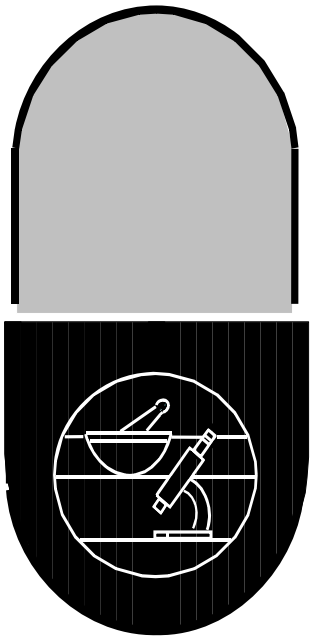
CUMULATIVE SUPPLEMENT 02
February 2006



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

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THERAPEUTIC EQUIVALENCE EVALUATIONS

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 Previously, a first-time-generic approved early in the month would not be published in the CS for several weeks.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

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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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
AVENTIS PHARMACEUTICAL PRODUCTS INC (AVENTIS PHARMS)	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

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

[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

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

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;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

	+	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

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

AMMONIUM LACTATE

CREAM; TOPICAL

AMMONIUM LACTATE

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

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

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;0.14MG/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)

		+	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

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

BRIMONIDINE TARTRATE

SOLUTION/DROPS; OPHTHALMIC

BRIMONIDINE TARTRATE

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

BRINZOLAMIDE

SUSPENSION/DROPS; OPHTHALMIC

AZOPT

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

BUMETANIDE

INJECTABLE; INJECTION

BUMETANIDE

>D>	AP		BEDFORD	0.25MG/ML	N74441	001	Jan 27, 1995	Feb	CRLD
>A>	AP	+		0.25MG/ML	N74441	001	Jan 27, 1995	Feb	CRLD

>D>			BUMEX						
>D>	AP	+	ROCHE	0.25MG/ML	N18226	001	Feb 28, 1983	Feb	DISC
>A>			@	0.25MG/ML	N18226	001	Feb 28, 1983	Feb	DISC

BUPROPION HYDROCHLORIDE

TABLET; ORAL

BUPROPION HYDROCHLORIDE

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

BUSULFAN

INJECTABLE; INJECTION

BUSULFEX

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

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL

>D>			CAFERGOT						
>D>	BR	+	NOVARTIS	100MG;2MG	N09000	002		Feb	DISC
>A>			@	100MG;2MG	N09000	002		Feb	DISC
			MIGERGOT						
>D>	BR		G AND W LABS	100MG;2MG	N86557	001	Oct 04, 1983	Feb	CRLD
>A>		+		100MG;2MG	N86557	001	Oct 04, 1983	Feb	CRLD

CALCIPOTRIENE

CREAM; TOPICAL

DOVONEX

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

OINTMENT; TOPICAL

DOVONEX

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

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

CALCITRIOL

INJECTABLE; INJECTION
CALCITRIOL

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

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	
		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	
		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	
		CEFTRIAXONE SODIUM							
		INJECTABLE; IM-IV							
		CEFTRIAXONE							
	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							
		CEFTRIAXONE							
	AP	AM PHARM	EQ 10GM BASE/VIAL	N65252	001	Feb 15, 2006	Jan	NEWA	

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

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

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

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

DESLORATADINE; 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; ORAL
DESMOPRESSIN 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 ESTRADIOL

TABLET; ORAL-28
MIRCETTE

>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 SULFATE

TABLET; ORAL
DEXTROAMPHETAMINE 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 HYDROCHLORIDE

SYRUP; ORAL
PROMETHAZINE DM

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

DIFLORASONE DIACETATE

CREAM; TOPICAL
DIFLORASONE 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; TOPICAL
DIFLORASONE 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

DIGOXIN

INJECTABLE; INJECTION
DIGOXIN

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

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
DILTZAC

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 +		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

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

>D>			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; LISINOPRIL

TABLET; ORAL
LISINOPRIL 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

INSULIN RECOMBINANT HUMAN

POWDER; INHALATION
EXUBERA

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

POWDER; INHALATION
EXUBERA

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

ISONIAZID

INJECTABLE; INJECTION
ISONIAZID

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

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION
KETOROLAC TROMETHAMINE

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

LANSOPRAZOLE; NAPROXEN

CAPSULE, DELAYED REL PELLETS, TABLET; ORAL
NAPRAPAC 250 (COPACKAGED)

>D>		TAP PHARM	15MG,N/A;N/A,250MG	N21507	002	Nov 14, 2003	Feb	CTNA

NAPRAPAC 375 (COPACKAGED)

>D>		TAP PHARM	15MG,N/A;N/A,375MG	N21507	003	Nov 14, 2003	Feb	CTNA

NAPRAPAC 500 (COPACKAGED)

>D>	+	TAP PHARM	15MG,N/A;N/A,500MG	N21507	004	Nov 14, 2003	Feb	CTNA

PREVACID NAPRAPAC 250 (COPACKAGED)

>A>		TAP PHARM	15MG,N/A;N/A,250MG	N21507	002	Nov 14, 2003	Feb	CTNA

PREVACID NAPRAPAC 375 (COPACKAGED)

>A>		TAP PHARM	15MG,N/A;N/A,375MG	N21507	003	Nov 14, 2003	Feb	CTNA

PREVACID NAPRAPAC 500 (COPACKAGED)

>A>	+	TAP PHARM	15MG,N/A;N/A,500MG	N21507	004	Nov 14, 2003	Feb	CTNA

LEVOBETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC
BETAXON

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

LIDOCAINE HYDROCHLORIDE

JELLY; TOPICAL
ANESTACON

AT	+	POLYMEDICA	2%	N80429	001		Jan	CDFR

LIDOCAINE; TETRACAINE

PATCH; TOPICAL
SYNERA

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

LISINOPRIL

TABLET; ORAL
LISINOPRIL

>A>	AB	AUROBINDO	2.5MG	N77622	001	Feb 22, 2006	Feb	NEWA
>A>	AB		5MG	N77622	002	Feb 22, 2006	Feb	NEWA
>A>	AB		10MG	N77622	003	Feb 22, 2006	Feb	NEWA
>A>	AB		20MG	N77622	004	Feb 22, 2006	Feb	NEWA
>A>	AB		30MG	N77622	005	Feb 22, 2006	Feb	NEWA

TABLET; ORAL
LISINOPRIL

>A>	AB	AUROBINDO	40MG	N77622	006	Feb 22, 2006	Feb	NEWA

LOVASTATIN; NIACIN

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

LUBIPROSTONE

CAPSULE; ORAL
AMITIZA

	+	SUCAMPO PHARMS	24UGM	N21908	001	Jan 31, 2006	Jan	NEWA

MEDROXYPROGESTERONE ACETATE

INJECTABLE; SUBCUTANEOUS
DEPO-SUBQ PROVERA 104

	+	PHARMACIA AND UPJOHN	104MG/0.65ML	N21583	001	Dec 17, 2004	Jan	CAHN

MEGESTROL ACETATE

SUSPENSION; ORAL
MEGESTROL ACETATE

AB		APOTEX	40MG/ML	N77404	001	Feb 16, 2006	Jan	NEWA

MEPROBAMATE

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

METFORMIN HYDROCHLORIDE

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

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

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

OMEPRAZOLE

FOR SUSPENSION; ORAL

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

CAPSULE; ORAL

ZEGERID

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

FOR SUSPENSION; ORAL

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

PHYTONADIONE

INJECTABLE; INJECTION

>D>			AQUAMEPHYTON						
>D>	BP	+	MERCK	1MG/0.5ML	N12223	002		Feb	DISC
>A>			@	1MG/0.5ML	N12223	002		Feb	DISC
>D>	BP	+		10MG/ML	N12223	001		Feb	DISC
>A>			@	10MG/ML	N12223	001		Feb	DISC
			VITAMIN K1						
>D>	BP		HOSPIRA	1MG/0.5ML	N87954	001	Jul 25, 1983	Feb	CRLD
>A>	BP	+		1MG/0.5ML	N87954	001	Jul 25, 1983	Feb	CRLD
>D>	BP			10MG/ML	N87955	001	Jul 25, 1983	Feb	CRLD
>A>		+		10MG/ML	N87955	001	Jul 25, 1983	Feb	CRLD

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

			KLOR-CON						
	AB		UPSHER SMITH	8MEQ	N19123	001	Apr 17, 1986	Jan	CRLD
			POTASSIUM CHLORIDE						
	AB	+	COPLEY PHARM	8MEQ	N70618	001	Sep 09, 1987	Jan	CRLD

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

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

PROMETHAZINE HYDROCHLORIDE

SUPPOSITORY; RECTAL

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

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

			PROPRANOLOL HYDROCHLORIDE						
	AP		SANDOZ	1MG/ML	N76400	001	Feb 26, 2003	Jan	CAHN

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

			REGONOL						
	AP		SANDOZ	5MG/ML	N17398	001		Jan	CAHN

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

			QUINAPRIL HYDROCHLORIDE						
	AB		TORPHARM	EQ 5MG BASE	N76240	001	Jan 26, 2006	Jan	NEWA
	AB			EQ 10MG BASE	N76240	002	Jan 26, 2006	Jan	NEWA
	AB			EQ 20MG BASE	N76240	003	Jan 26, 2006	Jan	NEWA

TABLET; ORAL
QUINAPRIL HYDROCHLORIDE

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

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL
QUINIDINE GLUCONATE

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

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

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

RANITIDINE

INJECTABLE; INJECTION
RANITIDINE

>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

>A> SELEGILINE HYDROCHLORIDE

>A> FILM, EXTENDED RELEASE; TRANSDERMAL
>A> EMSAM

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

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE

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

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION
ANECTINE

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

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	N16466	001		Jan	CAHN
	+		20MG/ML	N16466	002		Jan	CAHN

TRIPELENNAMINE 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

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

ACTRON

>D>	BAYER	12.5MG	N20499	001	Oct 06, 1995	Feb	DISC
>A>	@	12.5MG	N20499	001	Oct 06, 1995	Feb	DISC

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

MINOXIDIL

AEROSOL, FOAM; TOPICAL

MEN'S ROGAINE

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

NAPROXEN SODIUM

CAPSULE; ORAL

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

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

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APPL/PROD NO		PATENT NO	PATENT EXPIRATON DATE	PATENT CODES			EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ABACAVIR SULFATE; LAMIVUDINE - EPZICOM								
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					
ALBUTEROL SULFATE - PROAIR HFA								
021457 001							>A> I-235	Feb 03, 2009
ALENDRONATE SODIUM; CHOLECALCIFEROL - FOSAMAX PLUS D								
021762 001							NC	Apr 07, 2008
ALFUZOSIN HYDROCHLORIDE - UROXATRAL								
021287 001	>A>	4661491	May 27, 2007			U-706		
ANIDULAFUNGIN - ERAXIS								
021632 001							>A> NCE	Feb 17, 2011
APREPITANT - EMEND								
021549 001		5145684	Jan 25, 2011		DP			
APREPITANT - EMEND								
021549 002		5145684	Jan 25, 2011		DP			
ARIPIPRAZOLE - ABILIFY								
021436 001							>A> I-488	Mar 01, 2008
ARIPIPRAZOLE - ABILIFY								
021436 002							>A> I-488	Mar 01, 2008
ARIPIPRAZOLE - ABILIFY								
021436 003							>A> I-488	Mar 01, 2008
ARIPIPRAZOLE - ABILIFY								
021436 004							>A> I-488	Mar 01, 2008
ARIPIPRAZOLE - ABILIFY								
021436 005							>A> I-488	Mar 01, 2008
ARIPIPRAZOLE - ABILIFY								
021436 006							>A> I-488	Mar 01, 2008
ARIPIPRAZOLE - ABILIFY								
021713 001		6977257	Apr 24, 2022	DS	DP		>A> I-488	Mar 01, 2008
AZELASTINE HYDROCHLORIDE - ASTELIN								
020114 001							>A> D-102	Feb 17, 2007
BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE - TACLONEX								
021852 001	>A>	4866048	Dec 29, 2007	DS	DP	U-88	>A> NC	Jan 09, 2009
	>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		
BIVALIRUDIN - ANGIOMAX								
020873 001							I-486	Nov 30, 2008
BORTEZOMIB - VELCADE								
021602 001							ODE	Mar 25, 2012
BRIMONIDINE TARTRATE - ALPHAGAN P								
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					

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BROMFENAC SODIUM - XIBROM					
021664 001				I-485	Jan 27, 2009
BUDESONIDE - PULMICORT RESPULES					
020929 001	**>A>** 6899099	Dec 23, 2018	U-645		
	>A> 6899099*PED	Jun 23, 2019			
BUDESONIDE - PULMICORT RESPULES					
020929 002	**>A>** 6899099	Dec 23, 2018	U-645		
	>A> 6899099*PED	Jun 23, 2019			
BUDESONIDE - RHINOCORT					
020746 001	**>A>** 6986904	Apr 29, 2017	DP U-699		
BUDESONIDE - RHINOCORT					
020746 002	**>A>** 6986904	Apr 29, 2017	DP U-699		
CALCIUM CARBONATE; RISEDRONATE SODIUM - ACTONEL WITH CALCIUM (COPACKAGED)					
021823 001				M-52	Jan 24, 2009
CEFDITOREN PIVOXIL - SPECTRACEF					
021222 001	**>A>** 4839350	Jan 14, 2009	DS DP		
CONIVAPTAN HYDROCHLORIDE - VAPRISOL					
021697 001	5723606	Mar 03, 2015	DS DP U-698		
DESFLURANE - SUPRANE					
020118 001	5617906	Apr 08, 2014	DP		
DESLORATADINE; PSEUDOEPHEDRINE SULFATE - CLARINEX D 24 HOUR					
021605 001	6979463	Mar 28, 2022	DP		
DESLORATADINE; PSEUDOEPHEDRINE SULFATE - CLARINEX-D 12 HOUR					
021313 001				**>A>** NCE	Dec 21, 2006
				>A> NC	Mar 03, 2008
				>A> PED	Jun 21, 2007
DOCETAXEL - TAXOTERE					
020449 001	**>A>** 5750561	Jul 03, 2012	DP		
ESOMEPRAZOLE MAGNESIUM - NEXIUM					
021153 001				I-484	Nov 24, 2007
ESOMEPRAZOLE MAGNESIUM - NEXIUM					
021153 002				I-484	Nov 24, 2007
ETHINYL ESTRADIOL; NORELGESTROMIN - ORTHO EVRA					
021180 001	**>A>** 5876746	Nov 20, 2015	DP U-514		
ETHINYL ESTRADIOL; NORETHINDRONE ACETATE - LOESTRIN 24 FE					
021871 001				**>A>** NP	Feb 17, 2009
FENOFIBRATE - FENOFIBRATE					
076433 001				PC	May 22, 2006
FENOFIBRATE - FENOFIBRATE					
076433 002				PC	May 22, 2006
FENOFIBRATE - LIPOFEN					
021612 001	**>A>** 5545628	Jan 10, 2015	U-701		
FENOFIBRATE - LIPOFEN					
021612 002	**>A>** 5545628	Jan 10, 2015	U-701		
FENOFIBRATE - LIPOFEN					
021612 003	**>A>** 5545628	Jan 10, 2015	U-701		
FLUNISOLIDE - AEROSPAN HFA					
021247 001				NP	Jan 27, 2009
FLUOCINOLONE ACETONIDE - RETISERT					
021737 001	**>A>** 6217895	Mar 22, 2019	DP		
	>A> 6548078	Mar 22, 2019	DP		
FLUOCINONIDE - VANOS					
021758 001				**>A>** I-487	Mar 02, 2009
FLUTICASONE PROPIONATE - FLOVENT HFA					
021433 001				**>A>** NPP	Feb 28, 2009
FLUTICASONE PROPIONATE - FLOVENT HFA					
021433 002				**>A>** NPP	Feb 28, 2009

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APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
FLUTICASONE PROPIONATE - FLOVENT HFA					
021433 003				**>A>** NPP	Feb 28, 2009
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50					
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			
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50					
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			
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50					
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			
FULVESTRANT - FASLODEX					
021344 001	4659516	Oct 01, 2006			
GLIMEPIRIDE - AMARYL					
020496 001				**>A>** M-54	Nov 28, 2008
				>A> PED	May 28, 2009
GLIMEPIRIDE - AMARYL					
020496 002				**>A>** M-54	Nov 28, 2008
				>A> PED	May 28, 2009
GLIMEPIRIDE - AMARYL					
020496 003				**>A>** M-54	Nov 28, 2008
				>A> PED	May 28, 2009
GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL					
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			
GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL					
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			
GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL					
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			
HYALURONIDASE RECOMBINANT HUMAN - HYLENEX RECOMBINANT					
021859 001				NCE	Dec 02, 2010
IBANDRONATE SODIUM - BONIVA					
021455 001	4927814	Jul 09, 2007	DS DP U-642		
	6143326	Apr 21, 2017	U-642		
IBANDRONATE SODIUM - BONIVA					
021858 001	**>A>** 4927814	Jul 09, 2007	DS DP U-700	NDF	Jan 06, 2009
				NCE	May 16, 2008

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INSULIN DETEMIR RECOMBINANT - LEVEMIR						
021536 001					**>A>** I-489	Oct 19, 2008
INSULIN RECOMBINANT HUMAN - EXUBERA						
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			
INSULIN RECOMBINANT HUMAN - EXUBERA						
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			
IPRATROPIUM BROMIDE - ATROVENT HFA						
021527 001	6983743	May 26, 2020	DP			
LANSOPRAZOLE - PREVACID						
020406 001	6749864	Feb 13, 2007	DP			
LANSOPRAZOLE - PREVACID						
020406 002	6749864	Feb 13, 2007	DP			
LANSOPRAZOLE - PREVACID						
021281 001	6749864	Feb 13, 2007	DP			
LANSOPRAZOLE - PREVACID						
021281 002	6749864	Feb 13, 2007	DP			
LANSOPRAZOLE - PREVACID						
021428 001	6749864	Feb 13, 2007	DP			
LANSOPRAZOLE - PREVACID						
021428 002	6749864	Feb 13, 2007	DP			
LANTHANUM CARBONATE - FOSRENOL						
021468 003	5968976	Mar 19, 2016	DP	U-613		
LANTHANUM CARBONATE - FOSRENOL						
021468 004	5968976	Mar 19, 2016	DP	U-613		
LENALIDOMIDE - REVLIMID						
021880 001	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		

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LENALIDOMIDE - REVLIMID								
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		
LIDOCAINE; TETRACAINE - SYNERA								
021623 001							>A> NC	Jun 23, 2009
LOPINAVIR; RITONAVIR - KALETRA								
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					
LUBIPROSTONE - AMITIZA								
021908 001							NCE	Jan 31, 2011
MECASERMIN RINFABATE RECOMBINANT - IPLEX								
021884 001		5200509	Apr 06, 2010	DS				
		5681818	Oct 28, 2014			U-697		
MELOXICAM - MOBIC								
020938 001							ODE	Aug 11, 2012
							PED	Feb 11, 2013
MELOXICAM - MOBIC								
020938 002							ODE	Aug 11, 2012
							PED	Feb 11, 2013
MELOXICAM - MOBIC								
021530 001							I-469	Aug 11, 2008
							ODE	Aug 11, 2012
							PED	Feb 11, 2013
							PED	Feb 11, 2009
MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE - VUSION								
021026 001							>A> NP	Feb 16, 2009
MINOXIDIL - MEN'S ROGAINE								
021812 001	>A>	6946120	Apr 20, 2019		DP	U-702	NDF	Jan 20, 2009
MORPHINE SULFATE - KADIAN								
020616 004		5378474	Mar 23, 2010					
MORPHINE SULFATE - KADIAN								
020616 005		5202128	Apr 13, 2010					
		5378474	Mar 23, 2010					
MOXIFLOXACIN HYDROCHLORIDE - AVELOX								
021085 001	>A>	4990517	Dec 08, 2011	DS	DP	U-298		
	>A>	6610327	Oct 29, 2019		DP	U-298		
MOXIFLOXACIN HYDROCHLORIDE - AVELOX IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER								
021277 001	>A>	4990517	Dec 08, 2011	DS	DP	U-298		
	>A>	6548079	Jul 25, 2020		DP	U-298		

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NELARABINE - ARRANON					
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		
NICOTINE POLACRILEX - NICOTINE POLACRILEX					
077007 001				**>A>** PC	Aug 21, 2006
NICOTINE POLACRILEX - NICOTINE POLACRILEX					
077007 002				**>A>** PC	Aug 21, 2006
OCTREOTIDE ACETATE - SANDOSTATIN					
019667 001	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
OCTREOTIDE ACETATE - SANDOSTATIN					
019667 002	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
OCTREOTIDE ACETATE - SANDOSTATIN					
019667 003	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
OCTREOTIDE ACETATE - SANDOSTATIN					
019667 004	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
OCTREOTIDE ACETATE - SANDOSTATIN					
019667 005	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
OCTREOTIDE ACETATE - SANDOSTATIN LAR					
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			
OCTREOTIDE ACETATE - SANDOSTATIN LAR					
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			
OCTREOTIDE ACETATE - SANDOSTATIN LAR					
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			
OXALIPLATIN - ELOXATIN					
021492 001	5420319	Aug 09, 2016 DS			
OXALIPLATIN - ELOXATIN					
021492 002	5420319	Aug 09, 2016 DS			
OXALIPLATIN - ELOXATIN					
021759 001	5420319	Aug 08, 2016 DS			

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OXALIPLATIN - ELOXATIN								
021759 002		5420319	Aug 08, 2016	DS				
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX								
020667 001		4843086	Jun 27, 2006			U-231		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX								
020667 002		4843086	Jun 27, 2006			U-231		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX								
020667 003		4843086	Jun 27, 2006			U-231		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX								
020667 004		4843086	Jun 27, 2006			U-231		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX								
020667 005		4843086	Jun 27, 2006			U-231		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX								
020667 006		4843086	Jun 27, 2006			U-231		
QUETIAPINE FUMARATE - SEROQUEL								
020639 006		4879288	Sep 26, 2011	DS	DP	U-550		
QUETIAPINE FUMARATE - SEROQUEL								
020639 007		4879288	Sep 26, 2011	DS	DP	U-550		
RALOXIFENE HYDROCHLORIDE - EVISTA								
020815 001		RE38968	Jul 28, 2012			U-662		
		RE38968	Jul 28, 2012			U-657		
RANOLAZINE - RANEXA								
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		
RISEDRONATE SODIUM - ACTONEL								
020835 001							M-52	Jan 24, 2009
RISEDRONATE SODIUM - ACTONEL								
020835 002							M-52	Jan 24, 2009
RISEDRONATE SODIUM - ACTONEL								
020835 003							M-52	Jan 24, 2009
SALMETEROL XINAFOATE - SEREVENT								
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					
SALMETEROL XINAFOATE - SEREVENT								
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					
SELEGILINE HYDROCHLORIDE - EMSAM								
021336 001							**>A>** NDF	Feb 27, 2009
SORAFENIB TOSYLATE - NEXAVAR								
021923 001							ODE	Dec 20, 2012
SUNITINIB MALATE - SUTENT								
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 EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
SUNITINIB MALATE - SUTENT					
021938 002	>A> 6573293	Feb 15, 2021	DS DP U-703	NCE	Jan 26, 2011
SUNITINIB MALATE - SUTENT					
021938 003	>A> 6573293	Feb 15, 2021	DS DP U-703	NCE	Jan 26, 2011
TERIPARATIDE RECOMBINANT HUMAN - FORTEO					
021318 001	6977077	Aug 19, 2019	U-597		
THYROTROPIN ALFA - THYROGEN					
020898 001				M-53	Jan 23, 2009
TREPROSTINIL SODIUM - REMODULIN					
021272 001	5153222	Oct 06, 2014	U-455		
TREPROSTINIL SODIUM - REMODULIN					
021272 002	5153222	Oct 06, 2014	U-455		
TREPROSTINIL SODIUM - REMODULIN					
021272 003	5153222	Oct 06, 2014	U-455		
TREPROSTINIL SODIUM - REMODULIN					
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