATSON LABS	200MG	N83304	001		Jan	CRLD	
		@	200MG	N85720	001		Jan	DISC	
		+	400MG	N83308	001		Jan	CRLD	
		@	400MG	N85721	001		Jan	DISC	
		MILTOWN							
		@ MEDPOINTE PHARM HLC	200MG	N09698	004		Jan	DISC	
		@	400MG	N09698	002		Jan	DISC	
		TRANMEP							
		@ SOLVAY	400MG	N16249	001		Jan	DISC	
		<u>METFORMIN HYDROCHLORIDE</u>							
		TABLET, EXTENDED RELEASE; ORAL							
		GLUMETZA							
	BX	DEPOMED INC	500MG	N21748	001	Jun 03, 2005	Jan	CAHN	
	BX		1GM	N21748	002	Jun 03, 2005	Jan	CAHN	
		METFORMIN HYDROCHLORIDE							
	AB	SUN PHARM INDS (IN)	500MG	N77336	001	Feb 09, 2006	Jan	NEWA	
	AB		750MG	N77336	002	Feb 09, 2006	Jan	NEWA	

METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

METADATE CD

>A>	BX	UCB INC	40MG	N21259 004	Feb 19, 2006	Feb	NEWA
>A>			50MG	N21259 005	Feb 19, 2006	Feb	NEWA
>A>		+	60MG	N21259 006	Feb 19, 2006	Feb	NEWA
		RITALIN LA					
>D>		+	NOVARTIS	40MG	N21284 003	Jun 05, 2002	Feb CTEC
>A>	BX	+	40MG	N21284 003	Jun 05, 2002	Feb	CTEC

MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE

>A>		OINTMENT; TOPICAL					
>A>		VUSION					
>A>		+	BARRIER	0.25%;81.35%;15%	N21026 001	Feb 16, 2006	Feb NEWA

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCIN

>A>	AB	TRIAx PHARMS	EQ 50MG BASE	N50649 001	May 31, 1990	Feb	CAHN
>A>		@	EQ 75MG BASE	N50649 003	Feb 12, 2001	Feb	CAHN
>A>	AB	+	EQ 100MG BASE	N50649 002	May 31, 1990	Feb	CAHN
>D>	AB	WYETH PHARMS INC	EQ 50MG BASE	N50649 001	May 31, 1990	Feb	CAHN
>D>		@	EQ 75MG BASE	N50649 003	Feb 12, 2001	Feb	CAHN
>D>	AB	+	EQ 100MG BASE	N50649 002	May 31, 1990	Feb	CAHN

MIRTAZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL

MIRTAZAPINE

>A>	AB	AUROBINDO PHARMA LTD	45MG	N77376 004	Feb 28, 2006	Feb	NEWA
>A>	AB	BARR	45MG	N76307 003	Feb 28, 2006	Feb	NEWA

MOMETASONE FUROATE

LOTION; TOPICAL

MOMETASONE FUROATE

>A>	AB	TARO	0.1%	N76788 001	Mar 15, 2006	Feb	NEWA
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NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION; IRRIGATION

NEOSPORIN AND POLYMYXIN B SULFATE

AT		X GEN PHARMS	EQ 40MG BASE/ML;200,000 UNITS/ML	N65106 001	Jan 31, 2006	Jan	NEWA
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					
AT	+	MONARCH PHARMS	EQ 40MG BASE/ML;200,000 UNITS/ML	N60707 001		Jan	CTEC
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

	+	PDL BIOPHARMA INC	2.5MG/ML	N19734 001	Jan 30, 1992	Jan	CAHN
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NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

AFEDITAB CR

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

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

OCTREOTIDE ACETATE

AP	AM PHARM	EQ 0.2MG BASE/ML	N77450 001	Feb 10, 2006	Jan	NEWA
AP		EQ 1MG BASE/ML	N77450 002	Feb 10, 2006	Jan	NEWA

OCTREOTIDE ACETATE (PRESERVATIVE FREE)

AP	AM PHARM	EQ 0.05MG BASE/ML	N77457 001	Feb 10, 2006	Jan	NEWA
AP		EQ 0.1MG BASE/ML	N77457 002	Feb 10, 2006	Jan	NEWA
AP		EQ 0.5MG BASE/ML	N77457 003	Feb 10, 2006	Jan	NEWA

OFLOXACIN

TABLET; ORAL

OFLOXACIN

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

>D> OMEPRAZOLE

>D> FOR SUSPENSION; ORAL

>D> ZEGERID

>D>	+	SANTARUS	20MG/PACKET	N21636 001	Jun 15, 2004	Feb	CAIN
>D>	+		40MG/PACKET	N21706 001	Dec 21, 2004	Feb	CAIN

OMEPRAZOLE; SODIUM BICARBONATE

>A> CAPSULE; ORAL

>A> ZEGERID

>A>		SANTARUS	20MG;1.1GM	N21849 001	Feb 27, 2006	Feb	NEWA
>A>	+		40MG;1.1GM	N21849 002	Feb 27, 2006	Feb	NEWA

>A> FOR SUSPENSION; ORAL

>A> ZEGERID

>A>		SANTARUS	20MG/PACKET;1.68GM/PACKET	N21636 001	Jun 15, 2004	Feb	CAIN
>A>	+		40MG/PACKET;1.68GM/PACKET	N21706 001	Dec 21, 2004	Feb	CAIN

PENICILLIN V POTASSIUM

FOR SOLUTION; ORAL

PENICILLIN V POTASSIUM

AA	AM ANTIBIOTICS	EQ 125MG BASE/5ML	N61529 001		Jan	CAHN
AA		EQ 250MG BASE/5ML	N61529 002		Jan	CAHN

TABLET; ORAL

PENICILLIN V POTASSIUM

@ AM ANTIBIOTICS

@

EQ 250MG BASE	N61528 001		Jan	CAHN
EQ 500MG BASE	N61528 002		Jan	CAHN

PERGOLIDE MESYLATE

TABLET; ORAL

PERMAX

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

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETH VC PLAIN

+	ALPHARMA US PHARMS	5MG/5ML;6.25MG/5ML	N88761 001	Nov 08, 1984	Jan	CTEC
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PROMETHAZINE VC PLAIN

@	MORTON GROVE	5MG/5ML;6.25MG/5ML	N88897 001	Jan 04, 1985	Jan	DISC
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PHYTONADIONE

INJECTABLE; INJECTION

>D> AQUAMEPHYTON

>D>	BP	+	MERCK	1MG/0.5ML	N12223 002	Feb	DISC
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>A>			@	1MG/0.5ML	N12223 002	Feb	DISC
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>D>	BP	+		10MG/ML	N12223 001	Feb	DISC
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>A>			@	10MG/ML	N12223 001	Feb	DISC
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VITAMIN K1

>D>	BP		HOSPIRA	1MG/0.5ML	N87954 001	Jul 25, 1983	Feb	CRLD
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>A>	BP	+		1MG/0.5ML	N87954 001	Jul 25, 1983	Feb	CRLD
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>D>	BP			10MG/ML	N87955 001	Jul 25, 1983	Feb	CRLD
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>A>		+		10MG/ML	N87955 001	Jul 25, 1983	Feb	CRLD
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POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

KLOR-CON

AB			UPSHER SMITH	8MEQ	N19123 001	Apr 17, 1986	Jan	CRLD
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POTASSIUM CHLORIDE

AB	+		COPLEY PHARM	8MEQ	N70618 001	Sep 09, 1987	Jan	CRLD
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PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HYDROCHLORIDE

@	CLONMEL HLTHCARE	EQ 1MG BASE	N72705 001	May 16, 1989	Jan	DISC
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@		EQ 5MG BASE	N72707 001	May 16, 1989	Jan	DISC
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PROMETHAZINE HYDROCHLORIDE

SUPPOSITORY; RECTAL

PROMETHEGAN

+	G AND W LABS	50MG	N87165 001	Aug 14, 1987	Jan	CRLD
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PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

PROPRANOLOL HYDROCHLORIDE

AP			SANDOZ	1MG/ML	N76400 001	Feb 26, 2003	Jan	CAHN
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PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

REGONOL

AP			SANDOZ	5MG/ML	N17398 001		Jan	CAHN
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QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

QUINAPRIL HYDROCHLORIDE

AB			TORPHARM	EQ 5MG BASE	N76240 001	Jan 26, 2006	Jan	NEWA
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AB				EQ 10MG BASE	N76240 002	Jan 26, 2006	Jan	NEWA
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AB				EQ 20MG BASE	N76240 003	Jan 26, 2006	Jan	NEWA
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TABLET; ORAL

QUINAPRIL HYDROCHLORIDE

AB	TORPHARM	EQ 40MG BASE	N76240 004	Jan 26, 2006	Jan	NEWA
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QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL

QUINIDINE GLUCONATE

BX	+	MUTUAL PHARM	324MG	N89338 001	Feb 11, 1987	Jan	CTEC
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BX		WATSON LABS	324MG	N87810 001	Sep 29, 1982	Jan	CMFD
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QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

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

INJECTABLE; INJECTION

RANITIDINE

>A>							
>A>	AP	BEDFORD	EQ 25MG BASE/ML	N77458 001	Feb 16, 2006	Feb	NEWA

RANOLAZINE

TABLET, EXTENDED RELEASE; ORAL

RANEXA

	+	CV THERAP	500MG	N21526 002	Jan 27, 2006	Jan	NEWA
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>A> SELEGILINE HYDROCHLORIDE

>A> FILM, EXTENDED RELEASE; TRANSDERMAL

>A> EMSAM

>A>		SOMERSET	6MG/24HR	N21336 001	Feb 27, 2006	Feb	NEWA
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>A>			9MG/24HR	N21336 002	Feb 27, 2006	Feb	NEWA
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>A>	+		12MG/24HR	N21336 003	Feb 27, 2006	Feb	NEWA
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SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE

>A>	AB	PUREPAC PHARM	25MG	N40353 003	Mar 15, 2006	Feb	NEWA
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SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION

ANECTINE

AP	+	SANDOZ	20MG/ML	N08453 002		Jan	CAHN
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	@		50MG/ML	N08453 003		Jan	CAHN
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	@		500MG/VIAL	N08453 001		Jan	CAHN
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	@		1GM/VIAL	N08453 004		Jan	CAHN
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SUMATRIPTAN SUCCINATE

>D>	INJECTABLE; INJECTION						
>D>	IMITREX						
>D>	+ GLAXOSMITHKLINE	EQ 6MG BASE/0.5ML	N20080	001	Dec 28, 1992	Feb	CDFR
>A>	INJECTABLE; SUBCUTANEOUS						
>A>	IMITREX						
>A>	+ GLAXOSMITHKLINE	EQ 6MG BASE/0.5ML (12MG/ML)	N20080	001	Dec 28, 1992	Feb	CDFR
>A>	IMITREX STATDOSE						
>A>	+ GLAXOSMITHKLINE	EQ 4MG BASE/0.5ML (8MG/ML)	N20080	002	Feb 01, 2006	Feb	NEWA
>A>	+	EQ 6MG BASE/0.5ML (12MG/ML)	N20080	003	Dec 23, 1996	Feb	NEWA

SUNITINIB MALATE

CAPSULE; ORAL

SUTENT

PFIZER

12.5MG

N21938 001 Jan 26, 2006 Jan NEWA

25MG

N21938 002 Jan 26, 2006 Jan NEWA

+

50MG

N21938 003 Jan 26, 2006 Jan NEWA

TESTOSTERONE

GEL; TRANSDERMAL

ANDROGEL

AB + UNIMED PHARMS 1%

N21015 001 Feb 28, 2000 Jan CTEC

TESTOSTERONE

AB WATSON LABS 1%

N76737 001 Jan 27, 2006 Jan NEWA

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

DELATESTRYL

@ INDEVUS PHARMS

200MG/ML

N09165 001

Jan CAHN

AO + 200MG/ML

N09165 003

Jan CAHN

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION

THALLOUS CHLORIDE TL 201

>D> AP MOUNT SINAI MEDCTR 1mCi/ML

N75569 001 Nov 21, 2001 Feb CAHN

>A> AP TRACE RADIOCHEMICALS 1mCi/ML

N75569 001 Nov 21, 2001 Feb CAHN

TINIDAZOLE

TABLET; ORAL

TINDAMAX

MISSION PHARMA

250MG

N21618 001 May 17, 2004 Jan CAHN

+

500MG

N21618 002 May 17, 2004 Jan CAHN

TRAMADOL HYDROCHLORIDE

TABLET; ORAL

TRAMADOL HYDROCHLORIDE

@ IVAX PHARMS

50MG

N75963 001 Jul 03, 2002 Jan DISC

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION

ARISTOCORT

@ SANDOZ

25MG/ML

N11685 003

Jan CAHN

@

40MG/ML

N12802 001

Jan CAHN

TRIAMCINOLONE HEXACETONIDE

INJECTABLE; INJECTION

ARISTOSPAN

+	SANDOZ	5MG/ML
+		20MG/ML

N16466 001

Jan CAHN

N16466 002

Jan CAHN

TRIPLENNAMINE HYDROCHLORIDE

TABLET; ORAL

PBZ

@ NOVARTIS 50MG

N05914 002

Jan DISC

UNOPROSTONE ISOPROPYL

SOLUTION/DROPS; OPHTHALMIC

RESCULA

>D> + NOVARTIS 0.15%

N21214 001 Aug 03, 2000 Feb CAHN

>A> + R TECH UENO LTD 0.15%

N21214 001 Aug 03, 2000 Feb CAHN

VECURONIUM BROMIDE

INJECTABLE; INJECTION

VECURONIUM BROMIDE

AP + BEDFORD 20MG/VIAL

N75549 002 Jun 13, 2000 Jan CRLD

ZONISAMIDE

CAPSULE; ORAL

ZONISAMIDE

AB GLENMARK PHARMS 25MG

N77651 001 Jan 30, 2006 Jan NEWA

AB 50MG

N77651 002 Jan 30, 2006 Jan NEWA

AB 100MG

N77651 003 Jan 30, 2006 Jan NEWA

OTC DRUG PRODUCT LIST - 26TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2006

2-1

CROMOLYN SODIUM

SPRAY, METERED; NASAL

CROMOLYN SODIUM

ALPHARMA US PHARMS	5.2MG/SPRAY	N74800	001	Jul 26, 2001	Jan	CPOT
+ BAUSCH AND LOMB	5.2MG/SPRAY	N75702	001	Jul 03, 2001	Jan	CRLD
NASALCROM						
@ PHARMACIA UPJOHN	5.2MG/SPRAY	N20463	001	Jan 03, 1997	Jan	DISC

KETOPROFEN

TABLET; ORAL

>D>	ACTRON					
>D>	BAYER	12.5MG	N20499	001	Oct 06, 1995	Feb DISC
>A>	@	12.5MG	N20499	001	Oct 06, 1995	Feb DISC
>D>	ORUDIS KT					
>D>	+ WYETH CONS	12.5MG	N20429	001	Oct 06, 1995	Feb DISC
>A>	@	12.5MG	N20429	001	Oct 06, 1995	Feb DISC

LORATADINE

TABLET; ORAL

LORATADINE

APOTEX	10MG	N76471	001	Feb 14, 2006	Jan	NEWA
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MINOXIDIL

AEROSOL, FOAM; TOPICAL

MEN'S ROGAINE

+ PHARMACIA AND UPJOHN	5%	N21812	001	Jan 20, 2006	Jan	NEWA
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NAPROXEN SODIUM

>A>	CAPSULE; ORAL					
>A>	NAPROXEN SODIUM					
>A>	+ BANNER PHARMACAPS	EQ 200MG BASE	N21920	001	Feb 17, 2006	Feb NEWA

NICOTINE POLACRILEX

TROCHE/LOZENGE; ORAL

NICOTINE POLACRILEX

PERRIGO R AND D	EQ 2MG BASE	N77007	001	Jan 31, 2006	Jan	NEWA
	EQ 4MG BASE	N77007	002	Jan 31, 2006	Jan	NEWA

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE

>A>	WOCKHARDT	EQ 75MG BASE	N76760	001	Feb 24, 2006	Feb NEWA
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**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT
ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

CUMULATIVE SUPPLEMENT NUMBER 02 FEBRUARY 2006

NO FEBRUARY 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 FEBRUARY 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>ABACAVIR SULFATE; LAMIVUDINE - EPZICOM</u>					
021652 001	>A> 5034394	Dec 18, 2011	DS DP	>A> D-40	Aug 02, 2007
	>A> 5034394*PED	Jun 18, 2012			
	>A> 5047407	Nov 17, 2009	DS DP	U-257	
	>A> 5047407*PED	May 17, 2010			
	>A> 5089500	Jun 26, 2009		U-257	
	>A> 5089500*PED	Dec 26, 2009			
	>A> 5905082	May 18, 2016	DS DP		
	>A> 5905082*PED	Nov 18, 2016			
	>A> 6294540	May 14, 2018	DS DP	U-257	
	>A> 6294540*PED	Nov 14, 2018			
<u>ALBUTEROL SULFATE - PROAIR HFA</u>					
021457 001				>A> I-235	Feb 03, 2009
<u>ALENDRONATE SODIUM; CHOLECALCIFEROL - FOSAMAX PLUS D</u>					
021762 001				NC	Apr 07, 2008
<u>ALFUZOSIN HYDROCHLORIDE - UROXATRAL</u>					
021287 001	>A> 4661491	May 27, 2007		U-706	
<u>ANIDULAFUNGIN - ERAXIS</u>					
021632 001				>A> NCE	Feb 17, 2011
<u>APREPITANT - EMEND</u>					
021549 001	5145684	Jan 25, 2011	DP		
<u>APREPITANT - EMEND</u>					
021549 002	5145684	Jan 25, 2011	DP		
<u>ARIPIRAZOLE - ABILIFY</u>					
021436 001				>A> I-488	Mar 01, 2008
<u>ARIPIRAZOLE - ABILIFY</u>					
021436 002				>A> I-488	Mar 01, 2008
<u>ARIPIRAZOLE - ABILIFY</u>					
021436 003				>A> I-488	Mar 01, 2008
<u>ARIPIRAZOLE - ABILIFY</u>					
021436 004				>A> I-488	Mar 01, 2008
<u>ARIPIRAZOLE - ABILIFY</u>					
021436 005				>A> I-488	Mar 01, 2008
<u>ARIPIRAZOLE - ABILIFY</u>					
021436 006				>A> I-488	Mar 01, 2008
<u>ARIPIRAZOLE - ABILIFY</u>					
021713 001	6977257	Apr 24, 2022	DS DP	>A> I-488	Mar 01, 2008
<u>AZELASTINE HYDROCHLORIDE - ASTELIN</u>					
020114 001				>A> D-102	Feb 17, 2007
<u>BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE - TACLONEX</u>					
021852 001	>A> 4866048	Dec 29, 2007	DS DP	U-88	
	>A> 4866048	Dec 29, 2007	DS DP	U-193	
	>A> 5763426	Jun 09, 2015	DS DP		
	>A> 6753013	Jan 27, 2020	DP	U-88	
	>A> 6753013	Jan 27, 2020	DP	U-193	
<u>BIVALIRUDIN - ANGIOMAX</u>					
020873 001				I-486	Nov 30, 2008
<u>BORTEZOMIB - VELCADE</u>					
021602 001				ODE	Mar 25, 2012
<u>BRIMONIDINE TARTRATE - ALPHAGAN P</u>					
021770 001	5424078	Jun 13, 2012	DP		
	5424078*PED	Dec 13, 2012			
	6562873	Jul 10, 2021	DP		
	6562873*PED	Jan 10, 2022			
	6627210	Jul 18, 2021	DP		
	6627210*PED	Jan 18, 2022			
	6641834	Jul 28, 2021	DP		
	6641834*PED	Jan 28, 2022			
	6673337	Jul 26, 2021	DP		
	6673337*PED	Jan 26, 2022			

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>BROMFENAC SODIUM - XIBROM</u>					
021664 001				I-485	Jan 27, 2009
<u>BUDESONIDE - PULMICORT RESPULES</u>					
020929 001	>A> 6899099	Dec 23, 2018	U-645		
	>A> 6899099*PED	Jun 23, 2019			
<u>BUDESONIDE - PULMICORT RESPULES</u>					
020929 002	>A> 6899099	Dec 23, 2018	U-645		
	>A> 6899099*PED	Jun 23, 2019			
<u>BUDESONIDE - RHINOCORT</u>					
020746 001	>A> 6986904	Apr 29, 2017	DP U-699		
<u>BUDESONIDE - RHINOCORT</u>					
020746 002	>A> 6986904	Apr 29, 2017	DP U-699		
<u>CALCIUM CARBONATE; RISEDRONATE SODIUM - ACTONEL WITH CALCIUM (COPACKAGED)</u>					
021823 001				M-52	Jan 24, 2009
<u>CEFDITOREN PIVOXIL - SPECTRACEF</u>					
021222 001	>A> 4839350	Jan 14, 2009	DS DP		
<u>CONIVAPTAN HYDROCHLORIDE - VAPRISOL</u>					
021697 001	5723606	Mar 03, 2015	DS DP U-698		
<u>DESFLURANE - SUPRANE</u>					
020118 001	5617906	Apr 08, 2014	DP		
<u>DESLOMATADINE; PSEUDOEPHEDRINE SULFATE - CLARINEX D 24 HOUR</u>					
021605 001	6979463	Mar 28, 2022	DP		
<u>DESLOMATADINE; PSEUDOEPHEDRINE SULFATE - CLARINEX-D 12 HOUR</u>					
021313 001				>A> NCE >A> NC >A> PED	Dec 21, 2006 Mar 03, 2008 Jun 21, 2007
<u>DOCETAXEL - TAXOTERE</u>					
020449 001	>A> 5750561	Jul 03, 2012	DP		
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>					
021153 001				I-484	Nov 24, 2007
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>					
021153 002				I-484	Nov 24, 2007
<u>ETHINYL ESTRADIOL; NORELGESTROMIN - ORTHO EVRA</u>					
021180 001	>A> 5876746	Nov 20, 2015	DP U-514		
<u>ETHINYL ESTRADIOL; NORETHINDRONE ACETATE - LOESTRIN 24 FE</u>					
021871 001				>A> NP	Feb 17, 2009
<u>FENOFIBRATE - FENOFIBRATE</u>					
076433 001				PC	May 22, 2006
<u>FENOFIBRATE - FENOFIBRATE</u>					
076433 002				PC	May 22, 2006
<u>FENOFIBRATE - LIPOFEN</u>					
021612 001	>A> 5545628	Jan 10, 2015	U-701		
<u>FENOFIBRATE - LIPOFEN</u>					
021612 002	>A> 5545628	Jan 10, 2015	U-701		
<u>FENOFIBRATE - LIPOFEN</u>					
021612 003	>A> 5545628	Jan 10, 2015	U-701		
<u>FLUNISOLIDE - AEROSPAN HFA</u>					
021247 001				NP	Jan 27, 2009
<u>FLUOCINOLONE ACETONIDE - RETISERT</u>					
021737 001	>A> 6217895	Mar 22, 2019	DP		
	>A> 6548078	Mar 22, 2019	DP		
<u>FLUOCINONIDE - VANOS</u>					
021758 001				>A> I-487	Mar 02, 2009
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>					
021433 001				>A> NPP	Feb 28, 2009
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>					
021433 002				>A> NPP	Feb 28, 2009

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>FLUTICASONE PROPIONATE - FLOVENT HFA</u>					
021433 003				>A> NPP	Feb 28, 2009
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u>					
021077 001	>A> 4992474	Feb 12, 2008	U-211		
	>A> 4992474*PED	Aug 12, 2008	U-211		
	>A> 5126375	Feb 12, 2008			
	>A> 5126375*PED	Aug 12, 2008			
	>A> 5225445	Feb 12, 2008	U-211		
	>A> 5225445*PED	Aug 12, 2008	U-211		
	>A> 6536427	Mar 01, 2011	DP		
	>A> 6536427*PED	Sep 01, 2011			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u>					
021077 002	>A> 4992474	Feb 12, 2008	U-211		
	>A> 4992474*PED	Aug 12, 2008	U-211		
	>A> 5126375	Feb 12, 2008			
	>A> 5126375*PED	Aug 12, 2008			
	>A> 5225445	Feb 12, 2008	U-211		
	>A> 5225445*PED	Aug 12, 2008	U-211		
	>A> 6536427	Mar 01, 2011	DP		
	>A> 6536427*PED	Sep 01, 2011			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u>					
021077 003	>A> 4992474	Feb 12, 2008	U-211		
	>A> 4992474*PED	Aug 12, 2008	U-211		
	>A> 5126375	Feb 12, 2008			
	>A> 5126375*PED	Aug 12, 2008			
	>A> 5225445	Feb 12, 2008	U-211		
	>A> 5225445*PED	Aug 12, 2008	U-211		
	>A> 6536427	Mar 01, 2011	DP		
	>A> 6536427*PED	Sep 01, 2011			
<u>FULVESTRANT - FASLODEX</u>					
021344 001	4659516	Oct 01, 2006			
<u>GLIMEPIRIDE - AMARYL</u>					
020496 001				>A> M-54 >A> PED	Nov 28, 2008 May 28, 2009
<u>GLIMEPIRIDE - AMARYL</u>					
020496 002				>A> M-54 >A> PED	Nov 28, 2008 May 28, 2009
<u>GLIMEPIRIDE - AMARYL</u>					
020496 003				>A> M-54 >A> PED	Nov 28, 2008 May 28, 2009
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 001	5002953	Sep 17, 2011	DS DP U-690		
	5002953*PED	Mar 17, 2012			
	5741803	Apr 21, 2015	DS DP U-690		
	5741803*PED	Oct 21, 2015			
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 002	5002953	Sep 17, 2011	DS DP U-690		
	5002953*PED	Mar 17, 2012			
	5741803	Apr 21, 2015	DS DP U-690		
	5741803*PED	Oct 21, 2015			
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 003	5002953	Sep 17, 2011	DS DP U-690		
	5002953*PED	Mar 17, 2012			
	5741803	Apr 21, 2015	DS DP U-690		
	5741803*PED	Oct 21, 2015			
<u>HYALURONIDASE RECOMBINANT HUMAN - HYLENEX RECOMBINANT</u>					
021859 001				NCE	Dec 02, 2010
<u>IBANDRONATE SODIUM - BONIVA</u>					
021455 001	4927814	Jul 09, 2007	DS DP U-642		
	6143326	Apr 21, 2017	U-642		
<u>IBANDRONATE SODIUM - BONIVA</u>					
021858 001	>A> 4927814	Jul 09, 2007	DS DP U-700	NDF NCE	Jan 06, 2009 May 16, 2008

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>INSULIN DETEMIR RECOMBINANT - LEVEMIR</u>					
021536 001				>A> I-489	Oct 19, 2008
<u>INSULIN RECOMBINANT HUMAN - EXUBERA</u>					
021868 001	>A> 5740794	Apr 21, 2015	DP		
	>A> 5997848	Mar 07, 2014		U-704	
	>A> 6051256	Mar 07, 2014	DP		
	>A> 6257233	May 14, 2019		U-704	
	>A> 6423344	Mar 07, 2014	DP		
	>A> 6543448	Sep 21, 2014	DP		
	>A> 6546929	May 14, 2019		U-704	
	>A> 6582728	Jun 24, 2020	DP		
	>A> 6592904	Mar 07, 2014	DP		
	>A> 6685967	Sep 11, 2018	DP		
	>A> 6737045	Mar 07, 2014		U-704	
	>A> RE37872	Feb 12, 2010	DP		
	>A> RE38385	Feb 12, 2010	DP		
<u>INSULIN RECOMBINANT HUMAN - EXUBERA</u>					
021868 002	>A> 5740794	Apr 21, 2015	DP		
	>A> 5997848	Mar 07, 2014		U-704	
	>A> 6051256	Mar 07, 2014	DP		
	>A> 6257233	May 14, 2019		U-704	
	>A> 6423344	Mar 07, 2014	DP		
	>A> 6543448	Sep 21, 2014	DP		
	>A> 6546929	May 14, 2019		U-704	
	>A> 6582728	Jun 24, 2020	DP		
	>A> 6592904	Mar 07, 2014	DP		
	>A> 6685967	Sep 11, 2018	DP		
	>A> 6737045	Mar 07, 2014		U-704	
	>A> RE37872	Feb 12, 2010	DP		
	>A> RE38385	Feb 12, 2010	DP		
<u>IPRATROPIUM BROMIDE - ATROVENT HFA</u>					
021527 001	6983743	May 26, 2020	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
020406 001	6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
020406 002	6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021281 001	6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021281 002	6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021428 001	6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021428 002	6749864	Feb 13, 2007	DP		
<u>LANTHANUM CARBONATE - FOSRENOL</u>					
021468 003	5968976	Mar 19, 2016	DP	U-613	
<u>LANTHANUM CARBONATE - FOSRENOL</u>					
021468 004	5968976	Mar 19, 2016	DP	U-613	
<u>LENALIDOMIDE - REVLIMID</u>					
021880 001	5635517	Jul 24, 2016	DS		
	6045501	Aug 28, 2018		U-694	
	6315720	Oct 23, 2020		U-694	
	6555554	Jul 24, 2016			
	6561976	Aug 28, 2018	DP	U-694	
	6561977	Oct 23, 2020		U-694	
	6755784	Oct 23, 2020		U-694	
	6908432	Aug 28, 2018		U-694	
				ODE	Dec 27, 2012

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>LENALIDOMIDE - REVLIMID</u>					
021880 002	5635517	Jul 24, 2016	DS	ODE	Dec 27, 2012
	6045501	Aug 28, 2018		U-694	
	6315720	Oct 23, 2020		U-694	
	6555554	Jul 24, 2016	DP		
	6561976	Aug 28, 2018		U-694	
	6561977	Oct 23, 2020		U-694	
	6755784	Oct 23, 2020		U-694	
	6908432	Aug 28, 2018		U-694	
<u>LIDOCAINE; TETRACAINE - SYNERA</u>					
021623 001				>A> NC	Jun 23, 2009
<u>LOPINAVIR; RITONAVIR - KALETRA</u>					
021906 001	5541206	Jul 30, 2013	DS DP	U-688	
	5541206*PED	Jan 30, 2014			
	5635523	Jun 03, 2014		U-688	
	5635523*PED	Dec 03, 2014			
	5648497	Jul 15, 2014	DS DP		
	5648497*PED	Jan 15, 2015			
	5674882	Oct 07, 2014		U-688	
	5674882*PED	Apr 07, 2015			
	5846987	Dec 29, 2012		U-688	
	5846987*PED	Jun 29, 2013			
	5886036	Dec 29, 2012	DP		
	5886036*PED	Jun 29, 2013			
	6037157	Jun 26, 2016		U-688	
	6037157*PED	Dec 26, 2016			
	6703403	Jun 26, 2016		U-688	
	6703403*PED	Dec 26, 2016			
<u>LUBIPROSTONE - AMITIZA</u>					
021908 001				NCE	Jan 31, 2011
<u>MECASERMIN RINFABATE RECOMBINANT - IPLEX</u>					
021884 001	5200509	Apr 06, 2010	DS		
	5681818	Oct 28, 2014		U-697	
<u>MELOXICAM - MOBIC</u>					
020938 001				ODE PED	Aug 11, 2012 Feb 11, 2013
<u>MELOXICAM - MOBIC</u>					
020938 002				ODE PED	Aug 11, 2012 Feb 11, 2013
<u>MELOXICAM - MOBIC</u>					
021530 001				I-469 ODE PED PED	Aug 11, 2008 Aug 11, 2012 Feb 11, 2013 Feb 11, 2009
<u>MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE - VUSION</u>					
021026 001				>A> NP	Feb 16, 2009
<u>MINOXIDIL - MEN'S ROGAINE</u>					
021812 001	>A> 6946120	Apr 20, 2019	DP	U-702	Jan 20, 2009
<u>MORPHINE SULFATE - KADIAN</u>					
020616 004	5378474	Mar 23, 2010			
<u>MORPHINE SULFATE - KADIAN</u>					
020616 005	5202128	Apr 13, 2010			
	5378474	Mar 23, 2010			
<u>MOXIFLOXACIN HYDROCHLORIDE - AVELOX</u>					
021085 001	>A> 4990517	Dec 08, 2011	DS DP	U-298	
	>A> 6610327	Oct 29, 2019	DP	U-298	
<u>MOXIFLOXACIN HYDROCHLORIDE - AVELOX IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER</u>					
021277 001	>A> 4990517	Dec 08, 2011	DS DP	U-298	
	>A> 6548079	Jul 25, 2020	DP	U-298	

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>NELARABINE - ARRANON</u>					
021877 001	5747472	Feb 20, 2013	U-696		
	5747472	Feb 20, 2013	U-695		
	5747472	Feb 20, 2013	U-689		
	5821236	Feb 20, 2013	U-695		
<u>NICOTINE POLACRILEX - NICOTINE POLACRILEX</u>					
077007 001				>A> PC	Aug 21, 2006
<u>NICOTINE POLACRILEX - NICOTINE POLACRILEX</u>					
077007 002				>A> PC	Aug 21, 2006
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 001	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 002	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 003	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 004	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 005	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>					
021008 001	5538739	Jul 23, 2013		ODE	Nov 25, 2005
	5538739*PED	Jan 23, 2014		PED	May 25, 2006
	5639480	Jun 17, 2014			
	5639480*PED	Dec 17, 2014			
	5688530	Nov 18, 2014	U-268		
	5688530*PED	May 18, 2015			
	5922338	Jul 13, 2016			
	5922338*PED	Jan 13, 2017			
	5922682	Jul 13, 2016			
	5922682*PED	Jan 13, 2017			
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>					
021008 002	5538739	Jul 23, 2013		ODE	Nov 25, 2005
	5538739*PED	Jan 23, 2014		PED	May 25, 2006
	5639480	Jun 17, 2014			
	5639480*PED	Dec 17, 2014			
	5688530	Nov 18, 2014	U-268		
	5688530*PED	May 18, 2015			
	5922338	Jul 13, 2016			
	5922338*PED	Jan 13, 2017			
	5922682	Jul 13, 2016			
	5922682*PED	Jan 13, 2017			
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>					
021008 003	5538739	Jul 23, 2013		ODE	Nov 25, 2005
	5538739*PED	Jan 23, 2014		PED	May 25, 2006
	5639480	Jun 17, 2014			
	5639480*PED	Dec 17, 2014			
	5688530	Nov 18, 2014	U-268		
	5688530*PED	May 18, 2015			
	5922338	Jul 13, 2016			
	5922338*PED	Jan 13, 2017			
	5922682	Jul 13, 2016			
	5922682*PED	Jan 13, 2017			
<u>OXALIPLATIN - ELOXATIN</u>					
021492 001	5420319	Aug 09, 2016	DS		
<u>OXALIPLATIN - ELOXATIN</u>					
021492 002	5420319	Aug 09, 2016	DS		
<u>OXALIPLATIN - ELOXATIN</u>					
021759 001	5420319	Aug 08, 2016	DS		

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>OXALIPLATIN - ELOXATIN</u>					
021759 002	5420319	Aug 08, 2016	DS		
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 001	4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 002	4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 003	4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 004	4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 005	4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 006	4843086	Jun 27, 2006		U-231	
<u>QUETIAPINE FUMARATE - SEROQUEL</u>					
020639 006	4879288	Sep 26, 2011	DS DP	U-550	
<u>QUETIAPINE FUMARATE - SEROQUEL</u>					
020639 007	4879288	Sep 26, 2011	DS DP	U-550	
<u>RALOXIFENE HYDROCHLORIDE - EVISTA</u>					
020815 001	RE38968	Jul 28, 2012		U-662	
	RE38968	Jul 28, 2012		U-657	
<u>RANOLAZINE - RANEXA</u>					
021526 002	>A> 4567264	May 18, 2006	DS	NCE	Jan 27, 2011
	>A> 6303607	May 27, 2019		U-705	
	>A> 6369062	May 27, 2019		DP	
	>A> 6479496	May 27, 2019		U-705	
	>A> 6503911	May 27, 2019		DP	
	>A> 6525057	May 27, 2019		U-705	
	>A> 6562826	May 27, 2019		U-705	
	>A> 6617328	May 27, 2019		DP	
	>A> 6620814	May 27, 2019		U-705	
	>A> 6852724	May 27, 2019		U-705	
	>A> 6864258	May 27, 2019		U-705	
<u>RISEDRONATE SODIUM - ACTONEL</u>					
020835 001				M-52	Jan 24, 2009
<u>RISEDRONATE SODIUM - ACTONEL</u>					
020835 002				M-52	Jan 24, 2009
<u>RISEDRONATE SODIUM - ACTONEL</u>					
020835 003				M-52	Jan 24, 2009
<u>SALMETEROL XINAFOATE - SEREVENT</u>					
020236 001	>A> 4992474	Feb 12, 2008			
	>A> 4992474*PED	Aug 12, 2008			
	>A> 5126375	Feb 12, 2008			
	>A> 5126375*PED	Aug 12, 2008			
	>A> 5225445	Feb 12, 2008		U-182	
	>A> 5225445*PED	Aug 12, 2008			
<u>SALMETEROL XINAFOATE - SEREVENT</u>					
020692 001	>A> 4992474	Feb 12, 2008			
	>A> 4992474*PED	Aug 12, 2008			
	>A> 5126375	Feb 12, 2008			
	>A> 5126375*PED	Aug 12, 2008			
	>A> 5225445	Feb 12, 2008		U-211	
	>A> 5225445*PED	Aug 12, 2008			
<u>SELEGILINE HYDROCHLORIDE - EMSAM</u>					
021336 001				>A> NDF	Feb 27, 2009
<u>SORAFENIB TOSYLATE - NEXAVAR</u>					
021923 001				ODE	Dec 20, 2012
<u>SUNITINIB MALATE - SUTENT</u>					
021938 001	>A> 6573293	Feb 15, 2021	DS DP	U-703	NCE
					Jan 26, 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>SUNITINIB MALATE - SUTENT</u>					
021938 002	>A> 6573293	Feb 15, 2021	DS DP U-703	NCE	Jan 26, 2011
<u>SUNITINIB MALATE - SUTENT</u>					
021938 003	>A> 6573293	Feb 15, 2021	DS DP U-703	NCE	Jan 26, 2011
<u>TERIPARATIDE RECOMBINANT HUMAN - FORTEO</u>					
021318 001	6977077	Aug 19, 2019	U-597		
<u>THYROTROPIN ALFA - THYROGEN</u>					
020898 001				M-53	Jan 23, 2009
<u>TREPROSTINIL SODIUM - REMODULIN</u>					
021272 001	5153222	Oct 06, 2014	U-455		
<u>TREPROSTINIL SODIUM - REMODULIN</u>					
021272 002	5153222	Oct 06, 2014	U-455		
<u>TREPROSTINIL SODIUM - REMODULIN</u>					
021272 003	5153222	Oct 06, 2014	U-455		
<u>TREPROSTINIL SODIUM - REMODULIN</u>					
021272 004	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>